NCRP REPORT No. 149

A GUIDE TO MAMMOGRAPHY AND OTHER BREAST IMAGING PROCEDURES

NCRP

National Council on Radiation Protection and Measurements

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A Guide to Mammography and Other Breast Imaging Procedures

Recommendations of the
NATIONAL COUNCIL ON RADIATION PROTECTION AND MEASUREMENTS

Issued December 31, 2004

National Council on Radiation Protection and Measurements
7910 Woodmont Avenue, Suite 400 / Bethesda, MD 20814

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Library of Congress Cataloging-in-Publication Data

A guide to mammography and other breast imaging procedures.
p. cm. -- (NCRP report ; no. 149)

Includes bibliographical references and index.
ISBN 0-929600-84-3
1. Breast--Radiography. 2. Breast--Imaging I. National Committee on Radiation Protection II. Series.
RG493.5.R33G84 2004
618.1'907572--dc22

2004030765

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Preface

This Report supersedes NCRP Report No. 85, *Mammography—A User's Guide*. It represents a significant expansion of the original work by providing more relevant technical and clinical information on the practice of mammography. Financial support was provided by the American Cancer Society (ACS) and the National Cancer Institute (NCI Grant Number R24 CA74296-05). The contents are the sole responsibility of NCRP and do not necessarily represent the official views of ACS, NCI or the National Institutes of Health. This Report was prepared by NCRP Scientific Committee 72 on Radiation Protection in Mammography. Serving on Scientific Committee 72 were:

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The Council wishes to thank Dr. Ellen B. Mendelson, Northwestern University Medical School, Chicago, Illinois, for reviewing and updating Section 8.1, Ultrasound and Dr. Jean Paquelet, Grant Medical Center, Columbus, Ohio, for reviewing Section 2.

The Council also wishes to express its appreciation to the Committee members for the time and effort devoted to the preparation of this Report.

Thomas S. Tenforde
President

Contents

1. Introduction

1.1 Usefulness of Mammography

The practice of mammography can be divided into three categories: screening, diagnosis and surveillance. Screening involves examination of asymptomatic women in an attempt to detect breast cancer before a lesion is palpable. Diagnostic mammography is performed on women having symptoms or physical findings suspicious for breast cancer or for further mammographic workup of a nonpalpable finding detected at screening. Surveillance mammography provides follow-up of a breast that has been treated for cancer. The usefulness of mammography in the symptomatic patient is undisputed; mammography is primarily used to demonstrate the presence of breast cancer and, specifically to indicate the size, location and extent of tumor. There is also considerable evidence indicating the ability of mammography to detect nonpalpable cancer. In addition, randomized controlled trials of screening mammography have demonstrated a significant decline in breast cancer mortality among screened women age 50 and older (Strax *et al*., 1973; Tabar *et al*., 1985; 1987; 1992; 1996; 2000; 2001), age 40 to 49 (Chu *et al*., 1988; Shapiro *et al*., 1988), and overall for women age 40 and older (Hendrick *et al*., 1997; Humphrey *et al*., 2002; Tabar, 1987; Tabar *et al*., 1993; 1995).

1.2 Usefulness of Mammography for Breast Cancer Screening

There is little, if any, opposition to the practice of diagnostic mammography, probably because of the compelling clinical need for the information obtained. Many mammography examinations are performed for diagnostic purposes, and mammographic screening programs have also been widely implemented. There has been some opposition to screening in the past for a variety of reasons: (1) concern over a few published indications of a relatively unfavorable benefit/risk ratio, (2) concern about exposure to ionizing radiation, (3) concern about benefit in comparison to the number of false-positive mammograms, (4) the relatively high cost of mammography examinations and the cost of the biopsy procedures

generated by screening mammography, and (5) the limited willingness of third-party payers and government agencies to reimburse adequately for screening procedures.

The introduction of the American College of Radiology (ACR) Mammography Accreditation Program (MAP) in 1987 and the passage of the federal Mammography Quality Standards Act of 1992 (MQSA, 1992), followed by its implementation in 1994, established requirements for consistent minimum standards for mammography programs throughout the United States.

Furthermore, the regulatory climate for mammography in the United States has changed significantly with the passage of MQSA (1992) and its subsequent revision in the Mammography Quality Standards Reauthorization Act of 1998 (MQSRA, 1998).[1] Previously, mammography facilities were subject to a patchwork of state regulations and voluntary quality programs. With the implementation of MQSA (1992) by the U.S. Food and Drug Administration (FDA), a set of nationwide minimum quality standards now applies to all mammography facilities (Houn *et al.*, 1995).

Under MQSA (1992), each mammography facility must be accredited by an FDA-approved accreditation body. Currently, the approved accreditation bodies are the ACR and the States of Iowa, Arkansas, California and Texas. Once accredited, a facility must be certified by FDA or by one of the states approved by FDA as a certifying agency.

In order to be accredited and certified, each mammography facility must meet quality standards promulgated by FDA in its regulations.[2] These regulations address the facility's mammography equipment, its quality-assurance (QA) and quality-control (QC) program (including its mammography medical audit and a mechanism for addressing consumer complaints), its mammography personnel (interpreting physicians, radiologic technologists, and medical physicists), and its mammography reports. Issues related to the equipment and the QA and QC program (including the medical audit) are addressed in detail in this Report.

[1]Equipment standards for mammography are required by MQSA (1992) and MQSRA (1998). The Act can be found at http://www.fda.gov/cdrh/mammography, click on "The Act" under "Regulations."

[2]Implementation of equipment standards and other criteria for mammography can be found at http://www.fda.gov/cdrh/mammography, click on "The Code of Federal Regulations" under "Regulations" and scroll down to "Section 900.12(b) Equipment."

Under MQSA (1992), all mammography personnel (interpreting physicians, radiologic technologists, medical physicists) are required to meet both initial and continuing requirements. The initial requirements address licensure and certification, initial training in mammography and initial experience. The continuing requirements address both education and experience.

Also under MQSA (1992), the medical reports describing the results of the mammogram are required to be sent to the referring physician (or to the patient if the patient has no referring physician) in a timely fashion. The report must include one of a required set of final assessment categories and a recommendation for additional imaging or biopsy, if indicated. MQSA (1992) also requires that a summary of the report written in lay language be sent to ALL patients.

In addition to the requirement that each facility be accredited and certified, each facility is also subject to an annual on-site inspection by FDA (or by a state radiation control agency acting for FDA) and is required to pay an inspection fee. If the results of the inspection show that the facility has failed to comply with the MQSA standards in significant ways, the facility is required to respond to FDA in writing about how the noncompliance has been corrected. If significant noncompliance with the MQSA (1992) requirements persists, the facility is subject to a variety of sanctions including suspension of its certificate or the imposition of civil financial penalties.

Compliance with the requirements of MQSA (1992) has been very high and several General Accounting Office studies (GAO, 1995; 1997a; 1997b) have indicated that MQSA (1992) has led to improvements in the quality of mammography in the United States (CDRH, 2002a).

An essential component in determining the efficacy of a screening program is an evaluation of benefits versus risk of harm. For mammography, the major risks to be addressed include radiation-induced breast cancer and the effects of false-positive and false-negative diagnoses. The balancing of potential benefit and harm has been, and continues to be, difficult because of the limited amount of available data. However, it is possible to estimate the recall rate and biopsy-requested rate of mammography screening and to estimate the breast cancer mortality reduction from screening. It is also possible to estimate the average radiation dose received per examination, and the level of risk of radiation-induced breast cancer. When these are considered in the context of the natural incidence of carcinoma of the breast, a benefit/risk ratio can be

formulated. It must be emphasized that these are estimates based upon incomplete information, but that the level of reliability of the benefit estimates is probably as good as the data upon which the risk estimates are based. Because the doses are low and image quality has been greatly improved, it is believed that the benefit-risk ratio from screening with current state of the art mammography is likely to have increased substantially over that estimated in earlier studies.

Because of the substantial increase in mammography and mammographic screening and the anticipated further increase in utilization (CDRH, 2001), NCRP felt the need to update its previous report dealing with mammography, *i.e.*, NCRP Report No. 85, Mammography—A User's Guide (NCRP, 1986), as well as provide more relevant technical and clinical information on the practice of mammography.

1.3 Purpose and Scope

This Report is intended to be a practical guide to physicians who interpret mammographic images, technologists who perform mammographic examinations, as well as medical physicists who monitor mammographic facilities, evaluate image quality, and determine radiation dose.

Mammography is one of the most difficult radiographic examinations technically. Both specialized equipment and the correct use of that equipment are essential to the achievement of satisfactory results. Facilities should not perform the examination if they are unable or unwilling both to: (1) provide and maintain x-ray equipment, image receptors, film processors, and viewing conditions capable of producing the necessary images at acceptable dose levels; and (2) assure that the examination is performed with the proper technique factors, patient positioning, and compression. In fact, the implementation of MQSA (1992) has made it illegal for facilities to continue to perform mammography unless these conditions are fulfilled.

This Report contains several major sections, a summary and conclusions, and an extensive bibliography.

Sections 2 and 3 present conventional imaging techniques used for x-ray mammography. Positioning and breast anatomy are discussed in Section 2 along with optimum technique. Section 3 discusses recommendations for optimum choice of equipment.

A major consideration of any mammography system is the quality of the image. In Section 4 the factors which affect image quality

are defined, the parameters used to judge image quality are discussed, appropriate phantoms to measure these parameters are described, and the relationship between patient dose and image quality is examined for several imaging systems.

Mammography dosimetry is necessary to compare different imaging techniques and to evaluate their risks. Section 5 discusses the various dose or exposure parameters which have been employed as "risk" indicators and describes how to calculate mean glandular dose from measured exposures (free-in-air) and a knowledge of x-ray tube operating potential, beam quality, and x-ray tube target and filter material.

A QA program is necessary to insure consistent high-quality mammography at acceptably low dose levels. Section 6 discusses the various factors which should be evaluated and techniques for measuring them, limits beyond which corrective action should be taken, and the testing frequency and personnel requirements.

Section 7 contains a discussion of the benefits and risks of mammography derived from results of mass screening studies along with estimates of the risk of inducing breast cancer at mammographic screening radiation dose levels. Section 7 concludes with an analysis of the benefit to radiation risk relationship in mammography.

Several imaging techniques have been developed in recent years. Those now being applied to imaging of the breast are described in Section 8.

The summary and conclusions section of this Report briefly review the detailed material presented and present recommendations for: (1) equipment to obtain optimum mammograms; (2) QA programs; and (3) the necessity and frequency of mammographic examinations for women based on their symptoms, age, and risk factors.

2. Clinical Mammography

2.1 Anatomy

The fully-developed female breast is a well-differentiated apocrine sweat gland originating in the ectoderm that secretes milk during lactation. Each breast is cone-shaped, particularly in younger nulliparous females, extends from the sternum to the midaxillary line, and lies anterior to the pectoral muscle. A thin outer dermal layer covers a subdermal layer of adipose tissue that varies in thickness from several millimeters to 1 cm. Cooper's ligaments (Figure 2.1) are strings of fibrous connective tissue extending from the prepectoral fascia to the skin to support the glandular tissue. Cooper's ligaments also support blood vessels, lymph channels, and varying quantities of adipose tissue (Figures 2.2a and 2.2b).

Traditional anatomic dissections show that the glandular tissue consists of 15 to 20 lobes or segments containing ducts that branch and subdivide into smaller ducts as they extend into the deeper glandular tissue. The end units of the smallest ducts are composed of milk-forming lobules that drain radially through the ducts toward the nipple. Each lobe has its own segmental duct into which all the ducts from that lobe drain. There are wide lactiferous sinuses in the subareolar region; each of these receives the drainage from one or more segmental ducts. Each lactiferous duct then narrows as it passes through the nipple. This narrowed duct in the nipple is called a collecting duct. Sartorius (1986) has demonstrated that the nipple contains only five to seven collecting ducts.

Males and prepubescent females have only rudimentary glandular tissue. In the western world, a young woman's glandular tissue begins to proliferate early in her second decade, although maturation may be earlier or later. By the time a woman has completed puberty, her glandular tissue usually has developed to its maximum size. Hormonal variations related to menstrual cycles, pregnancy, and lactation cause the size of the glandular tissue to wax and wane. At menopause, glandular tissue gradually recedes, causing the breast to flatten somewhat, and become pendulous and less firm.

Although hormones cause the glandular tissue to become more dense, a woman's genetic predisposition and her ratio of total body

Fig. 2.1. Cooper's suspensory ligaments extend from the prepectoral fascia to the skin and support the glandular tissue in Sir Astley Cooper's original sketch (Logan-Young and Hoffman, 1994).

adipose tissue to total body weight also influence her ratio of glandular tissue to adipose tissue in her breast. For this reason, some young women have breasts consisting primarily of adipose tissue, while some elderly women have breasts with exceedingly dense glandular tissue.

Glandular tissue can extend throughout the entire breast; only a thin layer of retromammary adipose tissue separates it from the pectoral muscle. The upper outer quadrant, which extends towards the axilla, is known as the axillary tail or the tail of Spence. It is the thickest portion of the glandular tissue and the part reaching furthest from the nipple.

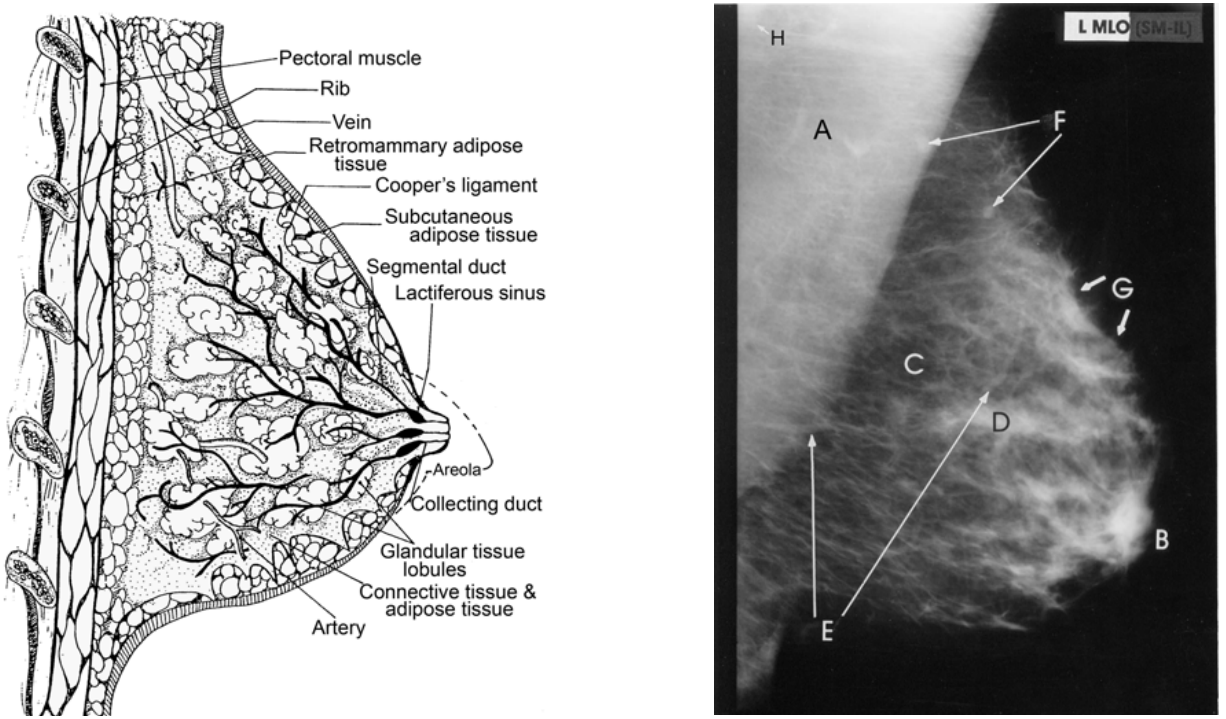


Fig. 2.2. (a) Schematic lateral view of female breast. (b) A mediolateral-oblique (MLO) projection of the breast demonstrating anatomic structures: (A) pectoralis muscle, (B) nipple, (C) adipose tissue, (D) glandular tissue, (E) blood vessel, (F) lymph nodes, (G) Cooper's ligaments, (H) latissimus dorsi muscle.

Breast cancer arises in the glandular tissue. Obviously, then, mammography's goal should be to image the glandular tissue with as much contrast and detail as possible within the limitations of acceptably low radiation exposure. The distribution of breast cancer is approximately proportional to the amount of glandular tissue in each quadrant of the breast (Figure 2.3). Nearly half of the breasts total glandular tissue is in the upper outer quadrant and 45 percent of all breast cancers develop in that same upper outer quadrant. Choosing the views that best delineate the glandular tissue of the breast is crucial to good mammography. Performing extra views, whenever necessary, is an indispensable part of a complete mammographic study.

Ectopic (misplaced) glandular tissue commonly develops in the low axillary region (Figure 2.4). On physical examination, this area may feel firm, finely nodular, or grainy. Frequently, one side contains more ectopic tissue than the other. The mammogram should always include the low-axillary region, because on rare occasions, ectopic tissue in this area may be harboring a cancer.

2.2 Viewing a Mammogram

There is no consensus regarding the optimal method to position the mammogram on the viewbox for interpretation. This lack of consensus is unfortunate because radiologists who become familiar

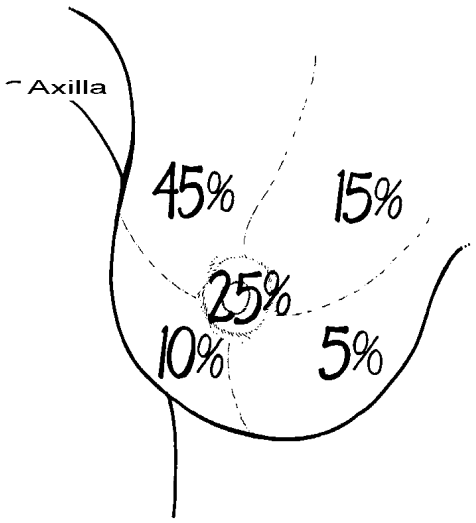


Fig. 2.3. Distribution of breast cancer by location.

Fig. 2.4. To visualize possible ectopic glandular tissue (arrows), the mammogram should always include the low-axillary region.

with one method have difficulty adapting to different methods when they move to a new facility. Surgeons have similar difficulties, because when they review mammograms with radiologists, there are variations in the way in which individual radiologists position the films while discussing the case. Therefore, even though there is no single method that will suit all radiologists, one possible arrangement of mammograms is shown in Figure 2.5. In this position the oblique views are visualized in the same anatomic position in which chest, abdomen and extremity radiographs are visualized, as if the radiologist were facing the patient. The right and left mammograms are easily able to be compared for asymmetry. Each mammographic image can also be compared with prior studies.

If no old films are available to compare for asymmetries, the right breast is contrasted with the left, but fortunately, most patients today do have old films for comparison. Comparing each view with a previous study of the same breast is much more accurate than comparing the right to the left breast. The oldest mammogram of good quality is placed adjacent to the current studies. If the patient has had more than two studies, the most recent previous mammograms should also be compared with the current study. If the appearance of the breast has changed for any reason, whether from a biopsy, reduction or augmentation mammoplasty, or beginning estrogen replacement therapy, the first mammogram after the altering event becomes the new baseline ("oldest") study. In pinpointing the location of a mass on the study, the radiologist faces the patient and regards each breast as though it were the face of a clock: the location of the lesion corresponds to its "time" on this imaginary clock.

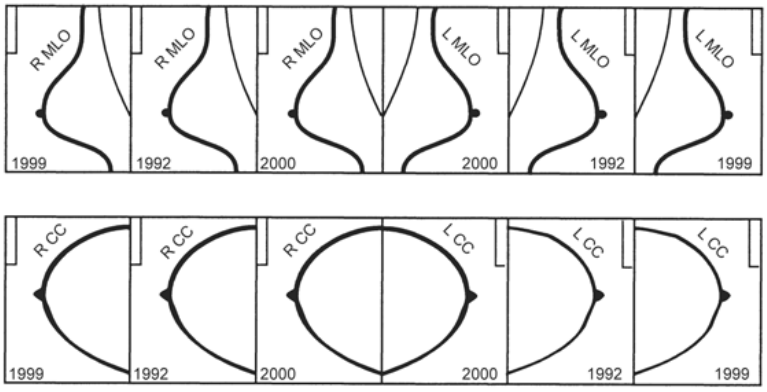


Fig. 2.5. One possible arrangement of mammograms for interpretation and comparison.

Except for the light emanating from the viewbox, the room should be dark. The viewboxes should ideally display two different levels of light, one average, the other, bright, for displaying studies of greater exposure. A rheostatically-controlled bright light should be available for viewing such overexposed areas as the skin line and for inspecting overexposed films. Some companies make viewboxes specifically designed for viewing mammograms. Some of these viewboxes are equipped with masking devices, built-in bright lights, and magnifiers.

The ACR's recommendations for mammography quality control to be performed by medical physicists (ACR, 1999) suggests performance criteria for mammographic viewbox measurements to be used as interim guidelines until further data are collected:

- luminance of the mammographic viewbox: capable of 3,000 cd m^{-2} (candela per square meter)[3]
- room ambient illumination level: 50 lux or less

Although ACR (1999) recommends 50 lux or less, it is desirable to keep the room ambient illumination level as close to zero as possible.

The "Guide to Good Practice" in the section, "Viewboxes and Viewing Conditions," of ACR (1999), outlines the essential requirements for viewboxes and viewing conditions. For instance, masking the area around the mammograms is a necessity. This obliterates extrinsic light, which reduces contrast and limits the visibility of densities that have not been "bright-lighted." Direct or reflected light from windows, other viewboxes, and any other sources should not impinge in any way on the mammographic viewbox (Kimme-Smith *et al*., 1997).

2.3 Image Identification

The Mammography Quality Standards Act (MQSA, 1992) requires marking the patient's name, unique identifier (such as medical record number or social security number; date of birth less desirable), date of examination, and the facility's name and address (city, state and zip code), the technologist who performed the examination, cassette/screen number, mammography unit number (if there is more than one at a facility) on the image receptor. Other MQSA requirements include breast [right (R)/left (L)] and projection/view [mediolateral-oblique (MLO)/craniocaudal (CC)]. It is recommended that breast and view markers be placed near the axillary edge of the film in relation to the breast.

[3]The unit cd m^{-2} is sometimes referred to as the "nit."

A flash card patient identification 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 identification 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.

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, operating potential (in kilovolt peak), milliampere second, exposure time, compression force, compressed breast thickness, and degree of obliquity.

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.

It is recommended that the angle at which the MLO view was performed be indicated. This is the angle of the x-ray beam from the vertical axis (same as the angle of the film tray to the horizontal) (Figure 2.6).

2.4 Breast Positioning

The routine two-view mammogram consists of a CC projection, and a MLO projection (ACR, 1993). The following sections describe these views. More specialized views are described in the ACR *Mammography Quality Control Manual* (ACR, 1999).

The technologist's alertness and diligence are the keys to good positioning. The technologist requires special training to learn correct positioning for mammography. The federal government and some states have already mandated this training for mammographic technologists. During positioning, the technologist should inspect the patient's breasts and record her observations on the patient's information sheet to help the radiologist interpret the mammogram. The technologist should note the location of any previous biopsies and record the presence and location of skin moles, scars, and any other skin conditions that might project over the imaged glandular tissue. When the breast is lifted up to position it on the image receptor, the tissue along the periphery of the breast should be palpated and additional special views of any thickening or mass that would not be imaged on the routine two-view mammogram should be obtained.

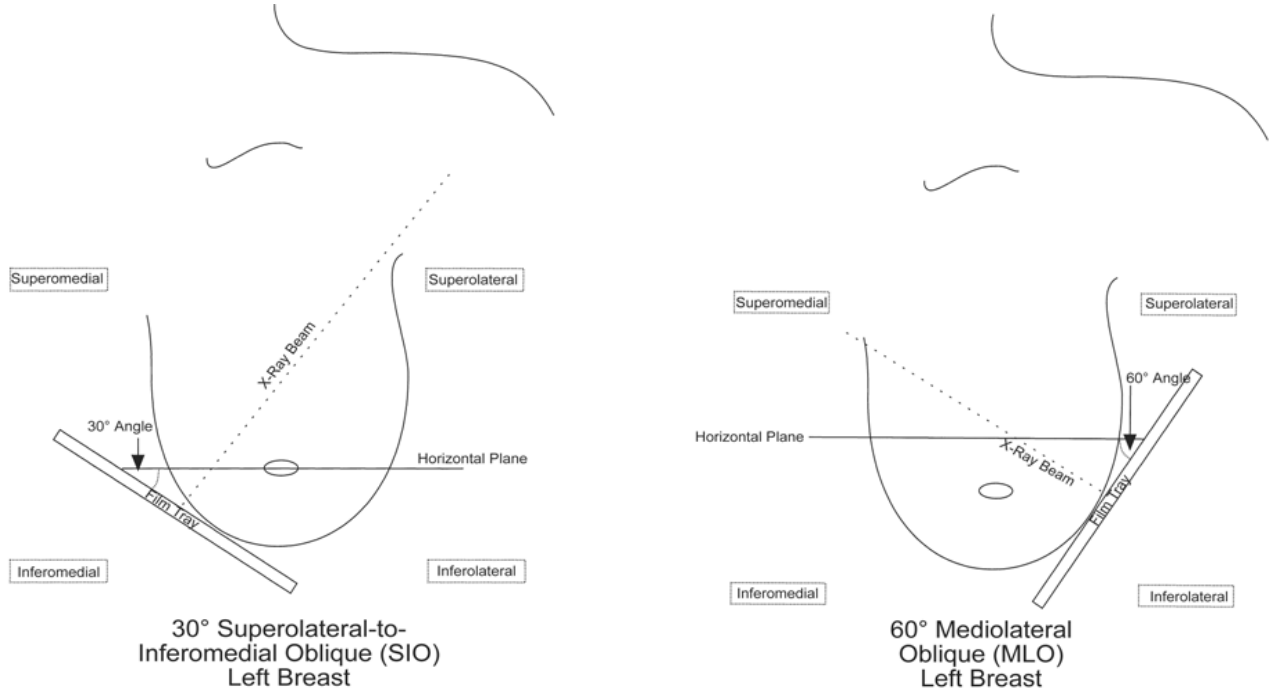


Fig. 2.6. For films to be interpreted correctly, it is necessary to label all images accurately and precisely. A full description of a view should include whether it is right or left breast, the angle of the image-receptor tray to the horizontal plane, and the direction of the x-ray beam.

The patient should stand during the mammographic examination unless a physical disability prevents her from doing so.[4] When the technologist positions the breast, she should smooth out the skin of the breast to eliminate wrinkles (Figure 2.7). Since there is a small degree of latitude of angulation for placing the breast on the image receptor, the technologist should roll the breast in her hands, at slight angles from the intended view, to determine the angle at which the breast can be compressed to its thinnest (Figure 2.8). This maneuver, which helps prevent overlapped glandular tissue, is extremely important for performing every view, whether routine or specifically tailored.

One of mammography's important goals is imaging as much posterior glandular tissue as possible, even at the expense of seeing the nipple in profile. It is not necessary for the nipple to be in profile for every view. If the nipple is not in profile on either the CC or the

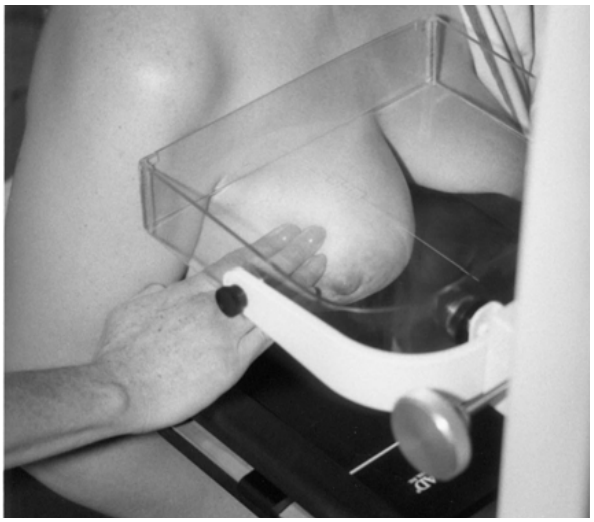


Fig. 2.7. To prevent pulling breast tissue out from under the compression plate, smooth skin wrinkles towards the nipple.

[4]While NCRP recognizes that a small percentage of breast cancers arise in male patients and that there are also a few male radiologic technologists performing mammography examinations, the Clinical Mammography section of this Report is written, in general, to reflect the predominant situation that the vast majority of mammography technologists and of mammography patients, in particular all of those enrolled in screening programs, are female.

ACR has chosen similar language for the Clinical Image Quality section of their *Mammography Quality Control Manual* (ACR, 1999).

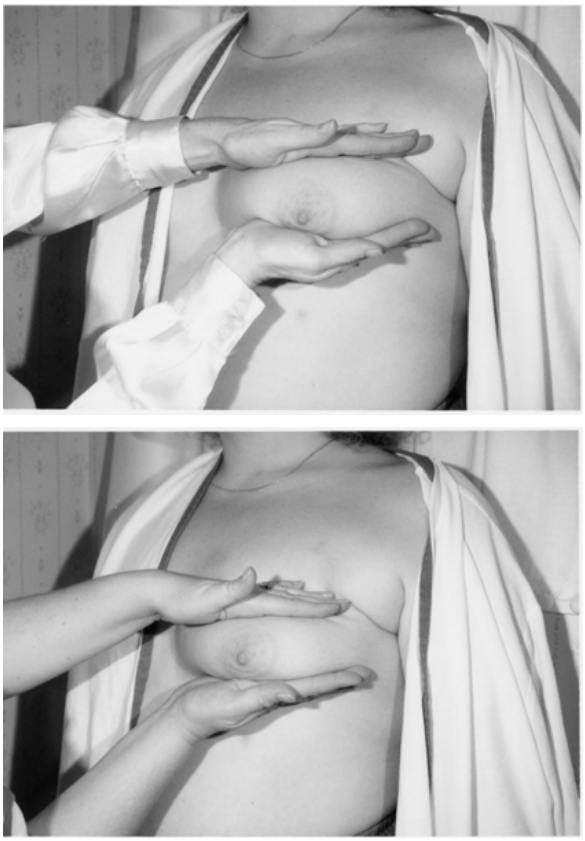


Fig. 2.8. The technologist rolls the breast: (top) to flatten it as much as possible and (bottom) before it is placed on the image receptor.

oblique views, the technologist should perform a coned-down third view with the nipple in profile.

The one exception to this rule is a mammogram on a man. Male glandular tissue is almost always subareolar. The radiologist needs to see its relationship to the nipple.

For this reason, the technologist should carefully position a man for the CC and oblique views with the nipple in profile. If all the glandular tissue is not discernible on these two views, the technologist should perform a third oblique view without the nipple in profile.

2.4.1 *Craniocaudal View*

For the standard CC view, the radiographic beam is directed from above and through the breast to the image receptor, which is

positioned caudal to the breast. It is essential to see as much of the medial aspect as possible on the CC view because frequently a small central or medial lesion is visible only on this view (Figure 2.9). On the MLO view, denser lateral tissue will overlap the less dense medial tissue and may obscure a small mass. A lesion close to the sternum may slide out from under the compression device when the patient is being positioned for the MLO image, which is another reason for including as much medial tissue as possible on the CC view.

The patient should stand with her feet pointed towards the image receptor. The technologist may stand either laterally or medially to the breast being imaged. It is usually easier to pull the medial half of the breast onto the film from the lateral side (Figure 2.10). The patient should steady themselves by grasping the support bar with her contralateral hand. The patient should

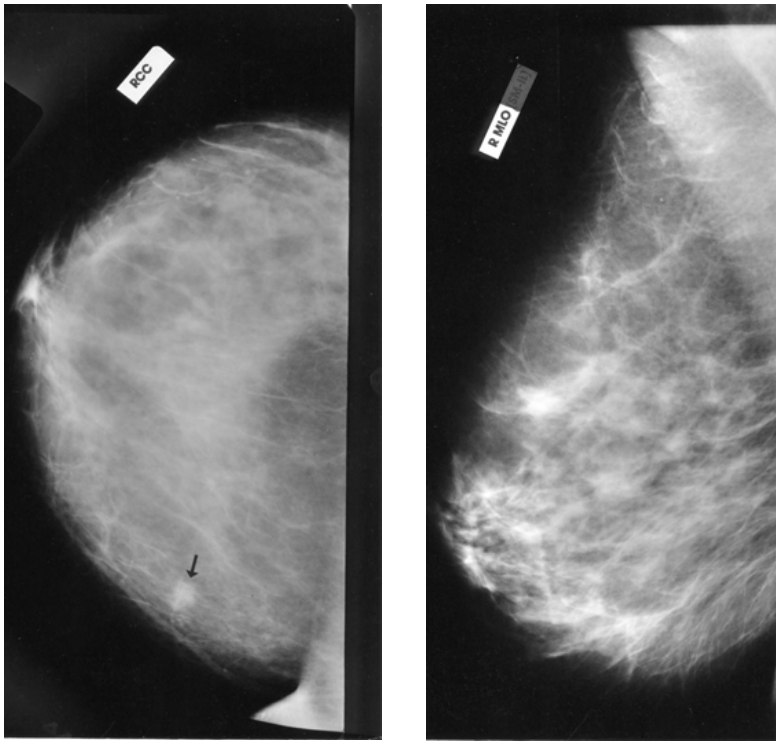


Fig. 2.9. An 8 mm diameter neodensity is visible (arrow) on a routine screening CC mammogram (left), but because of dense, overlapped glandular tissue in the lateral half of the breast, this density was not identifiable on either the MLO view (right) or the 90 degree mediolateral view. Open-surgical biopsy confirmed that this density was a carcinoma.

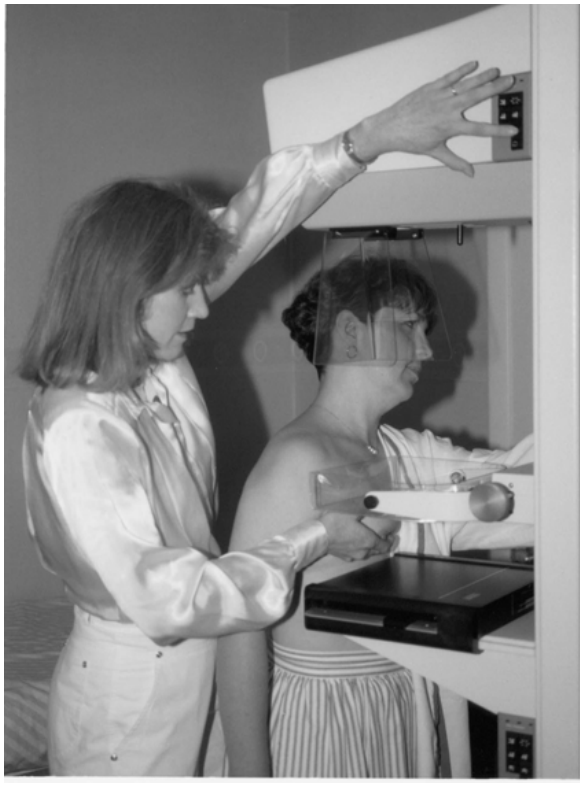


Fig. 2.10. The patient faces the mammography unit and relaxes her arm comfortably at her side on the side being radiographed. To help keep her balance, the patient grasps the support bar with the contralateral hand. The technologist lifts up the breast and then raises the C-arm to the level of the elevated inframammary crease.

loosely drop her ispilateral arm. After instructing the patient to relax her shoulders, the technologist should lift up the breast and then raise the film tray to the height of the elevated inframammary crease (Figure 2.10). Because the skin of the lower-half of the breast is more mobile than the upper half, the technologist can lift the breast quite high (Eklund and Cardenosa, 1992). Nevertheless, the technologist needs to be careful not to lift it too high, since an inferior lesion might not be included on the image (Figure 2.11). Conversely, if the position of the image receptor is too low, a superior lesion might not be imaged (Figure 2.12).

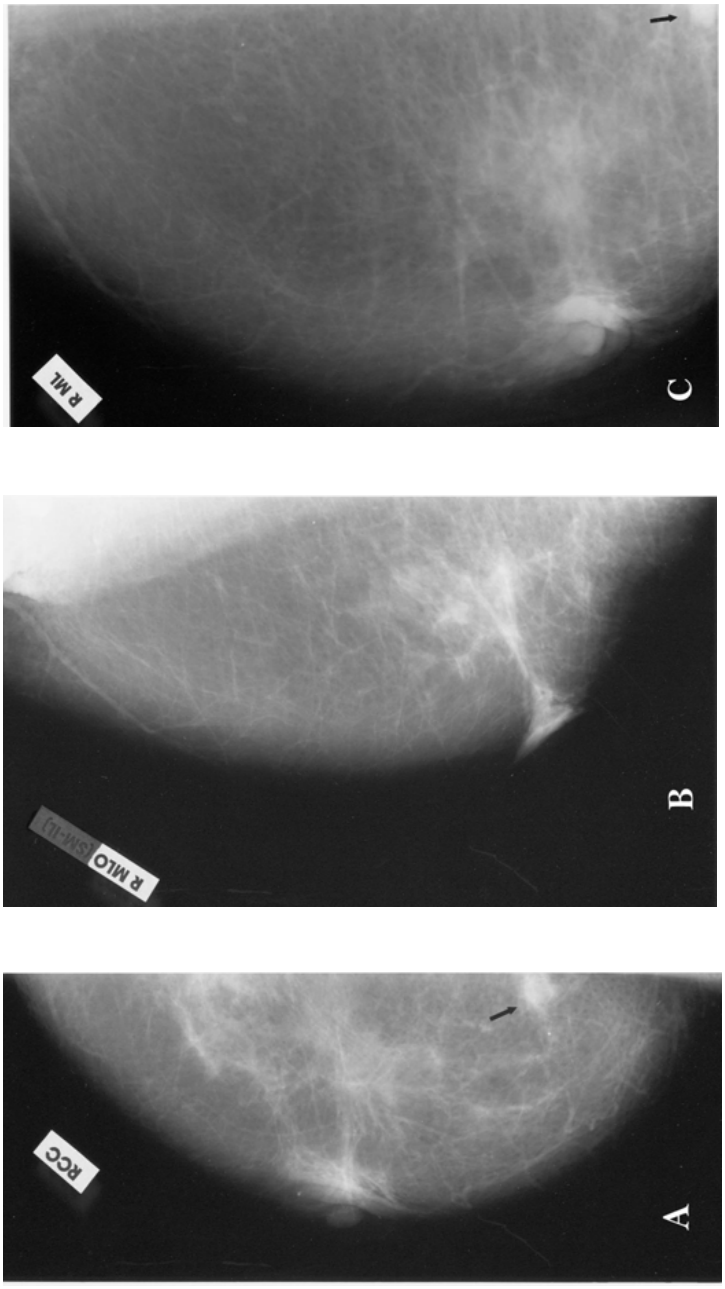
The technologist should then place her other arm behind the patient, hold the patient's opposite shoulder, and gently rotate the patient so that her sternum is as close to the film tray as possible.

The technologist can either move the patient's head or instruct the patient to move her head around the tube head toward the contralateral side (Figure 2.10). After placing the breast on the film tray, the technologist should again ask the patient to let her shoulders relax inferiorly to loosen the skin covering the upper chest wall (Figure 2.13). This assists the technologist in pulling as much of the upper half of the breast as possible onto the image receptor. To help in imaging the medial tissue, the technologist should lift the medial aspect of the opposite breast onto the image receptor (Figure 2.14). Next, the technologist grasps the lateral aspect of the breast and lifts as much of the tissue as possible onto the image receptor. The technologist needs to do this without rotating the patient's torso; otherwise, some medial tissue might rotate off the image receptor. Gently placing her hand behind the patient's back to prevent her from pulling back during compression, the technologist should then begin compressing the breast. If the skin overlying the breast is tight, the glandular tissue of the axillary tail often cannot be pulled onto the image receptor. In such instances, the technologist should not try to pull the upper outer portion of the breast onto the image receptor, because this tissue will swing medially, overlap the more sparse medial and central tissue, and might cover up a small cancer. If the CC view does not image the axillary tail and the axillary tail is overlapped on the oblique view, the technologist should perform an additional 20 to 30 degree oblique view. The technologist can pull back redundant tissue between the glandular tissue of the axillary tail and the axilla (Figure 2.15), because imaging this tissue on the CC view is unnecessary since the oblique view will image this area.

Bassett and colleagues (Bassett *et al*., 1993) found they could image the medial aspect of the pectoral muscle in 32 percent of their CC views (Figure 2.16). If the technologist questions whether this imaged tissue is a true mass, she should repeat the craniocudal view with the image receptor slightly angled obliquely in either direction from the CC view. The shape and size of the mass usually change, indicating that the pectoral muscle has produced the mass (Figure 2.17). A true mass does not change in either size or shape.

2.4.2 *Mediolateral-Oblique View*

Because the MLO view images significantly more of the axillary tail and the posterior aspect of the breast (Lundgren, 1977) than the lateral view, it has replaced the lateral view as the complement


R ML
C
R MLO
B
RCC
A

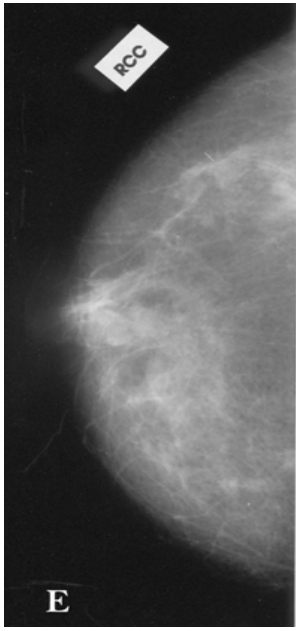


Fig. 2.11. This 60 y old woman's correctly performed right CC-view mammogram (A) demonstrated a posterior neodensity (arrow), which subsequently proved to be a carcinoma. This neodensity was not visible on her MLO view mammogram (B) but was perceptible on a lateral-view mammogram (C). When the CC-view mammogram was repeated with the inframammary crease deliberately raised too high (D), the lesion no longer was apparent (E) because the lower-half of the breast could not be stretched onto the image receptor. If the breast had been elevated too high on her original CC-view screening mammogram, both views would have completely missed this peripheral lesion.

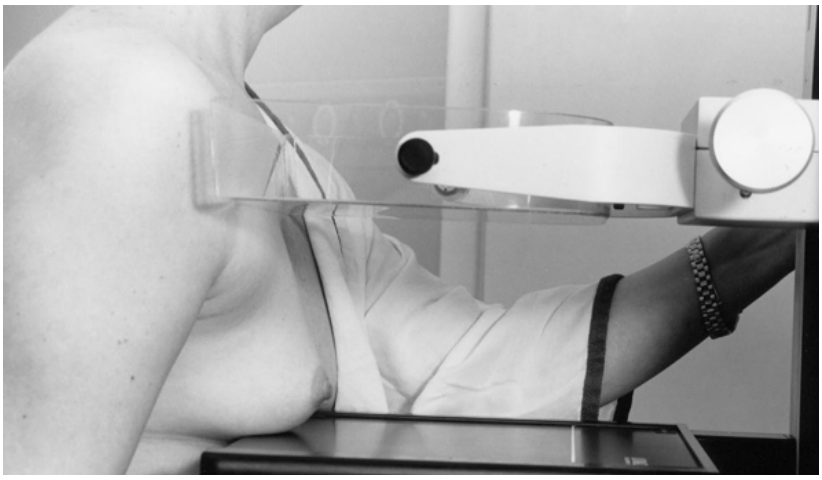


Fig. 2.12. If the image receptor is not raised sufficiently high, the breast will droop onto it, resulting in less imaged superoposterior tissue.

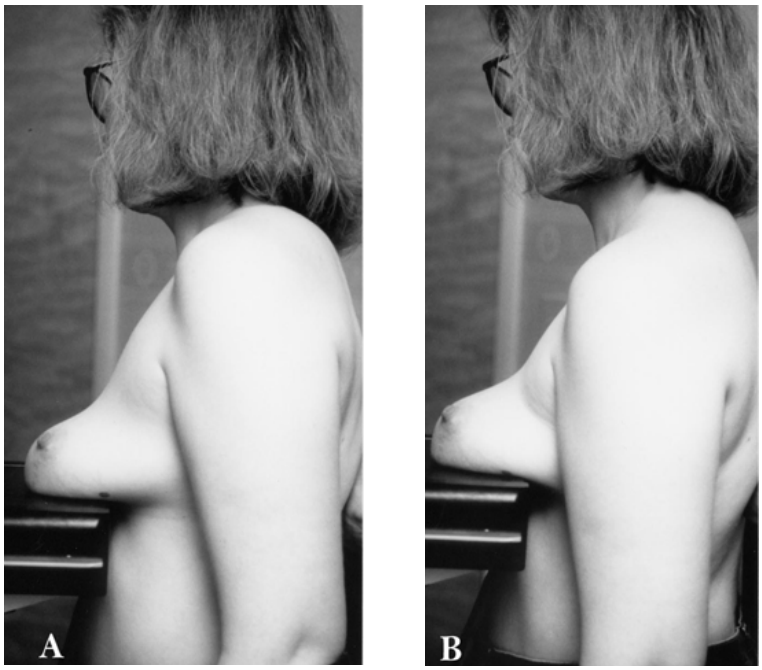


Fig. 2.13. Poor posture makes the breast easier to position. (A) An erect patient raising her shoulders, which tightens the skin. (B) The same patient relaxing her shoulder, so that the skin loosens and her breast naturally falls forward.

Fig. 2.14. To help visualize the medial tissue, the technologist lifts the opposite breast onto the image receptor.

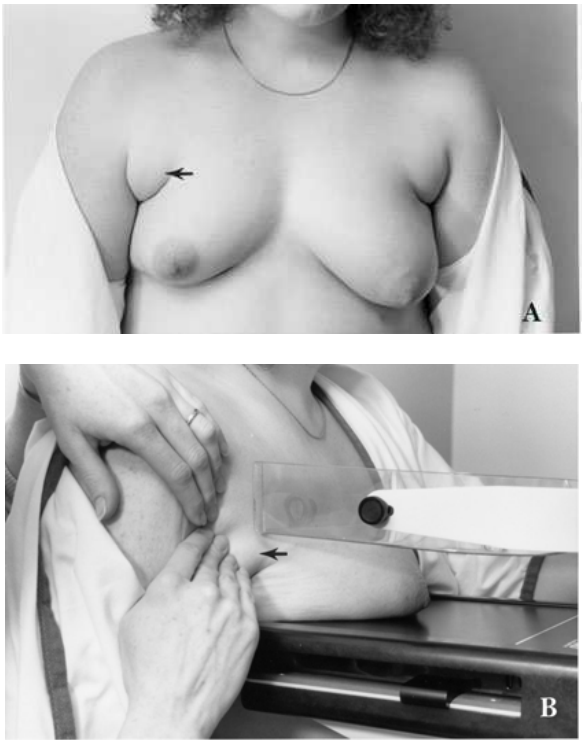
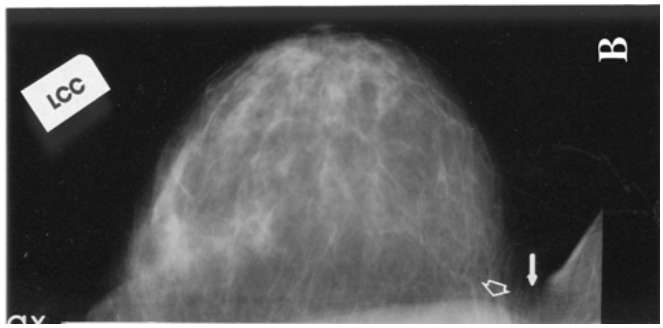


Fig. 2.15. Because the upper axillary skinfold (A-arrow) overlapped the glandular tissue in the upper outer quadrant, the technologist pulled it back (B) before performing the CC view. Since its position was high, it was clearly visible on the MLO view.



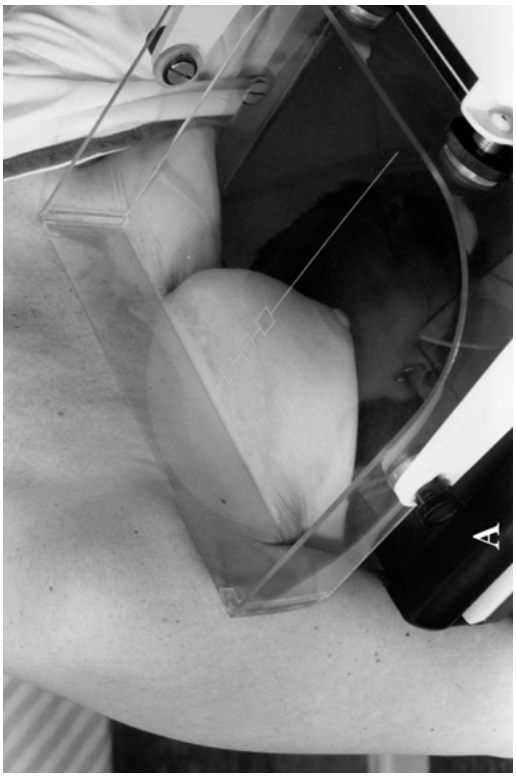


Fig. 2.16. The CC view (A). On the CC-view mammogram (B), a knuckle of pectoral muscle often overlaps the posteromedial breast tissue (open arrow). In about 30 percent of patients, the tissue beneath the medial cleavage will also be revealed (solid arrow).

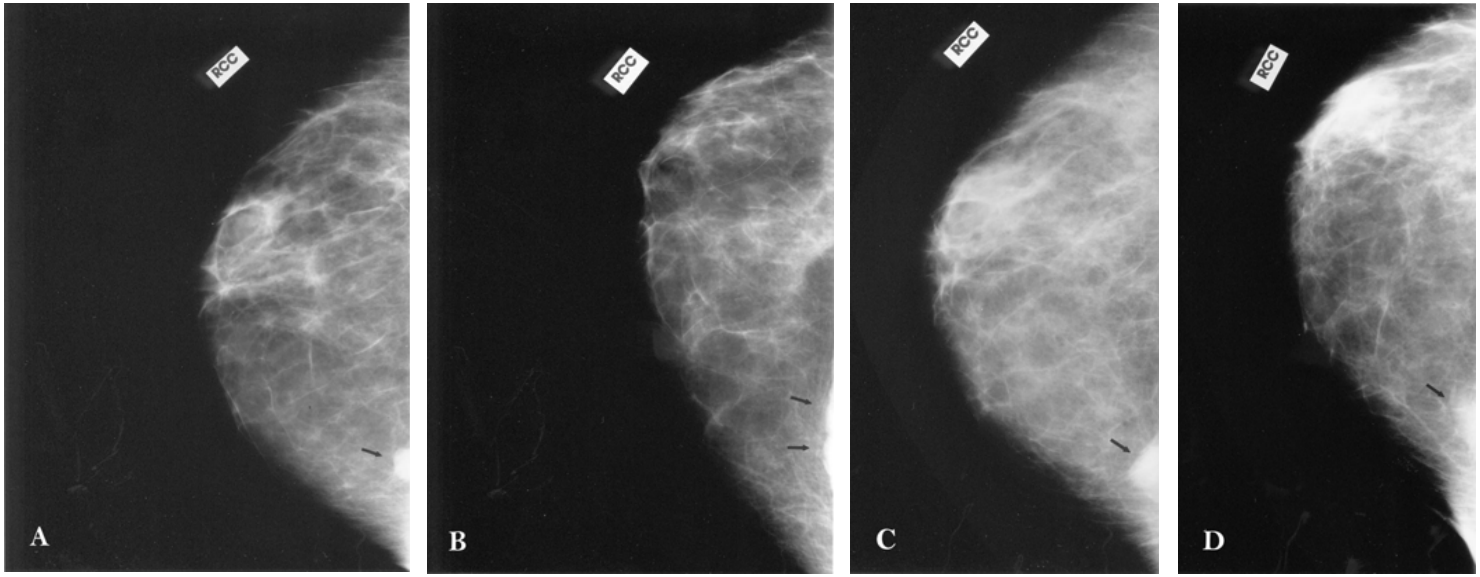


Fig. 2.17. When the pectoral muscle is visible on the CC view (A), it may imitate a cancer. Three different CC views (B, C and D) on the same patient show changing convexity and shapes, consistent with pectoral muscle rather than a true mass density.

to the CC view for the routine, two-view mammographic study. In the MLO view, the technologist rotates the C-arm so that the image receptor is parallel to the fibers of the pectoral muscle. She places the imaging system midway between the inferior and the lateral aspect of the breast (the lower outer quadrant), and directs the radiographic beam through the breast from superomedial to inferolateral.

Screen-film mammography has a narrow recording latitude. Moreover, screen-film mammography requires a soft, low-energy x-ray beam to maximize contrast. For these reasons, the breast needs to be compressed to a uniform thickness; otherwise, the thicker areas will be underpenetrated and the thinner areas overpenetrated. Because uniform thickness is so essential, it is necessary to use a flat compression device parallel to the film (Figure 2.18).

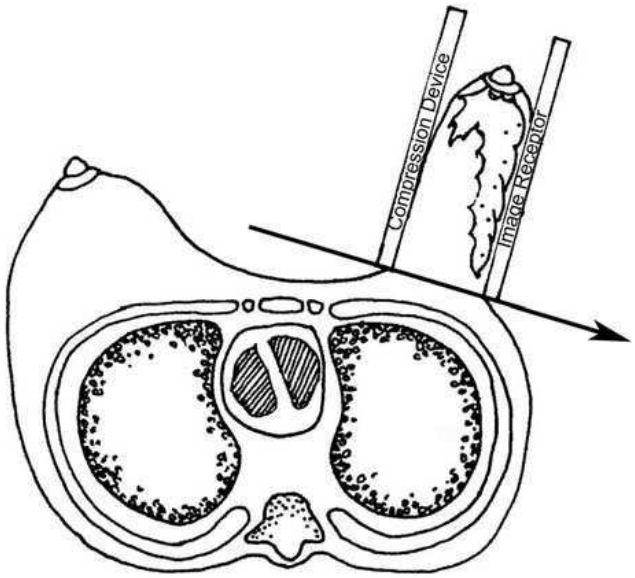


Fig. 2.18. A flat compression device that is parallel to the image receptor and has an angle of 90 degrees at the chest-wall grips the posterior aspect of the breast and pulls the tissue forward onto the image receptor. The flat compression device also compresses the entire breast more evenly than a compression device with a curved chest-wall angle. In the mediolateral or MLO view, a 90 degree angled compression device is more successful than a curved device at gripping and pulling the tissue away from the convexity of the rib cage, and thereby images more of the posterior tissue.

More posterior breast tissue is visible on the MLO view than on the lateral view. On the MLO view, compression is applied parallel to the lung axis of the pectoral muscle, 30 to 60 degrees off the vertical axis. This allows better compression of the muscle than achieved on the lateral views. Thus, on the MLO view, the muscle is less likely to pull the breast toward the chest wall and off the image field.

Since the obliquity of the pectoral muscle differs from one person to the next, the angle of the oblique view may vary from 30 degrees for a patient with a short torso to 60 degrees for a tall patient with a long torso; the angle is usually about 45 degrees. The technologist should determine the correct angle by rotating the C-arm until the image receptor is parallel to an imaginary line extending from the xiphoid process to the thickest portion of the pectoral muscle anterior to the axilla. The technologist should always compress both breasts at the same angle, unless the patient has a significant anomaly such as scoliosis. The technologist should record the angle of obliquity on the image label.

Initially, the patient should stand with the ipsilateral side adjacent to the image receptor, which is usually rotated 45 degrees so that the image receptor is parallel to the fibers of the patient's pectoral muscle. The patient's anterior chest wall is, then, parallel to the image receptor. The technologist should raise the patient's arm no more than 90 degrees until it is just barely above the image receptor with the patient's elbow slightly bent and just posterior to the image receptor. The technologist should ask the patient to place her hand on the support bar of the C-arm. If the technologist pulls the patient's arm back or raises it too high, the breast skin will be too tight. When the skin is taut, it resists the technologist's attempts to pull the breast away from the chest and onto the image receptor, which might result in missing a lesion.

The technologist should face the patient, reach an arm around each side of the patient, place one hand behind the patient's back to grip her shoulder on the side being positioned, and the other hand posteriorly and beneath the breast tissue (Figure 2.19). The lateral breast skin is more mobile than the medial skin, which facilitates pulling the breast tissue medially. The technologist should lift the patient's shoulder and her breast and pull the mammary tissue upward, outward and towards the sternum to tighten the posterior skin as much as possible (Figure 2.20). Next, the technologist should place the posterior axillary line of the skin on the outer edge of the image receptor and instruct the patient to lean against the tray to keep this posterior tissue from sliding away. The

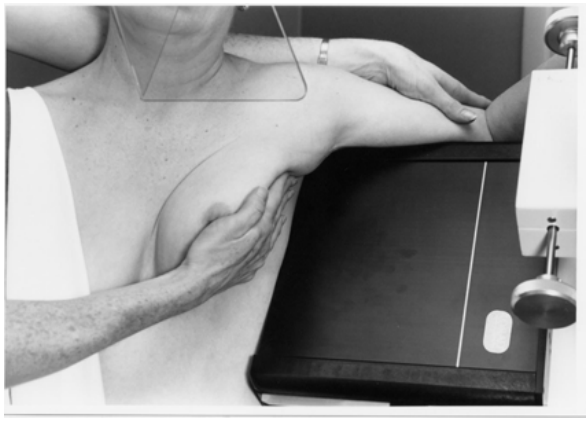


Fig. 2.19. The technologist lifts up the breast and pulls it tightly upward and outward, placing the posterior axillary line on the image receptor while with the other hand, she simultaneously lifts the patient's shoulder and rests the patient's arm along the superior edge of the image receptor.

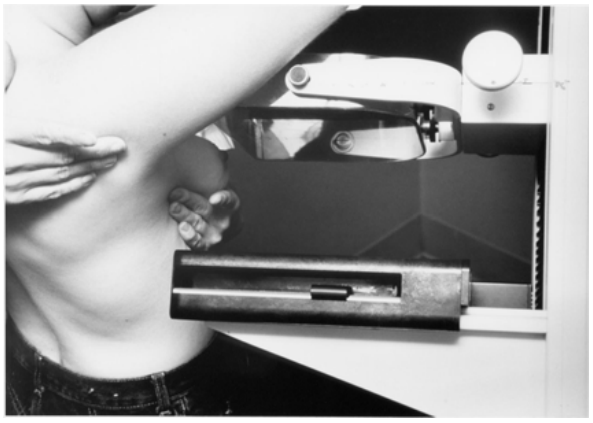


Fig. 2.20. The patient stands adjacent to the image receptor with her anterior chest wall parallel to the image receptor. The technologist places one hand posterolaterally to the breast tissue. Next, the technologist places her other hand behind the patient's shoulder on the side to be positioned.

technologist should then rotate the patient until her sternum touches the compression device. The technologist should then walk behind the patient, slightly lift her shoulder, and recheck the posterior tissue to make sure that it has not slipped from visualization.

The technologist should return to face the patient and ask the patient to relax her shoulders and let them droop, so the technologist can pull the shoulders closer together. Many patients instinctively draw back their shoulders thereby tightening the breast skin (Figure 2.21). The technologist must recognize and counteract this posture, or else the medial tissue will be too tight to pull onto the image receptor. Relaxing the patient's shoulders and bringing them closer together will loosen the skin covering the chest wall and enable the technologist to pull the looser medial tissue into view.

After the technologist has rotated the patient's upper torso 90 degrees (Figure 2.22), she needs to ask the patient to move her feet (Figure 2.23) to match the rotation of her upper body; this will stabilize the patient and help prevent breast motion during the exposure. With both hands, the technologist should pull and lift the breast up and away from the chest wall while applying motorized compression with the foot pedal (Figure 2.24). Not until the compression device has firmly gripped the breast tissue should the technologist remove her hand from under the compression paddle (Figure 2.25). This maneuver is necessary to prevent gravity from pulling the breast down and making the ducts droop instead of

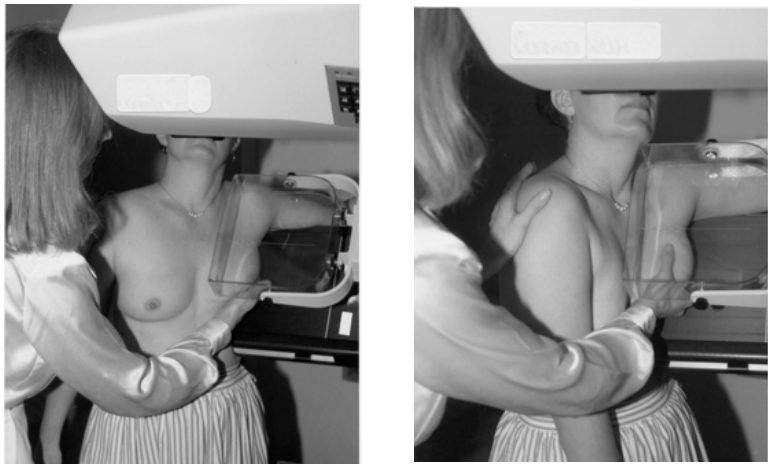


Fig. 2.21. This patient is instinctively drawing back her shoulders thereby tightening the skin of the breast (left). Hunching the shoulders (right) loosens the skin in the anterior chest wall, so more medial tissue can be positioned under the compression device.

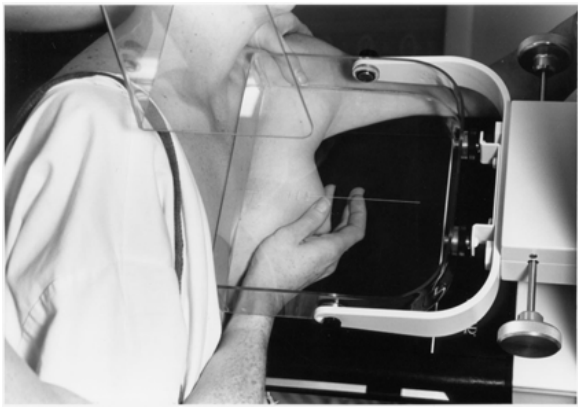


Fig. 2.22. The technologist rotates the patient until the compression plate touches the sternum while continuing, at the same time, to pull the breast upward and away from the chest.

Fig. 2.23. For the MLO view, the patient's feet initially are parallel to the image receptor. After the sternum is rotated towards the film tray, it is often difficult for the patient to keep her balance if her feet are at right angles to her torso (A). If her feet are rotated 90 degrees to match the torso position (B), it will be easier for the patient to tolerate compression without motion.

Fig. 2.24. Beginning compression with the motorized foot control frees both the technologist's hands for positioning the breast.

radiating straight out from the nipple like the spokes of a wheel. Its importance must be stressed because a cancer is identifiable when its spicules radiate at right angles to the ducts. If the ducts droop, discerning these spicules can be difficult (Figure 2.26). The technologist should then apply final compression with a hand-wheel control or with a similarly swiftly responsive control, which enables her to reduce compression quickly if the patient becomes uncomfortable. The technologist may need a rubber spatula or wooden ruler to hold very small breasts in position while bringing the compression paddle into place. Finally, to open up the inframammary crease, the technologist should pull the tissue beneath the inframammary crease down and away from the chest wall (Figure 2.27). The posterior axillary line, the sternum, the clavicle, and the humeral head should mark the boundaries of the imaged tissue (Figure 2.28).

Fig. 2.25. The technologist pulls the breast away from the chest wall, removing her hand only after the compression device has gripped the breast.

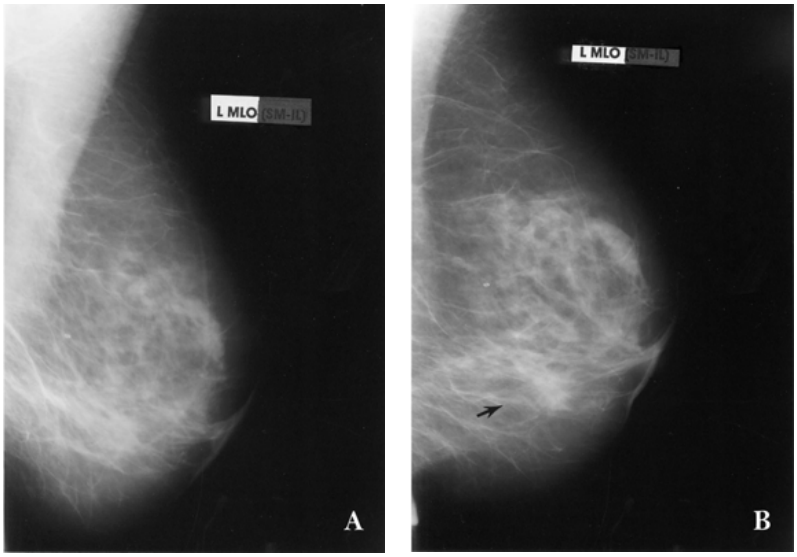


Fig. 2.26. When the ducts overlap in a poorly compressed breast (A), spicules radiating from a small cancer are more difficult to see. Lifting the breast up and away from the chest wall for the MLO view allows the ducts to radiate in straight lines from the nipple, permitting the spicules radiating from a small cancer (B-arrow) to be more readily perceptible.

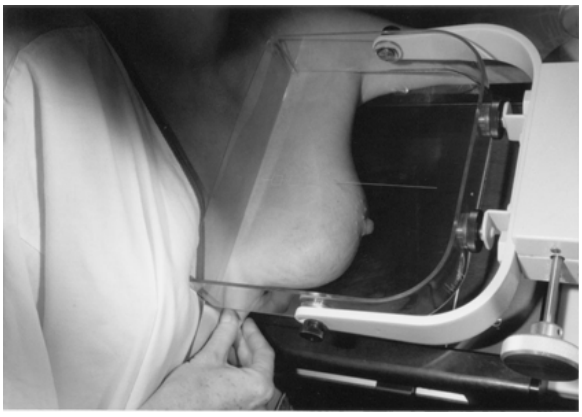


Fig. 2.27. To help visualize the inframammary crease, the technologist pulls the tissue beneath the inframammary fold after the compression plate is brought down.

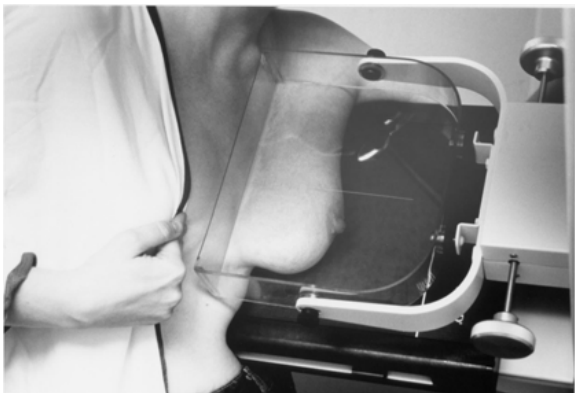


Fig. 2.28. The completed MLO position.

When the MLO projection is done correctly, Bassett *et al*. (1993) state that the pectoral muscle is usually visible (Figure 2.29) and should be identifiable within 1 cm of the nipple line or below it in 81 percent of patients. But in patients whose positioning is limited by a physical impairment such as arthritis, a stroke, an injury to the shoulder, kyphoscoliosis, or atrophy of the shoulder muscles, the pectoral muscle may not be identifiable. Ideally, the inframammary crease should also be discernible. But thin patients do not have enough subcutaneous adipose tissue to pull onto the image receptor, so that in actual practice, the inframammary crease is visible in only approximately 50 percent of patients.

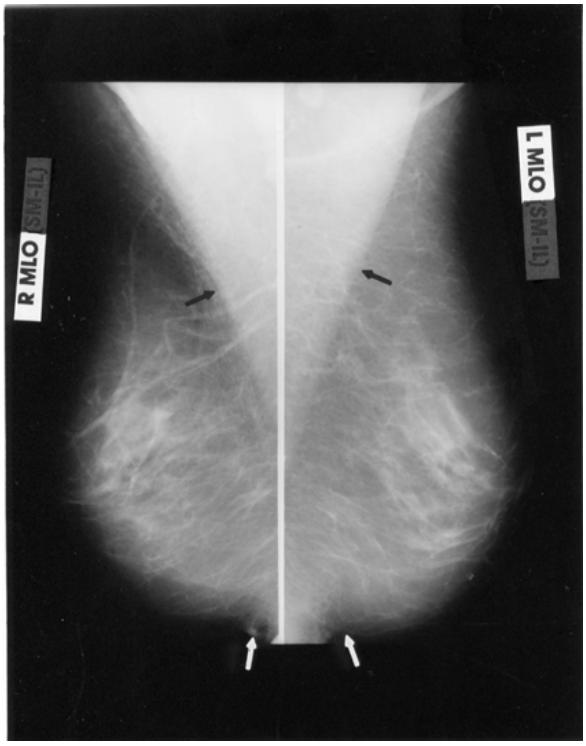


Fig. 2.29. This well-positioned MLO mammogram demonstrates the pectoral muscle (black arrows) and the inframammary crease (white arrows). The breasts have been pulled upward and outward to prevent them from drooping.

If the patient's abdomen protrudes and hinders the technologist from compressing the breast, the technologist should ask the patient to move her abdomen away from the image receptor by stepping back from the tray. The patient should then bend the upper part of her body forward and upward from her waist toward the image receptor to prevent her abdomen from interfering with compression.

The importance of the MLO view is to image as much posterior tissue as possible. It is important for the technologist to concentrate on pulling as much of the flexible posterolateral glandular tissue as possible onto the film tray, rather than positioning the image-receptor tray in the midaxilla behind the pectoral muscle. On the MLO view, the latissimus dorsi muscle will be imaged in approximately 10 percent of patients (Figure 2.30).

2.5 Clinical Considerations on Positioning

2.5.1 *Grid*

The grid, placed between breast and image receptor, absorbs scattered x rays and improves contrast (Figure 2.31), enabling the border of the glandular tissue to appear more crisply defined. Even so, the grid does not eliminate the need for firm compression, which spreads the tissue apart and permits the borders of small lesions to be perceived (Figure 2.32). The breast should be compressed as firmly as the patient permits.

Previously, many radiologists used the grid only for patients with dense glandular tissue or breast tissue that could not compress to <5 cm. Now, because the dose required for the newer films is much lower and because modern grids provide such enhanced contrast, using the grid for routine mammograms has become common practice.

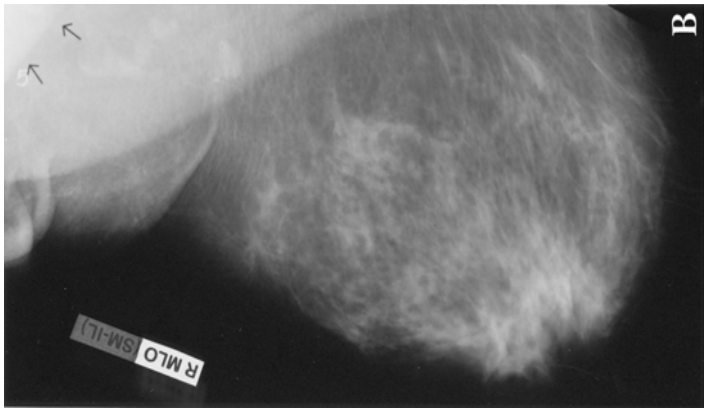
Two image-receptor sizes, housing corresponding sized grids are necessary. One, for small breasts, holds film measuring 18 × 24 cm, while the other, for larger breasts, holds film measuring 24 × 30 cm.

One large bucky equipped with devices to hold both the smaller and the larger films will not suffice. When a small-breasted patient lifts her arm above the larger tray, her skin becomes taut, which could prevent the technologist from pulling the patient's breast forward on the film and could result in missing a posterior cancer (Figure 2.33). Using only a small bucky would mean that many films would be necessary for imaging large-breasted patients. Therefore, as indicated above, two bucky sizes holding two image-receptor sizes and two corresponding sized grids are necessary.

2.5.2 *Magnification*

Radiographic magnification can provide improved visualization of fine detail. The grid and magnification usually cannot be used together, because of the limitations of the tube's output. Thus, the magnified image may lack sufficient contrast. Two factors help overcome magnification's diminished contrast and are extremely important for magnifying a questionable area:

- Increasing the air gap distance between the breast and the film. The greater the air gap, the greater the improvement in subject contrast (Section 4), because more scattered radiation will angle away from the film.
- Coning down. The smaller the magnified area, the less scattered radiation will be produced (Figure 2.34).


B
R MLO (SM-ILJ)


A

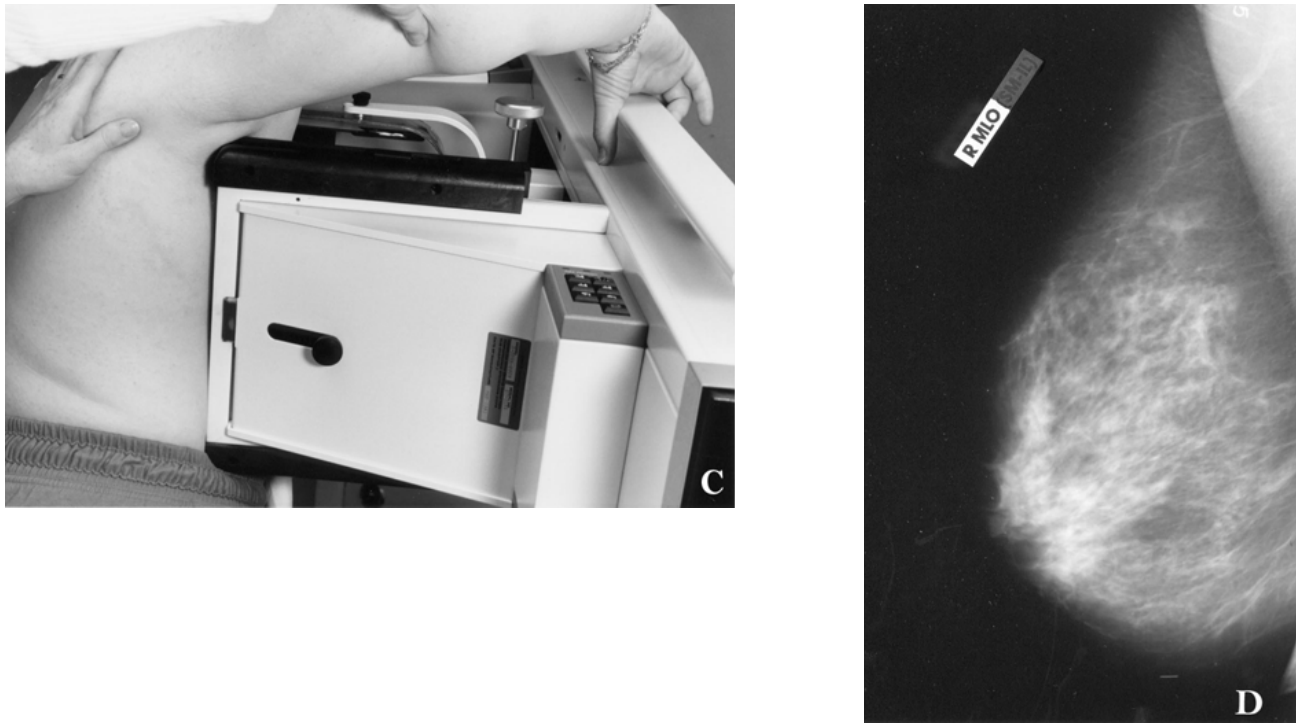


Fig. 2.30. When the technologist pulled as much of this patient's tissue as possible onto the image receptor, the tissue was visualized back to the level of the posterior axillary line (A) in the region of the latissimus dorsi muscle. Figure (B) demonstrates how much posterior glandular tissue including the latissimus dorsi muscle (arrows) is visible with this maneuver. Positioning the image receptor into the axilla behind the pectoral muscle (C) does not image as much posterior tissue (D).

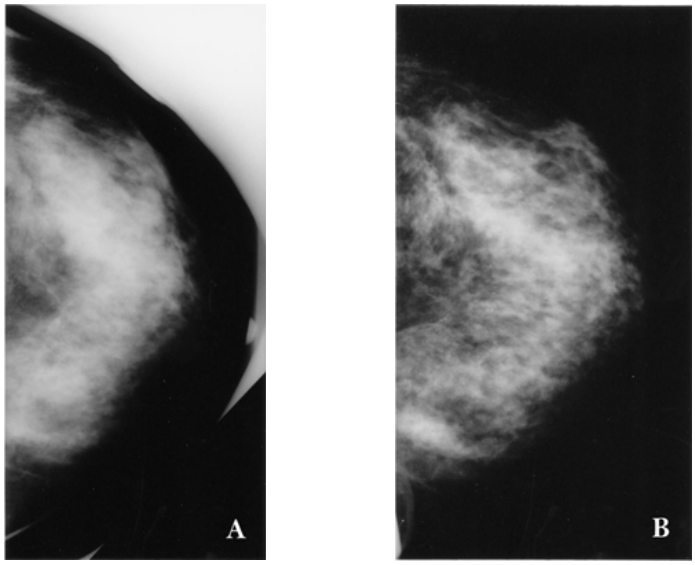


Fig. 2.31. This 37 y old woman's calcifications are not as identifiable on her left CC nongrid mammographic view (A) as they are on the same projection with the grid (B).

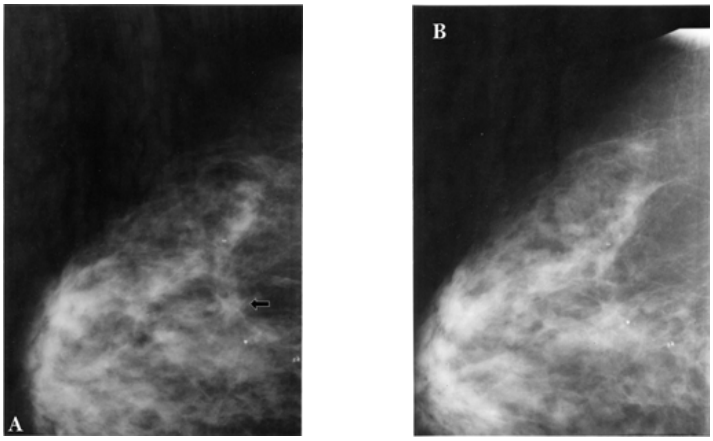


Fig. 2.32. With firm compression, the small cancer (arrow) is obvious on this CC-view mammogram (A), because compression displaces the islands of glandular tissue so that the border of the carcinoma stands out. With less firm compression, the mammogram (B) on the same patient produces less displacement of the glandular tissue, which makes the lesion more difficult to perceive.

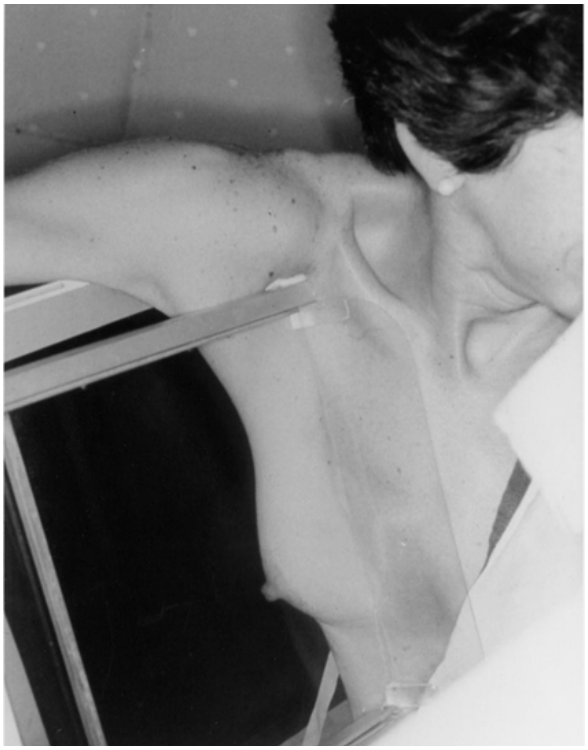


Fig. 2.33. If a posterior cancer were present in this patient's small breast, it might not be imaged because her arm must be raised above the edge of the large compression device. This stretches the skin and makes it difficult to pull the posterior aspect of the breast into view or onto the image receptor.

Coned-down magnified views of borderline abnormalities, perceived either on screening mammography or on tangential views of palpable densities, add much-needed information. If a lesion is benign, it will usually look more innocuous on magnification (Figure 2.35). If it is a cancer, however, magnification should make it appear more obvious (Figure 2.36). The area in question should not be magnified any more than the size of the small focal spot will permit without excessive blur (Section 3.1.10).

2.5.3 *Reliability of the Automatic Exposure Control*

Reliability of the automatic exposure control (AEC) is essential for large-volume screening, particularly for those radiologists who depend on delayed batch-processing. AEC should possess a minimum of three different sensor positions, as well as tissue-averaging

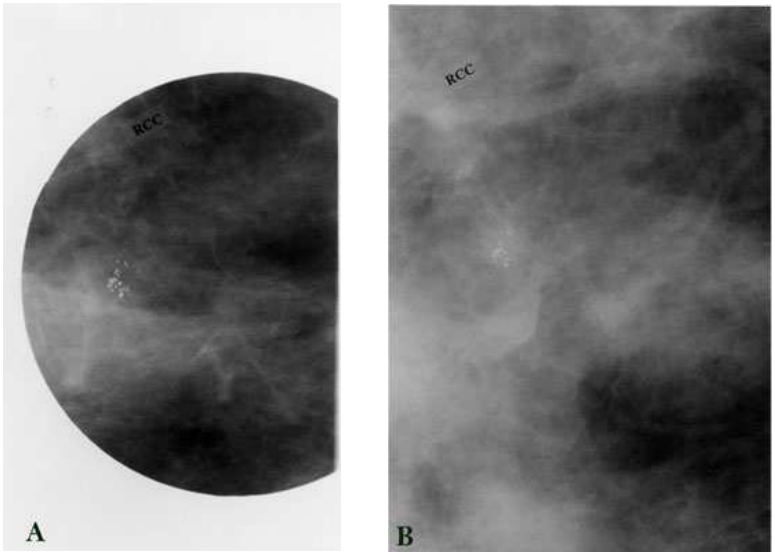


Fig. 2.34. (A) If the questionable area is small and if its location can be ascertained precisely, the round 5 cm spot-compression device can be used to separate the glandular tissue. It provides the best compression and with coning to this small area, the most contrast with magnification. (B) The rectangular, 9 cm wide spot-compression device permits imaging of a larger area of breast tissue, but the price is slightly poorer compression and contrast.

capability. Most units have as many as 11 separate density control settings. The unit should offer the technologist the option of either setting the operating potential, target material and filter manually before positioning, or permitting the x-ray machine to choose the tube potential, target material and filter based on breast thickness or measured attenuation. If the technologist does preset the operating potential, target material and filter, the unit should not be able to override the selection and change the technologist's choice. The design of the AEC must be such that the technologist can choose the best position for placing the sensor. The sensor should not be larger than a small breast. If the sensor extends beyond the breast, the image may be underexposed.

After the technologist reviews the patient's old studies to see where the densest tissue lies, the AEC should be placed under this densest tissue. If the technologist cannot do this, for instance, if the densest tissue lies in the upper outer quadrant or just under the areola in a large breast, then the density setting should be raised.

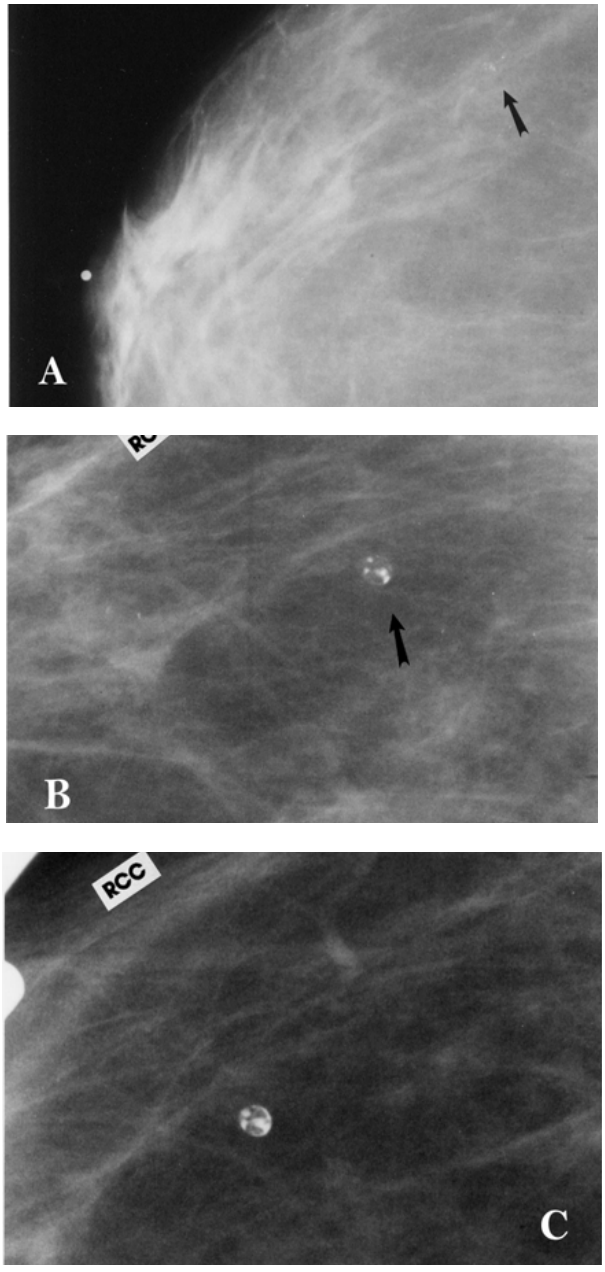


Fig. 2.35. Four tiny calcifications are visible on one contact grid study (A). A 2x magnified coned-down radiograph (B) shows benign rim calcium indicating that biopsy is unnecessary. One year later, the presence of further calcifications verified that these were benign (C).

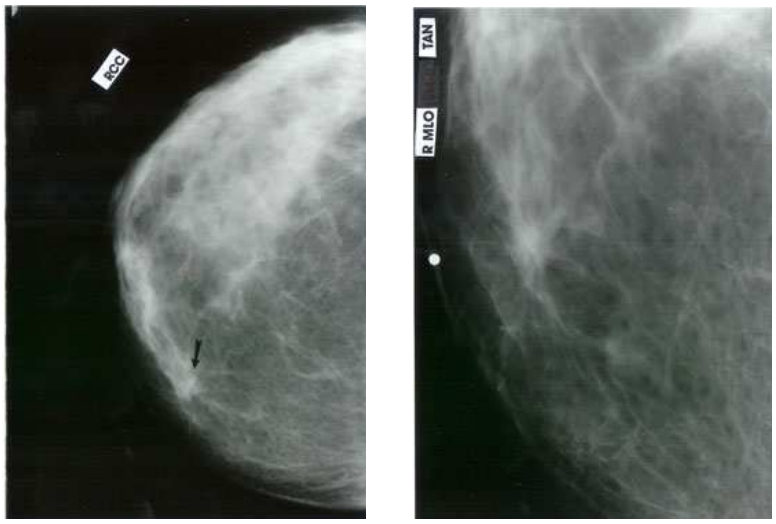


Fig. 2.36. Slight architectural distortion is visible on this screening right CC-view mammogram (left, arrow). When the C-arm is angled 10 degrees for a coned-down magnified-view mammogram (right), the border of this tissue is clearly irregular. Biopsy proved that this was a carcinoma.

Some newer AECs can average the density of the tissue over multiple locations in the breast, which makes positioning the sensor less critical.

On many units, the AEC-determined exposure time is derived from both the thickness and the density of the compressed breast. For large-volume screening to succeed, the phototimer must be exceedingly reliable. At least once a year, a physicist should check the reliability of the AEC with a phantom simulating the density of the breast across a range of breast thicknesses (2, 4, 6 and 8 cm) (ACR, 1999; MQSA, 1992).

When images are underexposed, the technologist should increase the density setting for repeat views. If, however, either the exposure for the underexposed film has reached the maximum exposure time or patient motion has occurred, the technologist should increase the operating potential but not the density setting to decrease exposure time.

2.5.4 *Compression*

Even though the grid is used for virtually every contact mammogram, firm compression is still necessary. The key to enlisting the patient's cooperation during compression is the technologist's

ability to allay the patient's fears and explain why compression is so essential. The technologist should tell the patient that some discomfort may be experienced, but that the patient controls the degree of compression. The technologist should compress no more than the patient will permit. If the technologist takes the time to explain carefully and compassionately, she usually can win the patient's confidence. When a patient understands the reason for firm compression and realizes that the control is theirs, not the technologist's, she will almost always be willing to cooperate. But she needs to know why compression is essential. The patient needs to know that many cancers have been missed only because the breast was inadequately compressed.

The technologist must negotiate an agreement with every patient about how much compression the patient thinks she can tolerate. Some patients have exceedingly tender tissue or low pain thresholds. It is better to obtain yearly mammograms on a patient who tolerates only minimal compression than procure one mammogram with firm compression on a patient who objects strenuously and never returns for another mammogram.

The technologist should begin compression with a foot-controlled motorized device because this frees both hands to rotate the torso and position the patient's breast. For final compression, a hand-wheel control for example can be used by the technologist to gauge the breast's resistance, to judge the degree of the patient's discomfort, and to slow down the speed with which the paddle descends so that the patient is not frightened. The control should be sufficiently sensitive for the technologist to "feel" the degree of resistance to compression. Without such a hand-wheel control, the technologist might have difficulty in accurately determining how much compression the patient can tolerate. If a patient sees that it is the technologist and not the machine that regulates final compression, she will be less uneasy about the procedure.

Automatic decompression after exposure or the technologist's ability to press a button on the control panel and release compression immediately after exposure, or in an emergency, are also vital to the patient's comfort and safety. A release switch should also be included on the C-arm.

Firm compression is obligatory (Logan and Norlund, 1979) for the following reasons:

- It minimizes geometric blurring. The larger the focal spot, the more essential is straight, firm breast compression that reduces object-film distance.

- It reduces scatter by making the tissue thinner, and thus it enhances subject contrast (Barnes and Brezovich, 1977). Increased subject contrast aids the discovery of calcifications; it makes the outlines of mass densities more identifiable.
- It diminishes motion blurring. If compression is inadequate, significant motion blurring may obscure the image. Most patients are willing to tolerate 2 or 3 s of firm compression.
- It reduces x-ray exposure. When breast compression is minimal, a proportionately higher breast entrance exposure is necessary. Firm compression thus decreases both the breast entrance exposure and the mean glandular dose.
- It reduces the dynamic range requirement of the image receptor (*e.g.*, film), which means that more information can be recorded on the image with greater contrast.

Because the grid improves contrast so much, some people believe that firm compression is unnecessary. This belief is incorrect. Even with the grid, firm compression offers three additional advantages:

- It provides more uniform film optical density. Nonuniform thickness of glandular tissue produces a wide range of film optical density. Firm compression flattens the tissue, reducing the variations in the density of the image. The grid does not flatten tissue. Greater compression allows the mammographer to use a lower operating potential, which enhances contrast even further and facilitates the discovery of subtle calcifications, low-density masses, asymmetries, and architectural distortion.
- It accentuates the difference in optical density between normal and malignant tissue. Cancers are usually denser than normal glandular tissue. Compression accentuates this difference in density because it flattens the more-elastic glandular tissue, but the radius of a cancer, which ordinarily is less distensible, usually remains unchanged.
- It separates tissue elements. By pushing the islands of overlapping glandular tissue apart, firm compression permits better imaging of the margins of suspicious lesions (Figure 2.32).

Spot compression (Figure 2.34) spreads out the glandular tissue better for assessing questionable areas. The thinner the compressed

breast and the more coned-down the area, the better the contrast. Many manufacturers supply a round, spot-compression paddle, 8 cm in diameter. A 9 cm wide, rectangular compression device (Figure 2.34) is useful in spot compression of slightly larger, nonspecific problematic areas. It is also helpful in compressing areas of the breast and axilla that are difficult to position.

2.5.5 *Technical Decisions*

Before the technologist reviews the patient's prior images, she should keep all the foregoing factors in mind. When checking the prior images, the technologist should observe the density of the glandular tissue: the denser the tissue, the higher the operating potential should be for an additional mammogram. She also needs to determine the location of the densest tissue, so that the correct position for the AEC detector is selected. The old images should also be searched for technical imperfections. If, for example, there is motion on the images, the technologist will need more time for encouraging the patient not to move. If the patient cannot refrain from moving, the technologist needs to use a higher operating potential to reduce the exposure time. If the glandular tissue is exceedingly posterior, maximum cooperation from the patient will be needed for optimal positioning.

The final decision about the correct operating potential depends on the technologist's final evaluation of the patient just before the mammogram is initiated. This evaluation includes:

- How much the breast can be compressed (the operating potential can be lower if the breast is compressed more thinly).
- How dense is the glandular tissue on previous mammograms. Dense tissue necessitates a higher operating potential.
- How long is the exposure that the patient can tolerate before motion becomes a problem. A higher operating potential may be necessary to shorten the exposure time.

Even if a patient is cooperative and the technologist observes no motion artifacts on the radiograph, the film may still be underexposed because the tube's limitations automatically terminated the exposure. In such an instance, the technologist cannot increase the density setting because the tube's limitations will prevent a longer exposure. The only recourse, then, is to increase the operating potential.

2.6 Double Interpretation of Screening Mammograms

Interpretation of mammograms by two radiologists increases the yield of diagnosed cancers by 5 to 15 percent (Thurfjell *et al*., 1994). When two readers interpret the films independently, the cancer detection rate is higher but costs are increased due to the second radiologist's time and the additional test(s) performed on recalled women. In consensus reading, the two readers discuss all cases in which there is disagreement in the diagnosis. This results in a lower recall rate but not as many additional diagnosed cancers. Of interest is the fact that the cancers picked up by one of the two readers only are more likely to be Stage 0 or 1 (Thurfjell *et al*., 1994). Double interpretation of mammograms is, at present, not routinely performed because of its increased cost and cannot be supported by the present low reimbursement for screening mammograms.

3. Equipment

3.1 X-Ray Unit

3.1.1 *Introduction*

While a variety of x-ray units have been used in mammography since its inception (Bassett *et al*., 1992; Gold, 1992; Vyborny and Schmidt, 1989), it is now widely recognized that quality mammography requires a dedicated mammographic x-ray unit (ACR, 1993; DHHS, 1987; Haus, 1990; Yaffe, 1991). In order to meet the stringent imaging needs of mammography such a unit must be equipped with a variety of essential features discussed in this Section. These include a small focal spot coupled with a relatively long source-to-image-receptor distance (*SID*) to minimize blur; a low energy x-ray beam and a specialized mammographic grid to provide high subject contrast; and specialized equipment for firm, uniform compression. Without these features, it is almost impossible to visualize small nonpalpable masses and very small microcalcifications, often the only indications of early carcinoma. Use of nondedicated radiographic equipment can result in missing many cancers and can lead to unwarranted biopsies, and is prohibited under MQSA (1992).

A number of authors have described the need for and features of dedicated, specially designed, mammographic equipment (AAPM, 1990; NCRP, 1986). A review of these descriptions indicates that there are a number of features that should be incorporated into a dedicated mammographic unit. Probably, the most comprehensive description of the features of a dedicated mammographic unit is that prepared by ACR (1993) and is frequently cited below. Another summary of these issues appears in *Seminars in Breast Disease* (Haus, 1999a).

The *minimum* set of features for an acceptable dedicated unit has been set by MQSA (1992) regulations. These regulatory requirements are outlined in Table 3.1.

In establishing these requirements FDA drew heavily on the ACR document mentioned above (ACR, 1993). The requirements of the final regulations apply to all mammography units under the purview of MQSA (1992), whether they are used for screening or diagnostic ("problem-solving") mammography.

TABLE 3.1—*MQSA equipment requirements.*

Adapted from MQSA (1992) Section 900.12(b) Equipment [also published in CFR Title 21, Chapter 1, Part 900–Mammography, Subpart B–Section 900.12 (b) Equipment]

(b) *Equipment*. Regulations published under Secs. 1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements.

(1) *Prohibited equipment*. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition includes systems that have been modified or equipped with special attachments for mammography. This requirement supercedes the implied acceptance of such systems in Sec. 1020.31(f)(3) of this chapter.

(2) *General*. All radiographic equipment used for mammography shall be specifically designed for mammography and shall be certified pursuant to Sec. 1010.2 of this chapter as meeting the applicable requirements of Secs. 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

(3) *Motion of tube-image receptor assembly.*

(i) 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.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

(4) *Image receptor sizes.*

(i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 × 24 centimeters (cm) and 24 × 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed from between the source and image receptor.

(5) *Light fields*. 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 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(6) *Magnification*.

(i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification value within the range of 1.4 to 2.0.

(7) *Focal spot selection.*

(i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) 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.

(8) *Compression*. All mammography systems shall incorporate a compression device.

(i) *Application of compression*. Effective October 28, 2002, each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

(ii) *Compression paddle.*

(A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, 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.

(C) Equipment 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.

TABLE 3.1—*continued*.

(D) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

(9) *Technique factor selection and display.*

(i) Manual selection of milliampere seconds (mAs) or at least one of its component parts (mA) and/or (s) shall be available.

(ii) The technique factors [peak tube potential[a] in kilovolt (kV) and either tube current in mA and exposure time in seconds, or the product of tube current and exposure time in mAs] to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp)[a] and mAs used during the exposure. The mAs may be displayed as mA and seconds.

(10) *Automatic exposure control.*

(i) Each screen-film system shall provide an AEC mode that is operable in all combinations of equipment configuration provided, *e.g.*, grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The positioning or selection of the detector shall permit flexibility in the placement of the detector under the target issue.

(A) The size and available positions of the detector shall be clearly indicated at the x-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

(iii) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(11) *X-ray film*. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(12) *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 screen's spectral output as specified by the manufacturer.

(13) *Film processing solutions.* For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(14) *Lighting*. The facility shall make special lights for film illumination, *i.e*., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

(15) *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.

From MQSA (1992) Section 900.12(e)(5)(x)—Radiation Output

(x) *Radiation output.*

(A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second [513 milliroentgen (mR) per second] when operating at 28 kVp in the standard mammography (moly/moly) 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 (moly/moly) mammography mode at any SID where the system is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

Adapted from MQSA (1992) Section 900.12(e)(5)(iii)(A)—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 cycles/millimeters (mm) (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 in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

[a]In this Report, the name used for this quantity is "operating potential," expressed as "kilovolt peak (kVp)" (see Glossary).

There are numerous features recommended by experts that go beyond the minimum set of features required by MQSA (1992). All of the features discussed below are highly desirable for dedicated mammographic units, particularly if the unit is used for both screening and diagnostic or problem-solving mammography. This is especially true if the unit is the only dedicated mammography unit available in a facility. All of these features are summarized in the tables at the end of each subsection.

Before purchasing a dedicated mammographic unit, there are several steps that should be undertaken. The unit's specifications should be reviewed in comparison with the critical features and specifications described below. Current owners of the unit(s) (make and model) under consideration should also be questioned with respect to the adequacy of its performance in each of these critical areas. The radiologist should also review both grid and magnification images of dense or difficult to compress breasts that have been imaged on the unit(s) under consideration. For this purpose, images should be obtained from competent radiologic colleagues rather than through the unit's manufacturer.

3.1.2 *Mechanical Assembly and General Considerations*

The mammographic unit should rigidly support the x-ray tube housing and image-receptor support device at opposite ends of a C-arm or similar assembly. The C-arm should be designed to allow continuous rotation to permit views to be obtained in various projections with the patient either erect or seated. The system should allow the technologist to rotate the C-arm 180 degrees relative to the vertical axis in one direction and at least 120 degrees and preferably 50 degrees in the other direction (ACR, 1993). This range of angulation allows for both routine and specialized projections, including the reverse CC view in which the breast must be compressed from below. It also insures that the technologist will always be able to compress the breast perpendicular to the long axis of the pectoralis major muscle in the MLO view and will therefore be able to include the posterior portion of the breast on the image despite differences in patient body build.

While it should be possible to position the C-arm of the mammographic unit to achieve any degree of obliquity (continuously variable angulation), detents at the common positioning angles, such as 0, 30, 45, 60 and 90 degrees, on either side of vertical should also be provided to help the technologist achieve reproducible positioning. The degree of angulation of the C-arm should be indicated on the unit and should be easy to read from any position on either side of the image-receptor support.

The C-arm should be designed so that the technologist can move it high enough to accommodate a tall patient and low enough for a patient in a wheelchair. There should be room enough under the image-receptor support and counterweight for a patient's legs if they are in a wheelchair or need to be seated for the examination. In general, this will require a range of vertical motion such that the center of the image-receptor support can be positioned from 66 to 140 cm above the floor for both CC and lateral views (ACR, 1993). If only standing patients need to be accommodated, the range of vertical motion can be from 97 to 140 cm. In addition, if a patient is in a wheelchair, if they must remain seated, or if they can stand but cannot move their feet easily for different views, it is more convenient for the technologist to move the C-arm side-to-side and in-and-out in a longitudinal or transverse motion from the main body of the unit. The unit should allow this flexibility. The unit should permit the technologist to perform more than one function at a time. For example, the technologist should be able to raise the C-arm vertically at the same time that they are lifting the compression paddle.

Controls for adjusting the position and height of the C-arm and for rotating it should be readily accessible to the technologist who must use these frequently throughout the mammographic examination. The unit should be equipped with mechanical, motorized or electromagnetic locks to fix the C-arm in any required position or orientation (ACR, 1993). These locks should be strong enough to prevent motion of the C-arm when the patient leans on the unit. The locks should be released by hand or foot controls and should not release in the event of a power failure.

Motorized controls for compression should be accessible on both sides of the C-arm, as well as being foot controlled, to allow for easy positioning on standard and specialized views. The control for releasing compression should also be on the C-arm, to permit quick release if the patient is feeling faint or suddenly feels that she can no longer tolerate the compression. In the event of a power failure, the compression should be released automatically. The switch for the light field should also be readily accessible, located on both sides of the C-arm or else positioned centrally where it is easy to reach.

A bar support should be available on each side of the C-arm for the patient to grip. Such a support is especially useful after the technologist has raised the patient's arm for the oblique views. The bar should extend to the height of the tube head and below the image-receptor support, so that the patient can reach it easily during positioning for any view. This bar is a necessity for assisting

the patient in supporting themselves, thereby, minimizing motion. When the bar is used for CC positioning, the patient should be able to reach it without stretching. The control buttons should not be on the bar support where the patient might accidentally grasp them.

The smaller the tube housing the better. If the tube housing projects toward the patient's head, the technologist will have difficulty including the patient's chest-wall tissue on the image in the CC view. A large tube head will also interfere with positioning for magnification, especially on the CC view. Moreover, on a superolaterial-to-inferomedical oblique view, the patient's shoulder will bump into the tube head. In addition, the tube housing should be equipped with a plastic face shield. This device should be designed to prevent the patient's face or hair from projecting between the x-ray tube and the breast and should not overlap the imaging field.

The image-receptor support device should be designed to hold the cassette firmly in place with the front edge of the cassette at the chest wall and a minimum of space between the cassette edge and the chest wall (ACR, 1993). There should be <2 mm movement side-to-side and the device should be tight enough to prevent movement of the cassette during an exposure. In addition, the image-receptor support device must be designed to limit the x-ray transmission through the support to no >0.876 μGy air kerma (0.1 mR) for any exposure (CDRH, 2002b).

A radiation shield should be provided to minimize operator exposure. The operator exposure should not exceed 5 mSv y^{-1} (ACR, 1993). Given reasonable assumptions concerning workload and technique [6.58 mGy air kerma (750 mR)] per exposure, four exposures per patient, 40 patients per day, 5 d $week^{-1}$, scattered radiation at the entrance of the shield equal to 0.001 times the exposure at the breast entrance surface, a shield with an attenuation equivalent to 0.08 mm of lead at 35 kVp is appropriate to meet this standard (ACR, 1993). The shield should extend from ≤15 cm above the floor to a height of 1.85 m. The width of the shield should be sufficient (at least 0.6 m) to provide reasonable assurance that the technologist will not be exposed during the conduct of an examination. If the shield is movable, there should be interlocks to prevent exposure when the shield is not in place. The exposure controls should be designed so that the operator cannot make an exposure when outside the shielded area.

The unit should also provide a means for recording on the patient's images, identifying information concerning the patient, the facility where the film was taken, and the technologist who took the film. Information concerning patient position (view, angulation,

etc.) and the appropriate technique variables (target-filter combination, operating potential, milliampere seconds, compressed breast thickness, compression force, etc.) should also be included. See Table 3.2 for a summary of desirable characteristics of the mechanical assembly.

TABLE 3.2—*Summary of the desirable characteristics of the mechanical assembly (ACR, 1993).*

C-arm
• continuous rotation (+180 degrees – 120 degrees (preferably –150 degrees) • detents at 0, 30, 45, 60 and 90 degrees • accurate angulation indicator available • controls readily accessible • bar-grip available (each side of C-arm) • small tube housing with plastic facial shield
Locks
• strong enough to prevent C-arm motion • should not release in the event of a power failure
Compression
• released by hand or foot controls plus controls on C-arm • release automatically with power failure
Image-receptor support device
• able to be positioned from 66 to 140 cm (97 to 140 cm standing patients only) • holds the cassette firmly in place • minimum “dead space” at chest wall • <2 mm cassette movement side-to-side • limit the x-ray transmission to <0.876 μGy (0.1 mR) for any exposure
Radiation shield
• attenuation equivalent to 0.08 mm of lead at 35 kVp extending from ≤15 cm above the floor to a height of 1.85 m, width sufficient to insure technologist not exposed
Recording system
• means of recording patient and technique information directly on film

3.1.3 *X-Ray Source Assembly*

A dedicated screen-film mammographic unit should have an x-ray tube with a molybdenum target and a thin beryllium window (1.5 mm thickness or less) together with an added molybdenum filter [sufficiently thick to meet the minimum half-value layer (HVL) requirements of CDRH (2002b) (ACR, 1993; AHCPR, 1994)]. This combination of target, window and filter materials has been shown to provide excellent contrast for the detection tasks present in mammography when the appropriate operating potential (≤28 kVp) is employed (Beaman and Lillicrap, 1982; Feig, 1987; Jennings *et al*., 1981). The x-ray beam from such a system has the low-energy characteristics required to achieve high subject contrast for breasts of average density and thickness. This is due to the 17.5 and 19.7 keV characteristic x rays from the molybdenum target and the strong suppression of the spectrum at energies >20 keV because of the k-shell absorption edge of the molybdenum filter (Figure 3.1a). Inordinate amounts of filtration in the x-ray beam from a glass window or excess filtration or otherwise inappropriate added filtration would have significant negative consequences (AAPM, 1990; Yaffe, 1991). Not only would beam quality be increased resulting in a loss of subject contrast, but also tube output would be reduced, resulting in increased exposure time. Longer exposure times could lead to problems with patient motion and higher patient doses due to film reciprocity law failure. Adjustments could be made to reduce exposure time (*e.g.*, increasing operating potential, using a higher milliampere and consequently, a larger focal spot, using a faster image receptor, etc.) but, each would have its own negative consequences for image quality (reduced contrast, increased blur, increased noise, respectively).

Alternative target and filter combinations may be employed, if they provide equivalent contrast-detail perceptibility at equal or reduced patient dose. For example, tubes with molybdenum targets and rhodium filters (Figure 3.1b), as well as those with rhodium targets and rhodium filters (Figure 3.1c), and tubes with tungsten targets and rhodium added filration (Figure 3.1d) have been used successfully in imaging patients (Beaman and Lillicrap, 1982). Such combinations are most effective in patients with larger or denser breasts. In such patients, these units can produce both better image quality and lower patient dose. In systems where the filter can be varied (for example, a molybdenum target with both molybdenum and rhodium filters), the type of filter in use should be displayed on the unit.

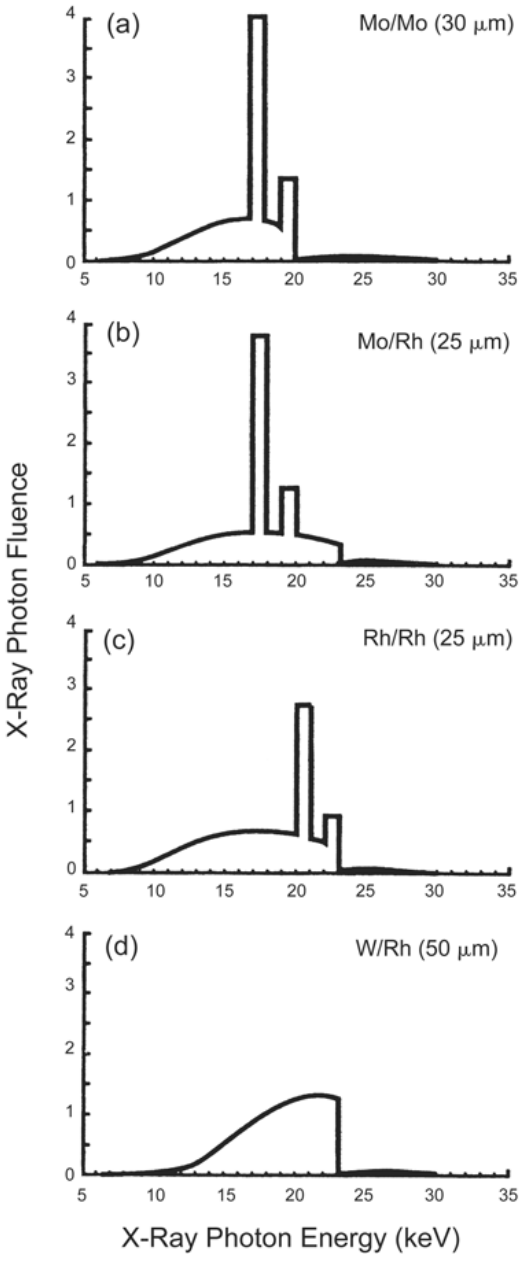


Fig. 3.1. X-ray spectra for 30 kVp operating potential for Mo/Mo (a), Mo/Rh (b), Rh/Rh (c), and W/Rh (d) source/filter assemblies (Barnes, 1999).

Tungsten targets, though used for mammography at one time, are now recognized as being inadequate to accomplish the subtle imaging tasks modern mammography involves. However, when used at an appropriately low operating potential and with suitable k-edge filters, tungsten target tubes have some advantages in mammography, particularly when imaging patients with dense breasts and large compressed breast thicknesses (Beaman and Lillicrap, 1982; Beaman *et al*., 1983; Bushong, 1992; Desponds *et al*., 1991; Jennings *et al*., 1981; Kimme-Smith *et al*., 1989a; Sabel *et al*., 1986; Stanton and Villafana, 1989). For tungsten target and k-edge filter combinations where the k-edge is ≥20 keV, the average beam energy will be higher than for a Mo/Mo combination and the dose will consequently be lower. In addition, the physical characteristics of tungsten also led to some advantages. The higher atomic number of tungsten (74), as compared with molybdenum (42) or rhodium (45), results in more efficient x-ray production and thus, in higher output exposure rates under otherwise identical conditions. In addition, the higher melting point of tungsten allows the use of smaller focal-spot sizes or higher tube currents. These factors can result in reduced blur due to improved geometric unsharpness or shorter exposure times leading to reduced motion unsharpness. One tungsten target unit is commercially available and it employs a 60 μm molybdenum filter, or a 50 μm rhodium filter with the latter used at higher tube potential settings for thick-dense breasts (Haus, 1991). The important characteristics of tungsten, molybdenum, and rhodium as target materials are compared in Table 3.3.

In a dedicated mammographic unit, the x-ray tube is generally oriented with the anode-cathode axis at right angles to the chest-wall edge of the image receptor with the cathode nearer the chest wall. The collimation is arranged in what is called a "half-field geometry" so that only the anode half of the x-ray field is utilized. In this geometry, the central ray, the ray perpendicular to the

TABLE 3.3—*Physical properties of molybdenum, rhodium and tungsten (adapted from Lide, 2004).*

Element	Atomic Number	Density ($g\ cm^{-3}$)	Melting Point (°C)
Molybdenum	42	10.2	2,610
Rhodium	45	12.4	1,966
Tungsten	74	19.3	3,370

image receptor, is not in the center of the x-ray field, as is typically the case in general radiography. Rather, the central ray is located at the chest-wall edge of the image receptor (Figure 3.2). The "coverage" or the size of the x-ray field at the plane of the image receptor is determined by:

$$C = SID\ (\tan \Theta), \tag{3.1}$$

where C is the coverage, SID is the source-to-image-receptor distance and Θ refers to the effective x-ray tube target angle, the angle between the central ray and the surface of the target. The factors must be such that the x-ray field will just cover the 24 cm

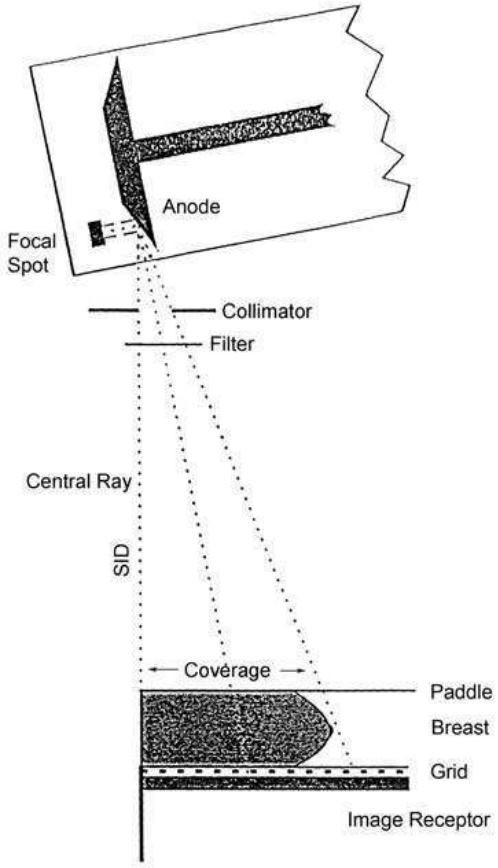


Fig. 3.2. Geometry of a mammography x-ray tube.

dimension of a 24 × 30 cm cassette. For a 60 cm *SID*, this requires an effective target angle of 22 degrees. In turn, this can be achieved by using an x-ray tube with a 22 degree target or by appropriately tilting an x-ray tube with a smaller target angle (*e.g.*, a six degree tilt of a 16 degree target).

The effective size of the x-ray tube focal spot (f_{eff}) is another important consideration in mammography and issues related to f_{eff} have been the topic of continuing debate since before the advent of dedicated mammographic systems. Detailed discussions have been provided by a number of authors over the past few decades (Braun, 1979; Gabbay, 1994), including the effect of the intensity distribution of the focal spot on geometric unsharpness (Nickoloff *et al.*, 1990). Along with the sharpness of the image receptor, the f_{eff} will determine the limiting resolution of the imaging system given the system geometry (*SID* and patient support to image-receptor distance). Considering the need to resolve microcalcifications that may be present in the breast, the f_{eff} needs to be small enough to minimize blur.

Modern mammographic screen-film combinations are capable of resolving 20 cycles mm^{-1} (ACR, 1993). Their noise properties, however, usually restrict visualization in biological structures to about 10 cycles mm^{-1} and below (Kratzat, 1988). As a consequence, in order to insure that the focal spot will not cause excessive blur, it has been recommended that the f_{eff} be able to resolve 12.5 cycles mm^{-1} (AAPM, 1990). Because of the imaging geometry in mammography, the f_{eff} is largest at the chest wall and decreases anteriorly (Figure 3.3). Thus, the f_{eff} should meet the 12.5 cycles mm^{-1} requirement at the chest wall. Furthermore, the blur due to the focal spot is greatest for objects such as microcalcifications at the top surface of the breast, farthest from the image receptor (Figure 3.4). Therefore, the 12.5 cycles mm^{-1} requirement must be met for an object in the plane located at the breast entrance surface.

It can be directly determined if a mammographic system meets this criterion by imaging a resolution pattern placed near the chest-wall edge of the x-ray field, 4.5 cm above the plane of the breast support (*i.e.*, at the typical location of the breast entrance surface). However, when considering the resolving capabilities of mammographic systems, it has been traditional to write specifications in terms of the f_{eff} and to measure performance by measuring f_{eff}. For contact mammography, the conditions mentioned above (resolving 12.5 cycles mm^{-1} at the chest wall for an object at the entrance surface of the breast) are met when the effective focal-spot size meets the following criterion (AAPM, 1990):

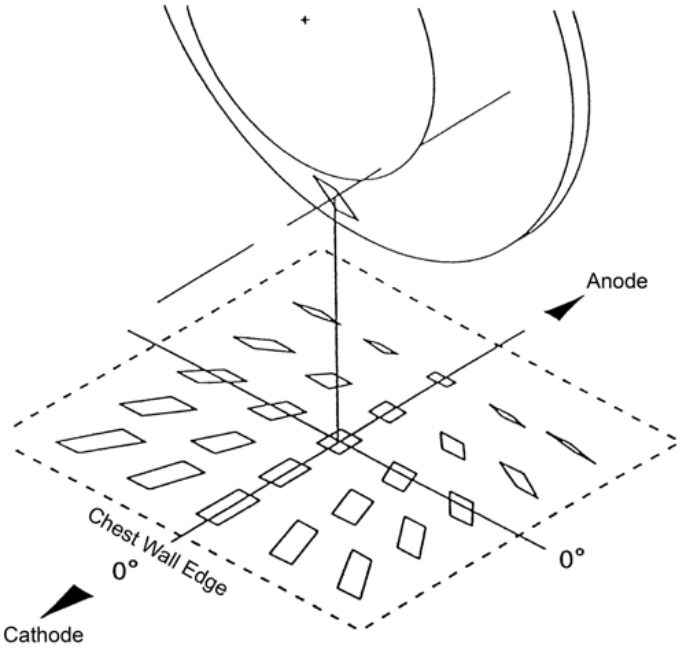


Fig. 3.3. Variation in focal-spot shape and size with position (Barnes, 1999).

$$f_{\text{eff}} = \frac{M}{[12.5\ (M-1)]} \tag{3.2}$$

where, the magnification $M = SID/(SID - 5)$ and $SID - 5$ is the distance from the focal spot to the entrance surface of the breast (assuming contact mammography, a 4.5 cm breast thickness, and a 0.5 cm separation between the patient support and the image-receptor plane). The effective focal-spot sizes required to meet these conditions are listed in Table 3.4 for several *SID*s.

This approach involves a number of complications. For example, the f_{eff} will generally be larger than the "nominal" focal-spot size listed in the unit's specifications. The National Electrical Manufacturers Association (NEMA, 1992) has set standards for focal-spot size and specified how x-ray tube focal spots may be labeled. As indicated in Table 3.5, the measured dimensions of the focal spot (length and width) are allowed to exceed the "nominal" (labeled) focal-spot size by up to 50 percent in width and length and by 100 percent in length when the nominal size is 0.3 mm or greater.

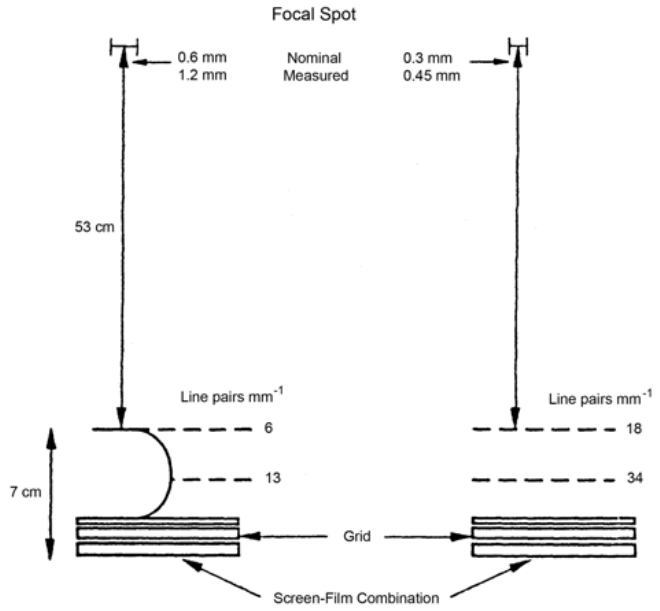


Fig. 3.4. Limiting resolution as a function of distance from the image-receptor and focal-spot size (Haus, 1999b).

TABLE 3.4—*Effective focal-spot size (f_{eff}) required at various SIDs (12.5 cycles mm^{-1} at 5 cm above the image receptor).*

SID (cm)	f_{eff} (mm)[a]
70	1.12
65	1.04
60	0.96

[a]Calculated values which assume a focal spot with uniform intensity distribution.

Additionally, the focal spot of the x-ray tube is normally located directly above the chest-wall edge of the image receptor and as mentioned above, the focal-spot size should be measured at the chest wall. However, the nominal size is not usually referenced to this location. The nominal size of the focal spot in National Electrical Manufacturers Association standards is defined along a

TABLE 3.5—*National Electrical Manufacturers Association focal-spot tolerance limits (NEMA, 1992).*

Nominal Focal-Spot Size (mm)	Maximum Focal-Spot Size (f_{eff})	
	Width (mm)	Length (mm)
0.1	0.15	0.15
0.15	0.23	0.23
0.2	0.30	0.30
0.25	0.40	0.40
0.3	0.45	0.65
0.4	0.60	0.85
0.5	0.75	1.1
0.6	0.90	1.3
0.8	1.2	1.6

"reference axis" (Figure 3.5). Therefore, in order to compare measured and "nominal" focal-spot sizes, the measurement made at the chest wall needs to be "corrected" to estimate its size at the reference axis.

The reference axis usually bisects the angle formed by the x-ray tube target and the ray perpendicular to the image receptor (at the chest-wall edge of the image receptor). Thus, for an x-ray tube with an effective target angle of 22 degrees (target angle of 16 degrees plus a tube tilt of six degrees), the reference axis will be 11 degrees away from the perpendicular ray at the chest wall. Thus, the nominal focal-spot size is defined, not at the chest wall (where it should be measured), but at a distance out in the x-ray field away from the chest wall. The effective target angle and the *SID* will determine the reference location in the x-ray field at which the manufacturer will specify the nominal focal-spot size. The focal-spot size at the reference location can be calculated as follows:

$$f_{\text{eff-ref-axis}} = f_{\text{eff-chest}} \left\{ 1 - \left[\frac{\tan(\Theta - \Phi)}{\tan \Theta} \right] \right\} \tag{3.3}$$

where Θ is the effective target angle and Φ is the angle between the tube target and the reference axis. Thus, in the case of the x-ray tube mentioned above (with the 22 degree target and the 11 degree

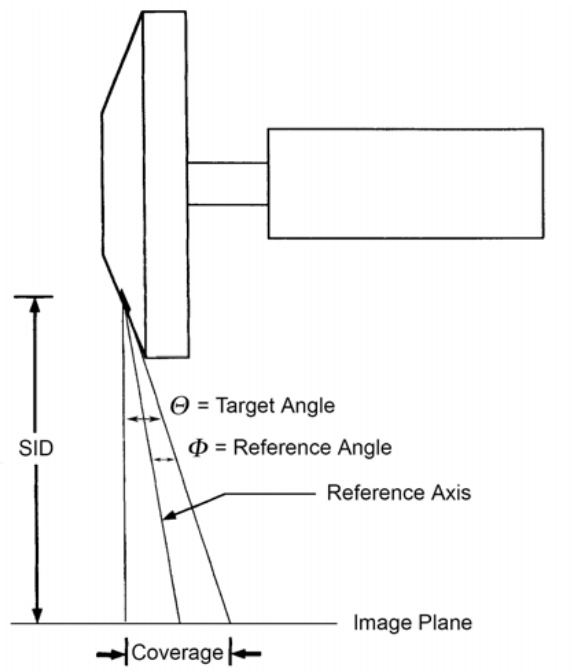


Fig. 3.5. Geometry of the mammography x-ray tube (Barnes, 1999).

reference axis), $f_{\text{eff-ref-axis}} = f_{\text{eff-chest}}(0.519)$. Therefore, if the unit's *SID* were 65 cm, the required effective focal-spot size (at the chest wall) would be 1.04 mm and the required effective focal-spot size at the reference location would be 0.54 mm. In order to insure that the effective focal-spot dimensions (length and width) do not exceed the recommended values, a nominal focal-spot size of 0.25 mm would be required.

If the manufacturer specifies the focal-spot size not only at a reference axis as just described, but also in the plane perpendicular to the reference axis (Figure 3.6), then a small additional correction will be required. This correction:

$$f_{\text{eff-ref-plane}} = f_{\text{eff-ref-axis}} \cos(\Theta - \Phi) \tag{3.4}$$

is generally quite small, on the order of two percent or less (Barnes, 1991).

Given all these complexities, it is not surprising that a simpler approach has been proposed (Yaffe *et al*., 1995) in which the limiting resolution, rather than the focal-spot size would be specified.

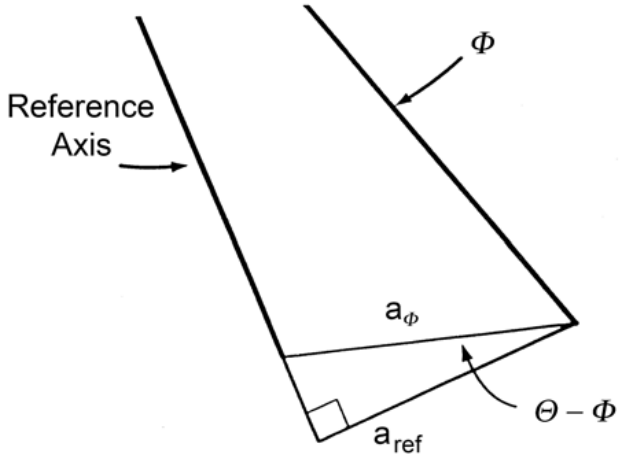


Fig. 3.6. Geometry associated with reference axis slit length correction between image plane and a plane perpendicular to the reference axis (Barnes, 1994).

The advantage of this approach is that a measure of the imaging performance of the unit (limiting resolution) would be specified, rather than the physical characteristics of a system component (the effective or nominal focal-spot size). ACR recommends measuring the limiting resolution by imaging a high-contrast radiographic bar pattern. The pattern should be placed parallel to the plane of the image receptor, 4.5 cm above the patient support, at a position in the x-ray field closest to the chest-wall edge of the image receptor, centered transversely. To duplicate the requirements specified above, it would be necessary to resolve 12.5 cycles mm^{-1} under these conditions. The most recent recommendations (ACR, 1993; AHCPR, 1994) are that 11 cycles mm^{-1} should be resolved under these conditions for a pattern oriented with the bars perpendicular to the anode-cathode axis and that 13 cycles mm^{-1} should be resolved with the bars oriented parallel to the anode-cathode axis. To be considered resolved, the images of the bars should just appear separated (*i.e.*, be seen as barely separated over 50 percent of their length when viewed at 5 to 10 times magnification). The measurement should be made from a film exposed to an optical density providing maximum resolution (ACR, 1993).

The heat loading capabilities of the focal spot are also an important consideration (Villafana, 1990). The smaller the heat loading capability, the smaller the allowable tube current and the longer

the exposure time, the greater the potential for motion unsharpness. The heat loading capabilities of the anode can be increased in a number of ways. Increasing the diameter of the rotating anode will lengthen the focal track and spread the heat over a larger area without increasing the focal-spot size. A rotating anode can also be constructed with special heat dissipation features such as a heat absorbing carbon backing. Smaller target angles also spread the heat out over a larger area. As mentioned below, the small voltage ripple provided by high-frequency generators also improves the heat loading capabilities of the x-ray tube. This is the result of more uniform tube current which results in more uniform heating of the focal track.

Many mammographic units have two focal spots, one used for contact mammography and the other used for magnification. Magnifying problematic areas provides considerable improvement in overall image detail (Section 3.1.10). When measured at the chest wall, the large focal spot should meet the criteria discussed above. The requirements applicable to the small focal spot required to permit effective magnification mammography are more stringent. In fact, the limiting resolution of the small focal spot when measured using typical magnification conditions should be no less than that measured for the large focal spot, using typical contact mammography conditions.

Obviously, in principle, the smaller the focal spot the better. However, a tube with a smaller focal-spot size is likely to have a lower output and may have a shorter life expectancy. This reflects only one of the many complex trade-offs that must be resolved in designing or selecting a mammographic system. See Table 3.6 for desirable characteristics of the x-ray source assembly.

3.1.4 *X-Ray Generator*

In order to produce an appropriate beam of adequate intensity, the x-ray generator of a dedicated mammographic unit should meet certain criteria. Given the modest power requirements of screen-film mammography, the x-ray generator power rating only needs to be in the 3 to 10 kW range (AAPM, 1990). However, the usable power will generally be limited by the load capacity (instantaneous heat capacity) of the x-ray tube focal spot.

It is important that the voltage waveform have a reasonably small ripple and, therefore, high-frequency generators are recommended (ACR, 1993; AHCPR, 1994). Not only do they have a small

TABLE 3.6—*Desirable characteristics of the x-ray source assembly.*

• Molybdenum target[a]
• Thin beryllium window
• Added molybdenum filter The filter in use should be displayed on the unit
• X-ray field coverage for 24 × 30 cm cassette
• Focal spot Resolve 11[b] and 13[c] cycles mm^{-1} at chest wall (object 4.5 cm above support) located directly above chest-wall edge of image receptor

[a]Alternative target and filter combinations may be employed if they provide equivalent contrast-detail perceptibility at equal or reduced patient dose.
[b]Resolution pattern oriented with bars perpendicular to the anode-cathode axis.
[c]Resolution pattern oriented with bars parallel to the anode-cathode axis.

ripple, but they also provide excellent exposure reproducibility (Villafana, 1990; Yaffe, 1991) and higher output exposure rates. A small voltage ripple results in a higher effective operating potential and since the efficiency of x-ray production varies approximately as the second power of the operating potential, a small ripple results in significantly higher output exposure rates. In fact, the output of a high-frequency unit is about a factor of two higher than an unsmoothed single-phase unit (AAPM, 1990; Yaffe, 1991). This results in shorter exposure times or lower input power which has the effect of extending filament life. Alternatively, high-frequency units allow longer *SID*s to be employed providing better geometric unsharpness without adversely affecting exposure time. The design and operation of high-frequency generators for mammography has been described in the literature (Gauntt, 1991).

When the voltage waveform has a small ripple, the tube current will be approximately constant and this results in more temporally uniform heating of the anode and, consequently, a greater single exposure-load capacity. These are important considerations given the small focal spots employed in dedicated mammographic units. The x-ray beam quality of high-frequency units is also more uniform over the exposure time, but somewhat higher than would be the case with a larger ripple and, this in turn, will lead to somewhat lower patient doses for high-frequency systems given the same source assembly and operating potential. High-frequency generators should have an operating potential ripple of less than

five percent and an exposure ripple of 10 percent or less (ACR, 1993). However, three-phase units in which the exposure ripple is 20 percent or less, are acceptable. In addition, the exposure waveform should have both a rise time (time until the operating potential is accurate and regulated) and a fall time (time to terminate the exposure) of <16 ms (ACR, 1993).

The generator should provide a means for adjusting the operating potential from 24 kVp to at least 32 kVp in 1 kV steps, as well as a means for compensating appropriately for fluctuations in line voltage (ACR, 1993; Yaffe, 1991). An operating potential somewhat lower (*i.e.*, down to 22 kVp) may be useful, particularly, for specimen radiography, while somewhat higher values (*i.e.*, up to 35 kVp) may be needed for magnification. The operating potential requirements may vary somewhat for target/filter combinations other than Mo/Mo. The operating potential should be displayed and the displayed value should be within ±1 kV of the actual kilovolt peak (kVp) applied to the x-ray tube.

Using the lowest possible operating potential produces an image with the greatest subject contrast which aids in the detection of small calcifications and masses. However, while some units provide an operating potential as low as 22 kVp, radiologists rarely use below 25 kVp for routine grid mammography because at a lower operating potential, the dose increase to the patient is significant while the improvement in image quality is quite small. An operating potential lower than 25 kVp should be reserved for specimen radiography, for coned-down views of questionable areas compressible to a thickness of 2 cm (with or without magnification) and for mammograms of elderly patients whose breasts can be compressed to <2 cm.

Although a low operating potential is always preferable, it may not always be possible in certain situations. These situations include imaging of patients with dense breasts or breasts that are difficult to compress. In these patients, use of a low operating potential can result in underpenetration of the dense regions of the breast, as well as excessive exposure times, particularly on low output units, leading to problems of patient motion and high doses due to film reciprocity law failure. Additionally, patients unable to remain still because of their age, nervousness, or certain medical conditions such as Parkinson's disease, may be impossible to image at the lowest operating potential due to patient motion. Use of a higher operating potential may be necessary to achieve appropriately short exposure times with these patients. See Table 3.7 for desirable characteristics of the x-ray generator.

TABLE 3.7—*X-ray generator.*

- High-frequency generator of 3 to 10 kW
  - Operating potential ripple <5%
  - Exposure ripple ≤10%
  - Exposure waveform rise time and fall time <16 ms
- Operating potential selection
  - 24 to 32 kVp in 1 kV steps
  - Displayed value within ±1 kV of actual kVp

3.1.5 *X-Ray Beam Geometry*

As mentioned above, unlike general radiographic units in which the central ray from the focal spot falls on the center of the image receptor, mammographic x-ray tubes and beam limitation devices are arranged in a half-field geometry [Figure 3.7 (left)]. In this arrangement, the ray which is perpendicular to the image receptor falls on the chest-wall edge of the image receptor (AAPM, 1990; ACR, 1993; Villafana, 1990; Yaffe, 1991). Therefore, the plane defined by the focal spot and the chest-wall edge of the image receptor will be tangent to the chest wall of the patient. If this were not the case, some breast tissue would be projected off the image receptor and would not be imaged [Figure 3.7 (right)].

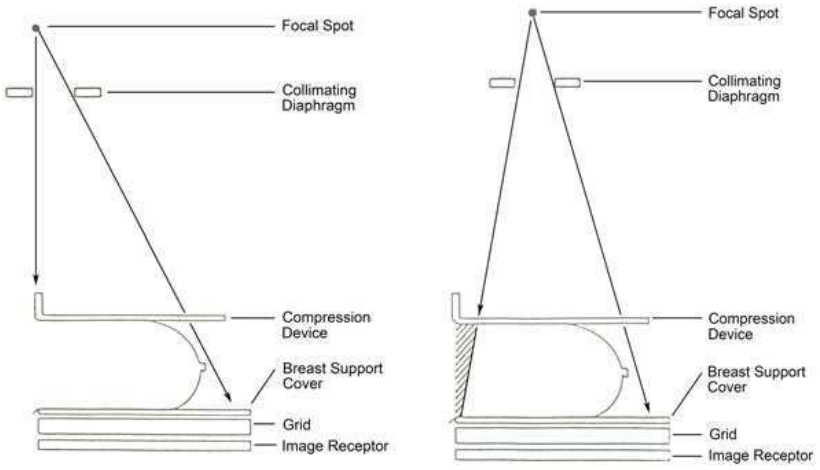


Fig. 3.7. (Left) correct alignment. (Right) incorrect alignment (tissue excluded from image) (Barnes, 1999).

The *SID* should be appropriate for the target angle and the focal-spot size of the x-ray tube, and the combination should meet the limiting resolution and coverage criteria given in Section 3.1.4. *SID*s for dedicated mammographic units should be ≥55 cm for contact imaging (and ≥60 cm for magnification) (ACR, 1993).

Shorter *SID*s would require unusually small f_{eff}. This would result in longer exposure times if the milliamperes are limited due to reduced focal-spot loadability. Short *SID*s also compromise localization procedures, since limited space is available between the x-ray tube head and the patient. For magnification imaging, short *SID*s result in a smaller air gap for a given magnification, yielding a higher scatter-to-primary ratio (*S*/*P*) and a higher patient dose. In addition, the shorter the *SID* the greater the beam divergence and, therefore, the greater the difference in magnification from the top to the bottom of the breast, particularly for thicker breasts. Finally, short *SID*s result in higher patient doses. This results from the greater proportionate reduction of beam intensity between the entrance surface of the breast and the image receptor simply due to the inverse square law. Assuming a 5 cm separation between the breast entrance surface and the image receptor, a 40 cm *SID* unit will require about an eight percent higher exposure at the breast entrance than one with a 55 cm *SID* for the same exposure to the image receptor (Villafana, 1990).

The x-ray unit should also provide means to restrict or collimate the x-ray beam to accommodate the range of image-receptor sizes in use, typically 18 × 24 cm and 24 × 30 cm. This may be accomplished with the use of interchangeable rectangular apertures, moving blade collimators, or both. If interchangeable apertures are provided, each should be clearly labeled to indicate the intended image-receptor size or function. In any event, the x-ray field should not extend beyond the image receptor (the film in the cassette), except at the chest wall where it may not extend beyond by more than two percent of the *SID*. It is preferable for the x-ray field to extend just to the edges of the image receptor on all sides so that the processed film is black outside the breast image and extraneous light (viewbox glare) will not interfere with image interpretation.[5]

[5]Equipment standards for mammography are required by MQSA (1992) and MQSRA (1998). The Act can be found at http://www.fda.gov/cdrh/mammography, click on "The Act" under "Regulations." Implementation of equipment standards and other criteria for mammography required by MQSA can be found at http://www.fda.gov/ cdrh/mammography, click on "The Code of Federal Regulations" under "Regulations" and scroll down to Section 900.12(b) Equipment.

The area of the primary x-ray field should be indicated by an illuminator with an intensity of ≥160 lux at the level of the image-receptor support (ACR, 1993). If the illuminator is intended to be a "light localizer" as defined in the federal x-ray performance standard, then it must comply with the requirements of that standard and the x-ray and light fields should also align properly so that the sum of any misalignments on opposite sides is within two percent of the *SID* in order that proper positioning of the breast in the x-ray field can be insured.

Ideally, the x-ray beam restriction system should change automatically when the size of the cassette holder or the grid is changed. If this feature is not available, the system should be designed with interlocks to prevent exposure if the wrong size collimation is selected for the image receptor in use (Yaffe *et al*., 1995). This will prevent cone cutting and failure to image part of the breast due to interference from the collimator on a large cassette when a small diaphragm is selected. It will also prevent unnecessary exposure to the operator and patient when a large diaphragm is selected for use with a small size cassette, particularly in the MLO view.

The means of collimation should be readily changeable after the technologist has positioned the patient. This is particularly important while collimating for magnification. In this regard, a diaphragm located in the front of the tube head is inconvenient, since to change the diaphragm, the technologist must move the patient's head. Units should be designed so that the technologist can exchange the diaphragm or adjust the collimator from either side of the unit, rather than from the front.

When collimators are provided, the blades should not jam and technologists should be able to move each blade independently of the others. Movement of the C-arm or vibrations in the tube head should not loosen the blade and make it move as this could lead to cone cutting. See Table 3.8 for desirable characteristics of the x-ray beam geometry.

3.1.6 *X-Ray Beam Energy and Intensity*

Beam quality is a critical parameter in mammography and the HVL should be kept low in order to maximize subject contrast. The lower limit on the HVL is set by federal standards for purposes of patient protection. In the mammographic operating potential range, the limit [100 millimeters of aluminum (mm Al)] is defined as kVp/100. However, given the nature of the compression paddles used in mammography, the HVL should be no less than

TABLE 3.8—*Desirable characteristics of the x-ray beam geometry.*

- X-ray field
  - Half-field geometry
  - Perpendicular ray from focal spot to chest-wall edge of image receptor
  - Does not extend beyond image receptor except at chest wall
  - At chest wall it may extend beyond by ≤2% of *SID*
- *SID*
  - Appropriate for the focal-spot size (resolve 11 and 13 cycles mm^{-1})
  - ≥55 cm for contact imaging
  - ≥60 cm for magnification imaging
- Collimation
  - Accommodate range of image-receptor sizes
  - Automatically change with size of cassette holder or grid or have interlocks
  - Readily changeable after patient is positioned
  - Interchangeable apertures clearly labeled

kVp/100 + 0.03 (ACR, 1999). To insure appropriate image contrast, the HVL should also be no higher than kVp/100 + *C*, where *C* = 0.12 mm Al for Mo/Mo, 0.19 mm Al for Mo/Rh, and 0.22 mm Al for Rh/Rh (ACR, 1993). These standards should be met when the compression device is in the x-ray beam and the HVL measurement is made under the compression device at the location of the normal breast entrance surface. Since excessively soft x-ray beams result in increased patient dose with no improvement in image quality, it is critical that the lower HVL limit be met. Since excessively hard x-ray beams result in a loss of contrast, the upper HVL limit should also be met.

The HVL should not decrease by >20 percent upon removal of all materials [*i.e.*, the compression device between the x-ray filter and the breast (ACR, 1993)]. In this instance, the HVL should be measured at a point in the x-ray field 4 cm from the chest-wall edge of the image receptor and centered transversely. Most of the minimum filtration should be provided by the selective filter and not by other beam hardening materials, such as a glass window on the x-ray tube, a permanently installed glass mirror in the beam limiting device, or an inordinately attenuating compression device.

The x-ray beam output is also critical. Insufficient output can result in excessively long exposure times resulting in problems with patient motion. With some images, motion may be noticeable

when exposure times exceed 1 s and may become a significant problem at times of 2 s or more (Feig, 1987). With inadequate compression, considerable motion unsharpness can be seen with times as short as 0.2 s (NCRP, 1986). With long exposure times, patient doses may also be high due to the effects of reciprocity law failure of the film. Alternatively, insufficient output may require the use of higher than optimal kilovolt peak settings and this can result in inadequate subject contrast. When the focal spot intended for contact mammography is used, dedicated mammographic x-ray units with molybdenum targets and filters should be capable of delivering 200 $\mu C\ kg^{-1}\ s^{-1}$ for 3 s at 28 kVp at the location of the breast entrance surface under the compression device (ACR, 1993). This is a significantly higher output exposure rate than has been previously recommended (AAPM, 1990). The output should be measured under the compression device, 5 cm above the top surface of the image-receptor support and 4 cm out from the chest-wall edge of the image receptor (centered transversely). Because of differences in x-ray tubes, x-ray generator design, unit geometry, *SID*, etc., a specification based on a value of tube current can be misleading in predicting radiation output (AAPM, 1990). For this reason, the output should be specified in terms of $\mu C\ kg^{-1}\ s^{-1}$.

As mentioned in a previous section, a half-field geometry is used in mammography. Consequently, the heel effect is more pronounced than in general radiography and the beam intensity can fall significantly from the chest wall to the nipple edge of the image receptor (Table 3.9). The HVL also changes, increasing with increasing distance from the chest wall. See Table 3.10 for desirable characteristics of x-ray beam energy and exposure rate.

TABLE 3.9—*Heel effect for a 30 kVp exposure, and HVL versus distance from chest wall at 60 cm SID (Barnes, 1991).*

Distance from Chest Wall (cm)	Relative Exposure	HVL (mm Al)
3.3	1.000	0.293
6.1	0.973	0.296
9.3	0.923	0.298
12.4	0.879	0.303
15.5	0.782	0.310
18.7	0.664	0.318

TABLE 3.10—*Desirable characteristics of x-ray beam energy and exposure rate.*

• HVL
– ≥kVp/100 + 0.03
– ≤(kVp/100) + *C* where *C* = 0.12 mm Al for Mo/Mo, 0.19 mm Al for Mo/Rh, and 0.22 mm Al for Rh/Rh and decreases by <20% when compression paddle is removed
• Output
– ≥200 μC kg^{-1} s^{-1} (for 3 s at 28 kVp at breast entrance for the focal spot intended for contact mammography)

3.1.7 *Exposure Control*

Accurate control of the exposure is essential for providing consistent images within the optimal range of optical densities.

3.1.7.1 *Automatic Exposure Control*. Reliable automatic exposure control (AEC) systems are essential for high-quality mammography and should be designed to operate in all imaging modes (grid, nongrid and magnification) and with all imaging attachments, such as coned-down compression devices (ACR, 1993). A properly designed AEC provides better control over image optical densities than does manual exposure control. Radiographic density cannot be predicted with the required accuracy from compressed breast thickness or firmness on compression and shows only a poor correlation with patient age (Swann *et al*., 1987). The AEC device should either automatically compensate for changes in imaging formats or disallow exposure until appropriate technique factors are set. The need for an effective and reliable AEC system is especially acute for large volume screening practices, particularly for those that depend on delayed batch processing of the mammographic films.

Mammographic AEC has been described by various authors (Barnes, 1994; LaFrance *et al*., 1988). In general, the sensors in such systems are located behind the image receptor (screen-film cassette). The sensor may be a phosphor coupled to a photomultiplier tube, but will more typically be an ionization chamber or a solid-state detector. The sensor produces a current proportional to the exposure rate of the radiation incident on it and the current charges a capacitor (Figure 3.8). In the cases of the ionization chamber and the solid-state detector, an intermediate amplification step is required. The voltage across the capacitor is then proportional to the exposure to the sensor (and therefore to the

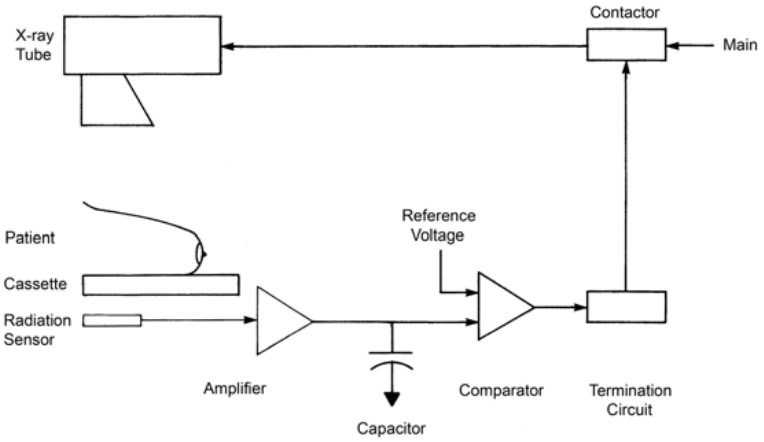


Fig. 3.8. Schematic of the basic elements of a mammographic AEC device.

patient). This voltage is compared to a reference voltage, and when the two voltages are equal the exposure is terminated.

Early AEC provided with dedicated mammographic units exhibited various performance problems (Kimme-Smith *et al*., 1987; LaFrance *et al*., 1988; NCRP, 1986). The sources of these problems have been identified (LaFrance *et al*., 1988) as beam hardening, film reciprocity law failure, and sensor dark current. Beam hardening is the dominant effect causing the AEC to terminate the exposure too soon. As breast thickness or density or both increases or as operating potential increases, the x-ray beam exiting the breast becomes more penetrating. Consequently, an increased proportion of the x-ray beam is transmitted through the image receptor and exposes the AEC sensor. This higher exposure rate causes the AEC to terminate the exposure too soon with the result that film densities decrease (Figure 3.9).

Modern AEC appropriately compensates for variations in the selected operating potential and breast density and thickness. This can be accomplished through circuit modifications which incorporate a nonlinear amplification step (LaFrance *et al*., 1988). The result is that short exposure times become shorter and long exposure times become longer. Also, microprocessor controlled AECs have been introduced (Frederick *et al*., 1991) which correct for changes in operating potential and breast density and thickness in a variety of ways. Compensation for operating potential can be accomplished by including the preset kilovolt peak as a factor in

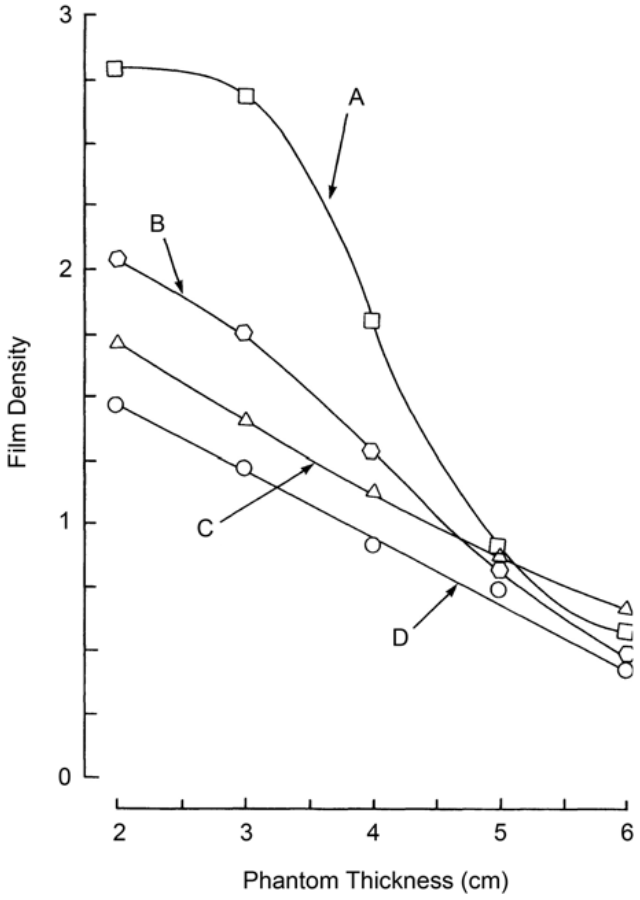


Fig. 3.9. Breast thickness tracking with typical AEC devices on four different (A through D) commercially available mammography units (Barnes, 1999).

the microprocessor controlled program of the AEC. This allows the variation of the AEC sensor sensitivity with operating potential to be taken into account in determining when the exposure should be terminated [*e.g.*, based on a table with different threshold values for each operating potential (Kimme-Smith, 1992)]. Variations in compressed breast thickness also result in beam hardening for which corrections must be made. The AEC can, for example, be equipped to evaluate the energy of the x-ray beam exiting the breast. Thicker and denser breasts are more attenuating and will result in a higher average exit beam energy. If the exit beam energy

is known, then the unit can correct for the variation of the AEC detector sensitivity with energy by making an appropriate adjustment in the threshold.

Thick or dense breasts or both also create problems because long exposure times result in reduced image-receptor response due to film reciprocity law failure. Modern AECs provide mechanisms to compensate for the effects of reciprocity law failure, typically in the unit's software.

Independent of the compensation method employed (including systems using automatic operating potential selection), the AEC should insure the production of uniform optical density images independent of breast thickness and operating potential. For a set of images made with tissue thicknesses of 2 to 6 cm and for the range of operating potential settings appropriate for those thicknesses, the optical densities should not vary by >0.15 optical density from the mean optical density of the set (ACR, 1999). This performance should be evaluated with a mean optical density >1.2. The type of film and processing should be specified, since the film characteristics will affect the degree of optical density change due to a fixed difference in exposure. Furthermore, the AEC should meet the same standard for a phantom thickness simulating an average breast thickness when imaged over the entire range of operating potential settings used clinically.

Equally important, AEC must be reproducible. It is not difficult for recently manufactured systems to meet the requirements of the federal performance standard which requires that the coefficient of variation of a set of exposures not exceed five percent (ACR, 1999; AHCPR, 1994). Exposures reproducible to this level should be possible in the AEC mode between 5 and 300 mAs.

At least three sensor positions (or multiple sensors) on the AEC should be provided (Feig, 1987; Logan, 1983). This range of positions allows the technologist to adjust for variations in individual patient anatomy, choosing the best position for placing the detector. This makes it possible to optimize the exposure to critical regions where pathology is most likely to be found. The field of the AEC detector should be large enough that a representative amount of breast tissue is sampled, but not so large that it would not be completely covered by a small breast (ACR, 1993; Feig, 1987). If the detector extends beyond the breast, part of the detector will be exposed to unattenuated x rays. Under such conditions, the detector will reach its threshold too soon and will terminate the exposure too early, resulting in an underexposed image. Some newer AECs can average the density of the tissue throughout the entire

breast, which makes positioning the AEC less critical (Kimme-Smith, 1992). The potential position and size of the AEC detector should be clearly indicated at the top surface of the breast (ACR, 1993), usually on the compression device. Ideally, the position of the AEC detector should be continuously variable along a line oriented in the chest wall to nipple direction.

The AEC system should also be provided with an optical density adjustment with at least nine clearly indicated density adjustment steps (ACR, 1993). There should be at least four steps above and below the normal density setting. Each step should alter the milliampere seconds by approximately 10 to 15 percent from the adjacent step. This is a somewhat more restrictive specification than the 15 to 20 percent recommended a few years ago (AAPM, 1990). The change was necessitated by the fact that step-to-step increments as small as 12.5 percent may sometimes be too large for fine density adjustment due to the high contrast of some mammographic films. There should also be adjustments provided so that the AEC system can be set appropriately for different screen-film combinations (AAPM, 1990).

The unit should offer the technologist the option of either setting the operating potential before positioning or permitting the x-ray unit to choose the operating potential. In the latter case, operating potential control is accomplished by beginning the exposure at a predefined kilovolt peak and then using the AEC to evaluate the exposure rate at the sensor location. If the breast is highly attenuating, the exposure rate will be low and the unit will increase the operating potential to achieve an exposure rate that will result in appropriate optical densities in a reasonable exposure time (Barnes, 1994). If the unit automatically selects the kilovolt peak and adjusts it during the exposure, there should be an accurate postexposure display of the actual kilovolt peak employed. If the technologist chooses to set the operating potential, the unit should not be able to override the technologist's selection.

When the unit is switched to AEC, the technique used most frequently should automatically be set as the default technique and these factors should be indicated on the control panel. If the preset technique is inadequate, it should be impossible to make an exposure (unless the unit is equipped with the auto operating potential feature discussed above and the unit is operating in that mode). Ideally, the AEC device should be capable of determining whether the back-up time is likely to be reached and, if so, should terminate the exposure within 50 ms, 5 mAs, or 13 $\mu C\ kg^{-1}$ and indicate the termination to the technologist (ACR, 1993). Alternatively the

system should, under such conditions, increase the operating potential so that the exposure can be made in a reasonable time. Long exposures such as those that would nearly reach the back-up time should be avoided because they are subject to motion artifacts and may need to be retaken. Exposures that reach the back-up time will be underexposed and also need to be retaken. In both cases, the patient dose is increased unnecessarily.

An indicator displaying the postexposure milliampere seconds should be provided and the displayed milliampere seconds should be held, or be retrievable, until the next exposure (AAPM, 1990; ACR, 1993). Dose estimation for individual patients is greatly facilitated by this type of display, which also assists in technique selection for manual exposures and retakes. The unit should also incorporate a back-up timer to limit the exposure in case of a system failure. If there is such a failure, the unit should indicate that the back-up time (or milliampere seconds) was reached. The back-up time should provide user selectable settings, but it should not be possible to set it below 250 mAs for contact mammography (ACR, 1993). Due to focal-spot loading considerations, it may be appropriate to have a 50 mAs lower limit for microfocal-spot tubes used in magnification mammography. The maximum limit allowed by the federal performance standard is 2,000 mAs for general radiography. A maximum limit of 600 mAs is more appropriate for mammography (ACR, 1993). In some designs the last manual exposure time is used as the backup and this can cause a problem, sometimes resulting in an underexposed film for which a retake is necessary. Table 3.11 presents desirable characteristics of exposure control devices (automatic and manual).

3.1.7.2 *Manual Exposure Controls*. Manual exposure controls are also essential, particularly for imaging patients with implants, for special views, for specimen radiography, and for certain QC tests. Manual exposure time or milliampere-seconds selections should range from 0.02 to 6 s (2 to 600 mAs at 100 mA) in 15 to 20 percent increments (AAPM, 1990; Yaffe, 1991). All time or milliampere-seconds selections should result in reproducible exposures with a coefficient of variation of <5 percent (CDRH, 2002b) from 5 to 300 mAs (ACR, 1993). Indicators displaying the preset milliampere seconds should also be provided in addition to the postexposure milliampere-seconds display. The radiation output of the unit using manual exposure control factors should be within five percent of that in the AEC mode for the same operating potential and post-exposure milliampere seconds (ACR, 1993).

TABLE 3.11—*Desirable characteristics of exposure control devices.*

- AEC
  - Optical density within ±0.15 over 2 to 6 cm breast thickness for range of kVp settings appropriate for those thicknesses
  - Reproducibility for average patient phantom over kVp settings used clinically
  - Coefficient of variation <5% between 5 and 300 mAs.
  - Technique used most frequently should be the default technique
  - Shows that back-up time is likely to be reached
  - If back-up time is likely to be reached the AEC should terminate exposure before 50 ms, 5 mAs, or 13 μC kg^{-1} is reached
  - Indicate termination
- Detector for AEC
  - At least three positions (or multiple sensors)
  - Position and size indicated at top surface of breast
  - Large enough to sample representative amount of tissue
  - Small enough to be covered by small breast
- Density adjustment on AEC
  - At least nine steps (10 to 15% exposure increments in *mAs*)
  - Adjustments provided for different screen-film combinations
- Postexposure display
  - Accurate postexposure display of actual kVp employed
  - Postexposure *mAs* display (held until the next exposure)
- Back-up timer
  - Activation indicator
  - User selectable settings
  - Not <250 mAs for contact mammography
  - Not <50 mAs for microfocal spot used for magnification
  - Maximum limit of 600 mAs
- Manual exposure control
  - Provide exposure time (or *mAs*) selections from 0.02 to 6 s (2 to 600 mAs) in 15 to 20% increments
  - Coefficient of variation ≤5% from 5 to 300 mAs
  - Display of preset *mAs* and postexposure *mAs*
  - Output within 5% of AEC for same kVp and postexposure *mAs*

3.1.8 *Compression Device*

Firm compression is essential in mammography for a variety of important reasons: reduces geometric unsharpness, reduces scattered radiation, diminishes motion unsharpness, reduces x-ray

dose, produces more uniform film density, accentuates the differences in density between normal and malignant tissue, and separates overlapping tissue elements. For all these reasons, a properly designed compression device must be provided on a mammographic x-ray unit (AAPM, 1990; ACR, 1993).

The impact of compression on scattered radiation may seem exaggerated. After all, the breast is not really "compressed," but simply spread out over a larger area. The same tissue is exposed and thus, the same volume of tissue is producing scattered radiation. However, the production of scattered radiation increases much more rapidly with increasing thickness than it does with increasing field size (Figure 3.10) (Barnes, 1994). Therefore, the breast thickness reduction achieved by firm compression results in a significant decrease in scattered radiation production, in spite of the increase in breast area. In addition, by reducing breast thickness, compression also reduces beam hardening which also improves contrast. In the absence of scattered radiation and with a Mo/Mo unit operated at 28 kVp, the contrast of microcalcifications increases seven percent per centimeter of decrease in compressed breast thickness (Wagner, 1991).

Proper compression device design (see below) is essential if adequate compression is to be achieved without the patient experiencing undue discomfort. However, as noted elsewhere in this Report (Section 2.5.4) (Eklund, 1991), there are a wide variety of factors that affect the patient's experience of compression, not least of which is the skill and sensitivity of the technologist. It is impossible to overestimate the technologist's role in achieving adequate compression and all the benefits that result.

The compression device should be an integral part of the x-ray unit, mounted rigidly, so that it may be positioned in a reproducible fashion (ACR, 1993; AHCPR, 1994). This will facilitate proper positioning and firm compression of all the breast tissue. A stiff compression device, which is perfectly flat and parallel to the image-receptor surface, should be utilized (AAPM, 1990; ACR, 1993; Feig, 1987; NCRP, 1986; Yaffe, 1991). It is important that the compression device remain as nearly flat and parallel to the image receptor as possible during compression. If the compression device does not remain parallel to the image receptor during compression, but rather slopes posteriorly, tissue at the base of the breast will be less compressed and relatively underpenetrated and many of the benefits of compression will be lost, particularly in the posterior regions of the breast. Unfortunately, early compression devices were designed to slope posteriorly. The advantages of a flat design were not recognized until the late 1970s (Logan and Norlund, 1979).

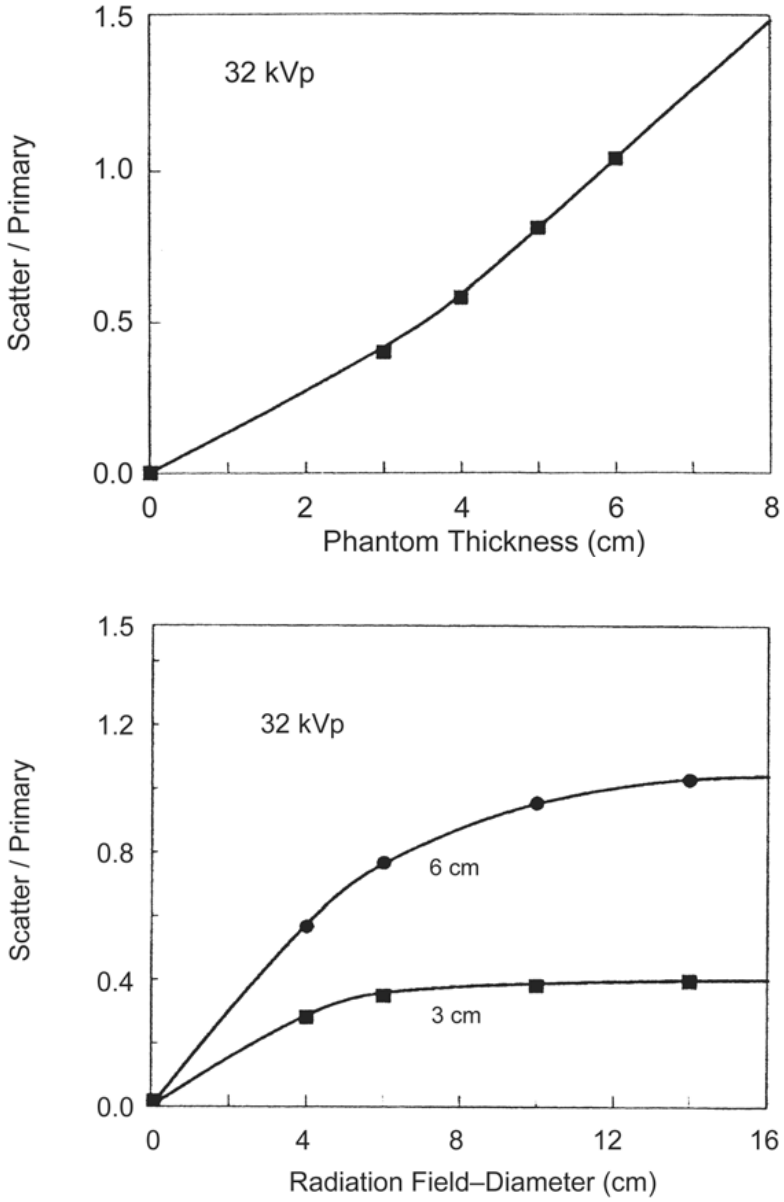


Fig. 3.10. (Top) Scatter-to-primary ratio (*S/P)* as a function of Lucite® (duPont, Wilmington, Delaware) phantom thickness for a 14 cm diameter radiation field at 32 kVp. (Bottom) *S/P* as a function of field size for 3 and 6 cm thick Lucite® phantoms at 32 kVp (Barnes, 1994).

The compressed breast thickness should be displayed on the unit and the display should be accurate to within 0.5 cm (ACR, 1993). This degree of accuracy will be impossible to achieve if the compression device does not remain rigid and flat when compression is applied. The display or scale should also be usable for both grid and nongrid work and must therefore correct for any differences in image-receptor support thickness in these instances. The accurate display of compressed breast thickness will allow documentation that will help insure consistency from exam-to-exam on the same patient and will be helpful in estimating patient dose.

The compression device must be rigid enough not to deform excessively (>1 cm), when maximum compression is applied and thick enough not to crack under firm compression (ACR, 1993). At the same time, it must not be so thick as to attenuate and harden the x-ray beam excessively and it must be transparent to light to facilitate proper positioning. The material used for the compression device should be such that, if the device fails (*e.g.*, cracks) minimal injury is caused to the patient. In addition, the edges of the compression device should be smooth for patient comfort. The corners of the posterior edge of the compression device should be slightly rounded to prevent a sharp edge that might be uncomfortable for the patient. But, only the most posterior 2 mm can be rounded. More rounding will result in underpenetration of the posterior aspect of the breast. The support at the sides of the compression device should be slender and strong, occupying as little space as possible, to make it easier for the technologist to pull the glandular tissue onto the film. The support should neither obscure imaged glandular tissue nor push the patient's arm away. Compression devices should be available in various sizes so that the overall size of the compression device will always correspond to the size of the breast and that appropriate compression can be applied in special circumstances (*e.g.*, spot compression).

The posterior (chest-wall) edge of the compression device should be bent upward at a sharp 85 degree angle along the posterior border (AHCPR, 1994; Logan and Norlund, 1979; NCRP, 1986) and should be at least 3 to 4 cm high (Figure 2.7) in order to push back the axillary fat fold, which overlies the posterior aspect of the breast in the CC view, and to prevent excess tissue high on the chest wall from overlapping the film (ACR, 1993; Feig, 1987; NCRP, 1986). This added height also helps prevent the plastic from fracturing during firm compression. The sharp posterior angle allows the compression device to grip the posterior aspect of the breast tissue during compression rather than allowing it to slide out from underneath, as will occur with a compression device that

has a more gently angled curvature. Most importantly, the edge of the compression device that is adjacent to the chest wall should be straight (Feig, 1987; Yaffe, 1991). A contoured chest-wall edge on the compression device will interfere with proper positioning and compression, particularly on the MLO view.

This compression device design enables improved visualization of the posterior aspect of the breast provided the device is properly aligned. When properly positioned, the vertical (chest-wall) edge of the compression device will lie in the plane defined by the chest-wall edge of the image receptor and the ray from the focal spot perpendicular to that edge. The chest-wall edge of the compression device should remain in this plane as the compression device is moved vertically through its full range of motion with respect to the image-receptor support device.

The compression device should be aligned with the posterior edge of the image receptor within one percent of the *SID* (ACR, 1999). If the compression device does not project far enough to be properly aligned with the chest-wall edge of the film, the edge of the compression device will project onto the film image and the thicker posterior breast tissue beyond the compression device will be undercompressed. On the other hand, if the compression device projects beyond the edge of the image receptor, it will push breast tissue away, failing to properly image the whole breast. Many mammographic units arrive at the mammography site with a misaligned compression device. For this reason, the compression device should provide a means of adjustment so that any misalignment can be readily corrected. During mammographic examinations, pressure from the patient's ribs will be exerted on the compression device and may result in misalignment.

Dedicated mammography units should be equipped with powered compression systems (electric, pneumatic or hydraulic) controlled by foot pedals to allow the technologist to use both hands to position the breast while applying compression (ACR, 1993). The foot pedals should be conveniently accessible from either side of the patient and should allow both application and release of compression force. Such a motorized compression system should be immediately responsive, should not delay or reverse, and should not slip after final compression is applied. The power drive on the compression system should not be excessively noisy. There is considerable debate over the degree of compression that such systems should provide (AAPM, 1990; Sullivan *et al*., 1991), but the current consensus is that the maximum force should be 200 N (newtons) (45 pounds) (ACR, 1993; DHHS, 1987). In a study of 560 patients who determined their own compression force (Sullivan

et al., 1991), the compression force applied during mammography ranged from 49 to 186 N (mean = 127 N, mode = 108 N) which suggests that the 200 N maximum is quite adequate.

There should be a readout of the applied compression force visible to the technologist during positioning, although such readouts may be prone to error (Clark *et al*., 1990). It should also be remembered that the force applied by the compression device is not a good predictor of the adequacy of compression nor of the patient's level of discomfort (Eklund, 1991).

As noted above, the technologist should begin compression with the foot controlled motorized device keeping her hands free to rotate the patient's torso and position the breast. For final compression, however, fine control is essential (Feig, 1987). This is typically provided by a hand control that will allow the technologist to gauge the breast's resistance and judge the degree of patient discomfort so the compression will not be too firm. This approach has significant advantages in terms of patient acceptance. It will also allow the technologist to slow down the speed with which the compression device descends so that the patient is not frightened. The hand control should be sufficiently sensitive for the technologist to "feel" the degree of resistance to compression. Without a hand control, the technologist may have difficulty in accurately determining how much compression the patient can tolerate.

As noted above, the technologist's ability to release the compression device instantly after exposure or in an emergency is vital to the patient's comfort and safety. The release switch should be on the C-arm. If the patient sees that it is the technologist and not the machine that regulates compression, they will be less uneasy about the procedure. Alternatively, the release switch can be on the control console which has the advantage of allowing somewhat quicker release of compression. Some systems have an automatic compression release feature. This may be useful under some conditions to minimize the time during which the breast is under compression. If such an automatic release feature is provided, there should be a means of overriding it when appropriate, such as in localization procedures. The compression device should be designed to release the compression automatically in the event of a power interruption.

A small compression device is also necessary to spot-compress questionable areas and spread out the glandular tissue so it can be better visualized. Significantly better compression can be applied locally to a restricted area than can be applied to the breast as a whole (Figure 2.35b) (Barnes, 1994). The thinner the compressed breast and the more coned-down the area imaged, the better the

contrast. For this reason, a dual-focus compression device has been developed. This compression device incorporates a raised section on the patient support that compresses the breast from below, in concert, with an identically sized spot-compression paddle positioned conventionally above the breast. A 9 cm wide rectangular compression device is useful in spot compression of slightly larger, nonspecific problematic areas. It is also helpful in compressing areas of the breast and axilla that are difficult to position. Table 3.12 presents desirable characteristics of compression devices.

TABLE 3.12—*Desirable features of compression devices.*

- Compression device
  - Integral part of the mammographic x-ray unit
  - Flat and parallel to the film surface
  - Provides minimal attenuation and hardening of the x-ray beam
  - Transparent to light
  - Thick enough not to crack under firm compression
  - Deforms <1 cm with maximum compression applied
  - Straight chest-wall edge that is bent upward at a nearly 90 degree angle along the posterior border and it extends upward at least 3 to 4 cm
  - Edges are smooth for patient comfort
  - Posterior corners are slightly rounded
  - The chest-wall edge is aligned with chest-wall edge of film to within +2 mm
  - Devices available for spot and dual-focus compression
- The compressed breast thickness display and control
  - Accurate to 0.5 cm
  - Display usable for both grid and nongrid
- Powered compression system
  - Compression system controlled by foot pedals
  - Conveniently accessible to allow easy application and release
  - Immediately responsive
  - No delay, reversal or slippage
  - Not excessively noisy
  - Maximum force should be 200 N (45 pounds)
  - Force readout is visible to technologist during positioning
  - A hand control is available for final compression
  - Hand control is sensitive so technologist can “feel” degree of resistance
  - Compression release switch is on the C-arm
  - Automatic release with override for localization procedures
  - Automatically release in the event of a power interruption

3.1.9 *Grid*

Dedicated mammographic units should be equipped with anti-scatter grids (ACR, 1993; AHCPR, 1994). Scattered radiation can cause a significant reduction in subject contrast in mammography resulting in impaired detection of calcifications and the outlines of tumor masses. The advent of specialized mammographic grids revolutionized the radiologist's ability to evaluate dense tissue (Barnes and Brezovich, 1978; Chan *et al*., 1985; Dershaw *et al*., 1985; Egan *et al*., 1983; Friedrich and Weskamp, 1978; Jost, 1979; Logan and Stanton, 1979; Sickles and Weber, 1986; Stanton and Logan, 1979).

The grid (Figure 3.11) placed between the breast and the image receptor, absorbs scattered radiation that would otherwise reach the image receptor, improves contrast, and results in better definition of

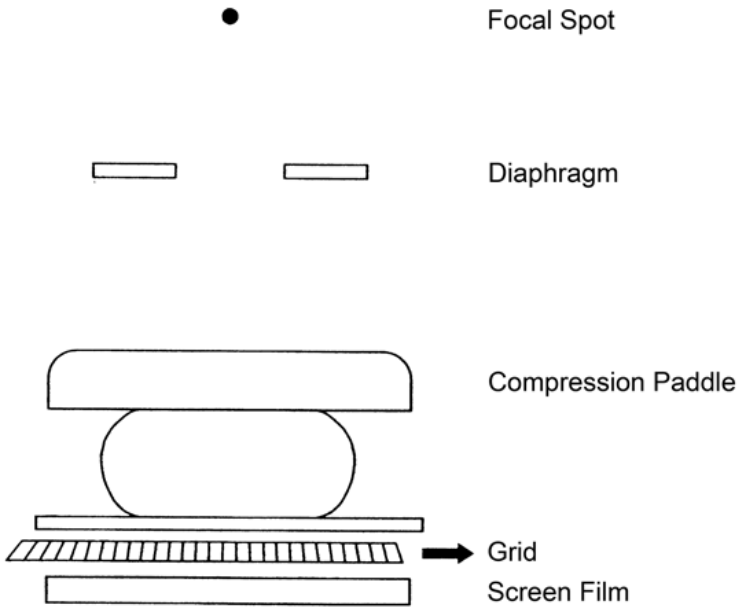


Fig. 3.11. Mammography bucky assembly. Black lines in the grid represent radiopaque lead strips that make up the grid. The lead strips are focused to the focal spot. Arrow indicates that the grid moves through a distance of >20 grid line spacings, that is, >20 ($d + D$) (where, d = width of lead lamellae and D = width of radiolucent interspace material) (Barnes, 1999).

the borders of glandular tissues. However, even with its advantages, the use of a grid does not eliminate the need for firm compression to spread apart the glandular tissues and to permit better visualization of the borders of small lesions. The use of a grid does result in increased patient dose and exposure time. However, units with high output can maintain exposure times at levels that do not create significant patient motion and film reciprocity law failure problems (Villafana, 1990).

The intensity of scattered radiation (S) reaching the image receptor [relative to the primary radiation intensity (P) at the same point] is described by S/P. In mammography, if a grid is not used, S/P can vary from 0.33 to 1 as the diameter of the radiation field increases from 4 to 14 cm and the breast phantom thickness increases from 3 to 6 cm (Barnes and Brezovich, 1978). Even higher S/Ps are associated with thicker breasts (*e.g.*, S/P = 1.5 at a thickness of 8 cm). The effect of such scattered radiation is to reduce contrast and the magnitude of the effect is described by the scatter degradation factor (SDF) where $SDF = 1/[1 + (S/P)]$ (Barnes, 1994). Thus, at an S/P of 0.33, only 75 percent of the available contrast will be imaged and at a S/P of one, only 50 percent of the contrast will be imaged. Control of scattered radiation, therefore, has the potential for significantly improving contrast (Figure 3.12).

Scattered radiation can be reduced by a factor of three through the use of an appropriate grid (AAPM, 1990; Yaffe, 1991). Since the grid absorbs 50 percent or more of the radiation beam, the contrast improvement is achieved only at the expense of increasing the exposure by a factor of 2 to 2.5 compared with nongrid techniques (AAPM, 1990; NCRP, 1986). It is possible to offset at least some of this increased exposure by increasing the operating potential (Friedrich and Weskamp, 1978).

Grids specifically designed for mammography are necessary since the materials and construction of general radiographic grids result in excessive attenuation of the unscattered portion of the low-energy mammographic x-ray beam, as well as increased geometric unsharpness due to the thickness of the grid assembly (ACR, 1993; Feig, 1987; Friedrich and Weskamp, 1978; NCRP, 1986). Special purpose mammographic grids are extremely thin, with lead grid strips, or septa, only about 1 mm in height. The septa are typically 16 μm thick and the interspaces are about 300 μm wide (Feig, 1987). The grid ratio (the height of septa relative to the distance between the septa) is usually in the range of 4:1 to 5:1 and the grid should have about 32 septa (or "lines") per centimeter. To minimize attenuation of the primary (image forming) radiation and

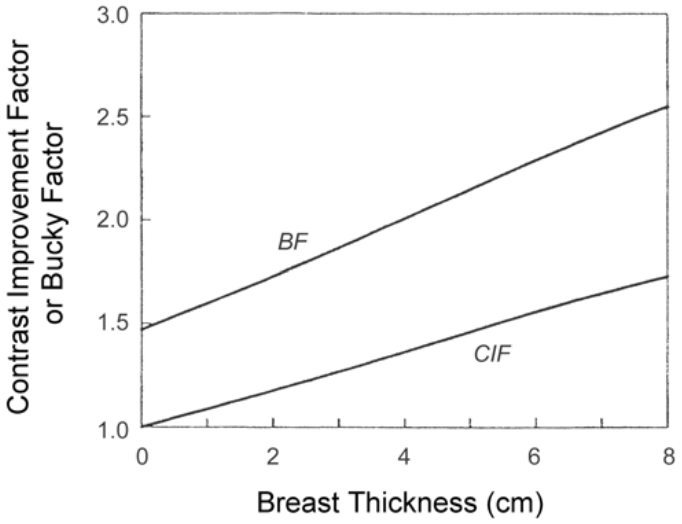


Fig. 3.12. Plots of the contrast improvement factor (*CIF*) and bucky factor (*BF*) of a typical mammography grid versus breast thickness (Barnes, 1999).

avoid an unnecessary increase in patient dose, the interspace and the grid cover materials should have a low x-ray attenuation and have a radiographically uniform structure (ACR, 1993; Yaffe, 1991). For this reason, the interspace material is usually fiber (paper) and the grid cover is often carbon fiber. The use of such materials will also reduce the extent to which the patient dose must be increased to compensate for the absorption by the grid. The typical grid ratio and "bucky factor" (the ratio of the milliampere seconds required with the grid to that required without the grid to obtain a given film optical density at a typical clinical operating potential) should be indicated on a label on the grid, as well as on the outside of the grid assembly. Disassembly of the equipment should not be required to verify the specifications of the components.

Recently, rhombic cellular structure air interspaced grids have been introduced (Figure 3.13). These grids have the potential to improve image contrast (and reduce grid absorption) compared with conventional grids (Figure 3.14).

Moving grids are widely used and a mammographic unit should be equipped with a mechanism designed to move the grid during the x-ray exposure, in such a manner, that the grid septa are not visible on the mammographic image. Images of a uniform phantom

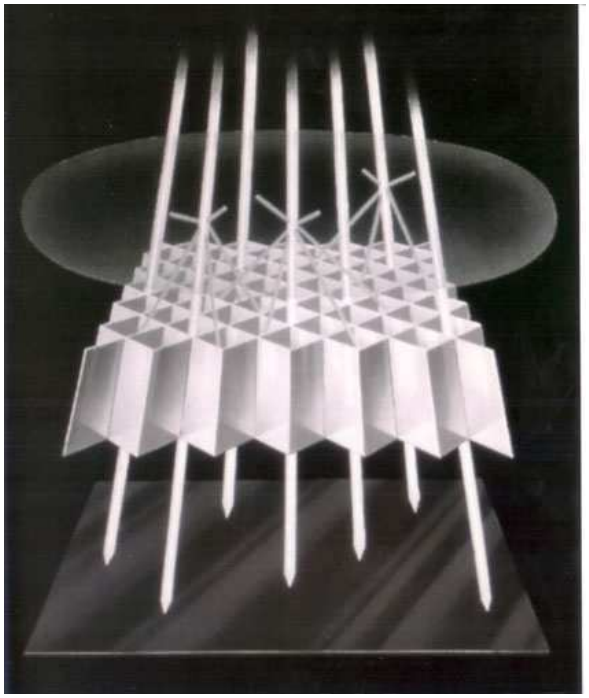


Fig. 3.13. High transmission cellular grid multidirectional scattered radiation absorption (courtesy of Lorad Corporation, Danbury, Connecticut) (Haus, 1999b).

taken after the grid system is activated and with only the compression device in the x-ray beam should not reveal any grid lines or other density fluctuations, since these will degrade the image. Moving grids may produce grid lines on mammograms when exposures are long enough to cover several oscillations of the grid. In such a case, the grid lines may be strongly imaged during those brief periods when the septa are at rest as the motion of the grid is reversed. Grid line artifacts may also occur at the end of very long exposures, if the grid oscillations diminish gradually (Dance *et al*., 1992). Such artifacts may also be produced when exposures are very brief or the oscillations are too slow. In this case, not enough time elapses for the images of the grid lines to be "averaged out." This type of problem can be more significant when high-speed screen-film combinations are used. In order to avoid these problems, it should be insured that test images of the moving grid show no grid lines or artifacts over a range of uniform phantom thicknesses from 2 to 6 cm at optical densities of about 1.3 (ACR, 1993).

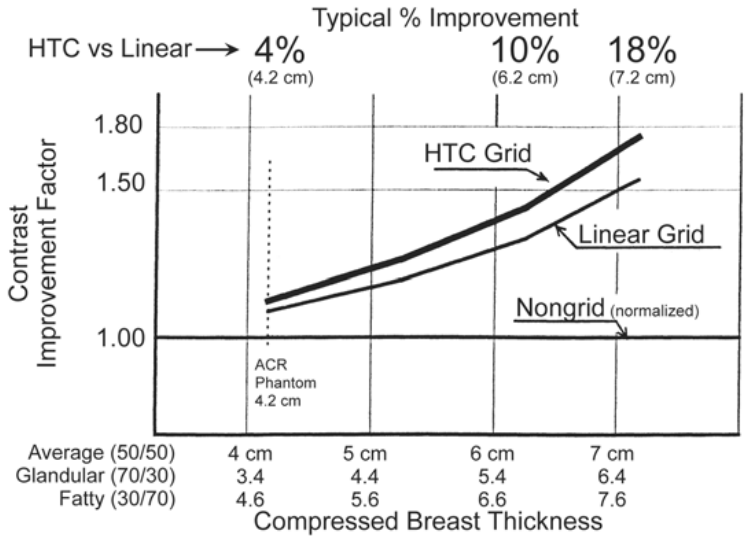


Fig. 3.14. Contrast improvement factor versus compressed breast thickness for high-transmission cellular (HTC) and linear grid. This is a relative curve. It changes with different breast composition and film gradient (courtesy of Lorad Corporation, Danbury, Connecticut) (Haus, 1999b).

With a moving grid, the grid assembly should be sufficiently rigid so that the grid motion is not impeded when the breast being imaged is under firm compression. This degree of rigidity can be demonstrated by placing a 4 cm thick (approximate) cassette sized phantom made of either acrylic or BR-12®,[6] 0.5 cm thick, in the center of the imaging area and compressing it using the full pressure of the compression device (ACR, 1999). Under these conditions, test images should demonstrate that the motion of the grid is not impeded. The grid cover should be of uniform construction so that structural artifacts are not superimposed on the mammographic image. As mentioned above, the grid itself should be uniform and have no regions of increased attenuation that would produce image artifacts.

Two sizes of moving grids are necessary: (1) for small breasts to accommodate cassettes for 18 × 24 cm film, and (2) for large breasts to accommodate cassettes for 24 × 30 cm film. Although many

[6]BR-12® is an epoxy resin-based tissue substitute (Gammex, Middleton, Wisconsin) (White *et al*., 1977).

patient's breasts can be accommodated on an 18 × 24 cm film, approximately 20 percent of patients require a 24 × 30 cm film to include the axillary tail (ACR, 1993). One large grid equipped with devices to hold both the smaller and the larger cassettes will not suffice. When a small breasted woman lifts her arm above the larger tray, the skin becomes taut, which could prevent the technologist from pulling the patient's breast forward on the film and could result in missing a posterior cancer.

The design of the unit's C-arm should be such that it facilitates switching from one grid size to another, as well as removing the grid entirely in those few cases where use of a grid would be inappropriate. Ideally, the mammographic unit should be equipped with an interlock feature that will prevent exposures when the grid is not in place or is in place but is disconnected from the unit, unless special action is taken to override the interlock. Such a feature would prevent the technologist from inadvertently making an exposure with the grid disconnected.

Despite the advantages of grids and the significant additional clinical information their use provides, these devices do have certain disadvantages. As noted above, the grid will absorb >50 percent of the radiation leaving the breast and compensating for this reduced exposure rate requires doubling the patient's dose. In general, the greater the contrast improvement provided by the grid the more the dose will need to be increased. Higher operating potential settings, increased filtration, increased exposure time, or use of a higher speed screen-film combination (or some combination of these factors) can counteract the higher dose, but not without corresponding consequences. The harder beams associated with higher operating potentials or greater filtration reduce subject contrast, undermining the grid's effectiveness. Longer exposure times can result in patient motion problems and may necessitate even greater increases in patient dose due to film reciprocity law failure. Faster imaging systems can result in significant increases in quantum noise and a consequent reduction in image quality.

Despite its minor disadvantages, the grid is absolutely essential for assessing dense glandular tissue and has revolutionized modern mammography. Previously, many radiologists only used the grid for patients with dense glandular tissue or breast tissue that could not be compressed to <6 cm (Dershaw, 1987; NCRP, 1986; Sickles and Weber, 1986). Because of the dose reductions achievable with newer screen-film combinations, the greater contrast enhancement capability of modern grids and the availability of higher output units (with shorter exposure times), using a grid for

virtually every routine mammogram has become common practice (Feig, 1987; NCI, 1993). See Table 3.13 for desirable characteristics of grids.

3.1.10 *Magnification Mammography*

Dedicated mammographic units intended for diagnostic or problem-solving mammography must have the capability of doing magnification mammography (AHCPR, 1994). A small focal spot should be provided for imaging in the magnification mode (ACR, 1993), as well as a magnification stand designed to support the breast in an elevated position, significantly above the plane of the image receptor. When imaged in this elevated position, a geometrically magnified image of the breast is produced. Such magnification images can often provide clinically significant information concerning microcalcifications and the borders of masses that cannot be obtained from nonmagnification images and are, therefore, useful in distinguishing malignant from benign breast disease (Sickles, 1979; 1980; 1987a; Sickles *et al*., 1977). In magnification mammography, image quality is improved for a variety of reasons

TABLE 3.13—*Desirable characteristics of grids.*

- Grid properties
  - Extremely thin septa of about 1 mm in height
  - Septa typically 16 μm thick
  - Septa interspace is about 300 μm wide
  - Ratio usually 4:1 or 5:1 with about 32 septa (lines) per centimeter
  - Septa are radiographically uniform structures
  - Interspace material between septa is usually fiber (paper)
  - Cover is made of carbon fiber for low x-ray attenuation
  - Ratio and bucky factor is indicated on label on grid, as well as on outside of grid assembly
  - No visible grid lines for AEC exposures of phantom thicknesses from 2 to 6 cm
- Bucky properties
  - Cover rigid enough so grid motion is not impeded under compression
  - Two sizes of grids for the two film sizes of 18 × 24 cm and 24 × 30 cm
  - Allows for easy switch of grids
  - Interlock to prevent exposure when grid is not in place or in place but disconnected from unit

(Haus, 1990; Haus *et al*., 1979). Magnification increases the effective resolution of the image receptor, because every detail in the enlarged image of the breast is magnified. Small structures, whose visibility was limited by the image-receptor blur during contact mammography, are imaged at a magnified size where the effect of blur is reduced. In addition, there is a decrease in the effective noise since quantum noise is not magnified. There is also a decrease in the scattered radiation that is recorded in the image due to the introduction of an air gap between the exit surface of the breast and the image receptor (Barnes, 1979; Barnes and Brezovich, 1978; Nielson and Fagerberger, 1986). The typical air gap is 16 to 30 cm for a 1.5 to 2 magnification factor depending on the *SID*. The increased dose associated with magnification mammography, as well as potential film reciprocity law failure problems can be offset by the use of a faster image receptor (Bassett *et al*., 1981).

The resolution improvement that can be achieved by magnification mammography depends on the size of the focal spot (and the location of the structure of interest in the breast) since image resolution is ultimately limited by geometric unsharpness (Haus *et al*., 1979). The degree of magnification provided should be between 1.5 and 2 times depending on the actual size of the focal spot, the unit geometry, *SID*, and other factors (ACR, 1993). Larger magnifications are likely to result in increased dose and excessive geometric blur, with associated motion unsharpness along with decreased field size in the breast.

The nominal size of the focal spot used for magnification should be 0.10 mm or less (Eklund and Cardenosa, 1992).

Since grids cannot generally be used in conjunction with magnification, it might be expected that magnification images lack sufficient contrast. Two factors prevent this from being the case. First, the air gap, the separation introduced between the exit surface of the breast and the image receptor, reduces the amount of scattered radiation detected by the image receptor. Rather than absorbing scattered radiation as is the case with a grid, the air gap provides an opportunity for scattered radiation to project off the film. The greater the air gap, the less scattered radiation will be recorded. Second, coning down the x-ray field size to as small an area as possible will limit the production of scattered radiation (Hall, 1989; Sickles, 1989). Scattered-radiation production is also limited by firm compression as it is in contact mammography. Compression is also critical for the other reasons mentioned for contact mammography, particularly in helping to prevent even the slightest motion during the relatively long exposure times typical of magnification mammography (Sickles, 1987a).

Spot compression coupled with magnification has been demonstrated to be particularly effective (Faulk and Sickles, 1992). A round or narrow compression device, no wider than 9 cm is essential for firm compression of the area to be magnified. As mentioned previously (Section 2.1.8), devices are also available which provide a small raised area on the patient support corresponding to the size and location of the spot-compression device and thus provide reciprocal compression from below as well as above.

Mammographic units used for magnification should be equipped with collimation systems that allow either exposure of the entire image-receptor or coned-down views; the light field should indicate clearly the location and size of the x-ray field (ACR, 1993). As mentioned above, a magnification stand is also necessary. This device is attached to the usual image-receptor support and allows for positioning the breast considerably above the plane of the image receptor. When imaging is performed in this elevated position, the dose to the patient is increased. However, assuming that a grid is not used (which will be true in virtually all cases), the dose will not be significantly increased compared to standard non-magnification grid imaging. At the same time, the breast image is magnified improving image resolution. The magnification stand should be easy to set up; otherwise magnification can become a burdensome chore.

The magnification stand should remain solidly in place and not slant downward with continued use, a downward slant means that the stand is no longer parallel to the image receptor and the compression device. The chest-wall edge of the magnification stand should align perfectly with a line between the focal spot and the posterior edge of the film. An abdominal shield should also be provided to prevent the patient's abdomen from projecting between the breast and the image receptor. Such an abdominal shield should be sturdy and rigid so that it can neither break easily nor be pushed into the x-ray field.

The unit should be designed so that the technologist can lower the C-arm enough to perform magnified views on short patients or those who must be imaged in the seated position. The space between the breast support and the tube head must be large enough to allow good positioning. If not, the patient's shoulder will hit the tube head and the technologist will not be able to pull all of the patient's breast onto the magnification stand. If the entire breast is not on the stand, the radiologist will not be able to visualize lesions at the chest wall. The unit should contain diaphragms matching the width of all the compression devices including the small compression device for the coned-down view. Table 3.14 presents the desirable characteristics of magnification mammography.

TABLE 3.14—*Desirable characteristics for magnification mammography.*

- Magnification
  - 1.5 to 2 times magnification available
  - Magnification stand provided and easy to set up
  - Magnification stand solidly attached
  - No downward slant with use
- Focal spot
  - 0.1 mm nominal focal spot
- Miscellaneous criteria
  - Chest-wall edge aligned with posterior edge of film
  - Sturdy, rigid abdominal shield available
  - Sufficient space between breast support and tube head to allow good positioning
  - Round or narrow compression device
  - No wider than 9 cm for spot compression
  - Collimation matching width of all compression devices

3.2 Screens, Films, and Film-Processing Systems

3.2.1 *Introduction*

The goal in screen-film mammography for mass screening and diagnosis is to produce consistently high-contrast, high-resolution, low-noise images at the lowest radiation dose consistent with these image-quality requirements. In recent years, there have been many significant technologic improvements in mammographic screen-film combinations (AAPM, 1990; Haus, 1991; 1999b; Kimme-Smith, 1991; Rothenberg and Haus, 1995; Yaffe, 1990). Until the early 1970s, direct-exposure (industrial type) x-ray films were used which often required long exposure times (causing blur due to motion) and resulted in high radiation exposure (Bassett *et al*., 1992; Egan, 1976; Gold *et al*., 1990; Haus and Cullinan, 1989). Films were processed manually in tanks or in film processors with long processing times. In the early 1970s, screen-film combinations for mammography became commercially available (Bassett *et al*., 1992; Haus and Cullinan, 1989; Ostrum *et al*., 1973; Wayrynen, 1979).

Today, mammography is performed with screen-film combinations having significantly improved imaging characteristics designed specifically for mammography. Film processing has also improved significantly over the years. Figure 3.15 shows characteristic curves of (1) a typical direct-exposure mammographic film

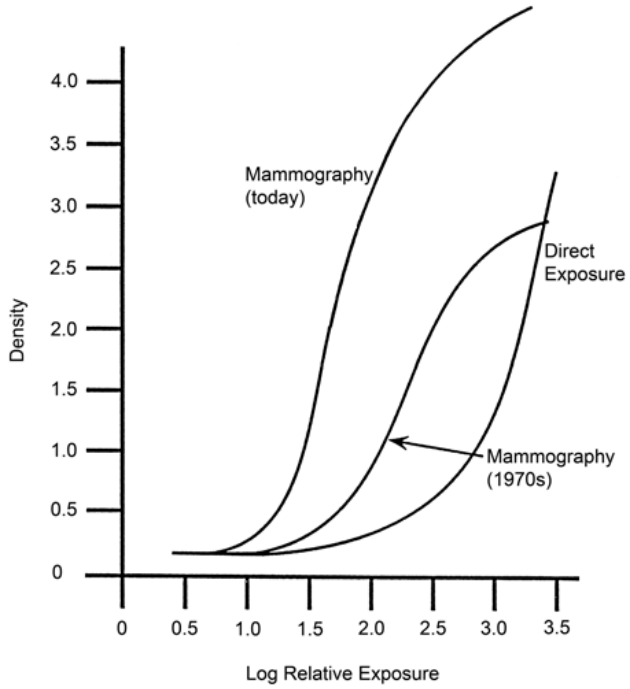


Fig. 3.15. Characteristics curves for (a) a direct-exposed film, (b) a single-screen, single-emulsion film used in the 1970s and early 1980s, and (c) a single-screen, single-emulsion film combination used for mammography today (Haus, 1999b).

widely used approximately 40 y ago; (2) a typical single-screen, single-emulsion film combination commonly used in the 1970s and early 1980s; and (3) a typical single-screen, single-emulsion film combination used today. These curves illustrate relative speed and contrast differences.

3.2.2 *Screens*

The great majority of mammographic images are produced with a single-intensifying screen used as a back screen in combination with a single-emulsion film (Figure 3.16). Many mammographic screens incorporate phosphors containing metals from the lanthanide series of elements such as terbium-activated gadolinium oxysulfide (Gd_2O_2S:Tb). Screens may incorporate light absorbers in the phosphor that increase sharpness. Intensifying screens have a

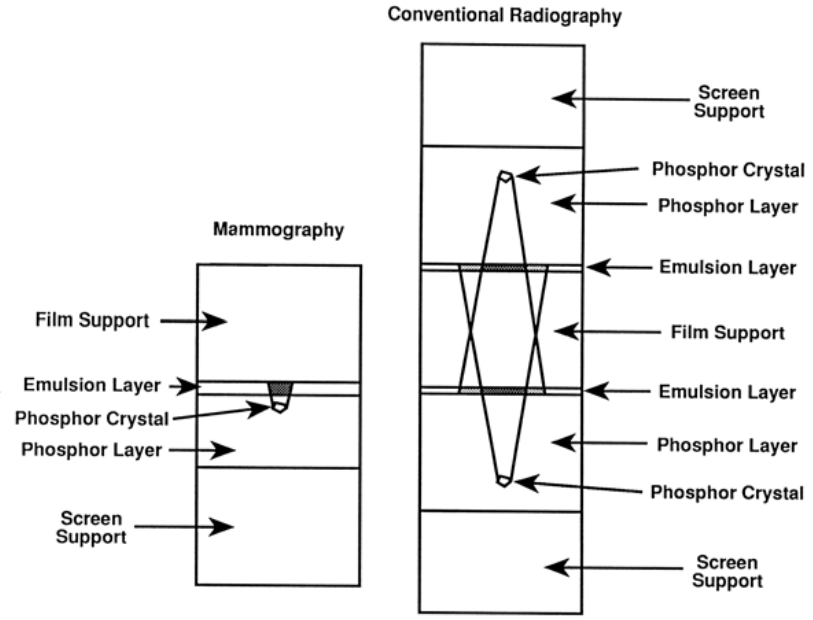


Fig. 3.16. Diagrams comparing physical configurations for a single-emulsion film in contact with a single back-intensifying screen (as used for mammography) and double-emulsion film sandwiched between two intensifying screens (used for other radiologic procedures). Note that the x-ray source would be above in both cases (Haus, 1999b).

protective overcoat to resist surface abrasion and are edge-sealed to minimize edge wear and moisture absorption. The screen base includes a backing layer to eliminate screen curl. Mammographic screens consisting of Gd_2O_2S:Tb material have their primary emission peak emit in the green spectral region (545 nm) and they also emit in other regions of the visible spectrum from 382 to 622 nm (Figure 3.17) (Haus, 1999b).

In the future, intensifying screens with other phosphors may become available that may offer benefits such as increased spatial resolution and reduced radiographic noise, without increasing radiation dose (Kitts, 1997).

3.2.3 *Films*

Most films used in mammography are single emulsion and are used in combination with a single back screen (AAPM, 1990; ACR, 1993; Haus, 1991; 1999b; Kimme-Smith, 1991; Yaffe, 1990). Some

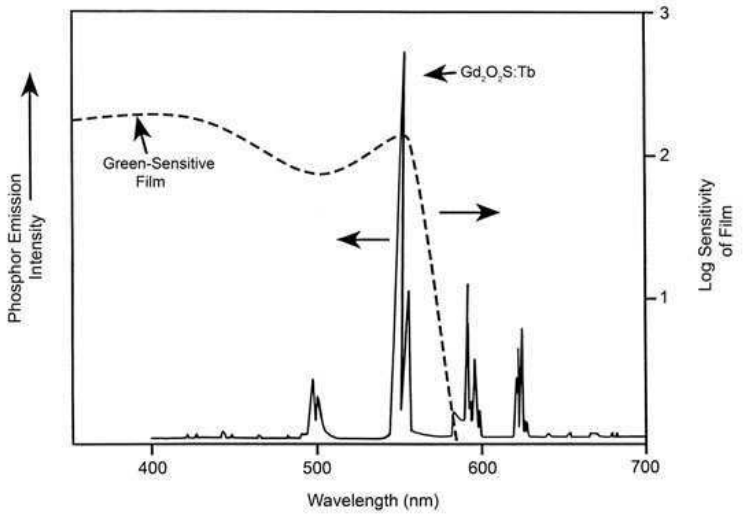


Fig. 3.17. Relative emission spectrum of a Gd_2O_2S:Tb. The screen superimposed on a graph showing the spectral sensitivity of a commonly used mammographic film. The high spectral emission peak of the green emitting screen coincides with the high sensitivity of the film to green light (Haus, 1999b).

companies have introduced double-emulsion films used in combination with a single-intensifying screen for mammography. Single-emulsion films used for mammography are coated with larger amounts of silver halide and gelatin on a single side than are double-emulsion films used in conventional radiography. Three-dimensional silver halide grains have been widely used for mammography film emulsions. Recently, mammography films have been introduced with cubic grain emulsions. The uniform chemical and spectral sensitization of cubic grains result in high contrast, especially in the toe portion of the curve, which is very useful in mammography.

3.2.4 *Film-Processing System*

Film processing must be considered as part of a system, which includes the automatic film processor, film type, and chemicals (Batz and Haus, 1993; Haus, 1993; Haus and Jaskulski, 1997). These components must be considered together as a system and must be properly optimized, in order to obtain appropriate image quality in terms of proper optical density and film contrast of the

processed radiograph. The resulting film speed affects the radiation dose to the patient. Automatic film-processor variables include: (1) processing cycle time, (2) temperature, (3) chemicals, (4) replenishment, (5) agitation, and (6) drying. Figure 3.18 illustrates the operation of a typical automatic film processor.

3.2.4.1 *Processing Cycle Time*. Processing cycle time is usually defined as the time it takes for: (1) the leading edge of the film to enter and exit the processor or (2) the leading edge of the film to enter and the trailing edge of the film to exit the processor. The latter definition will be used in this Section. Processing cycles range

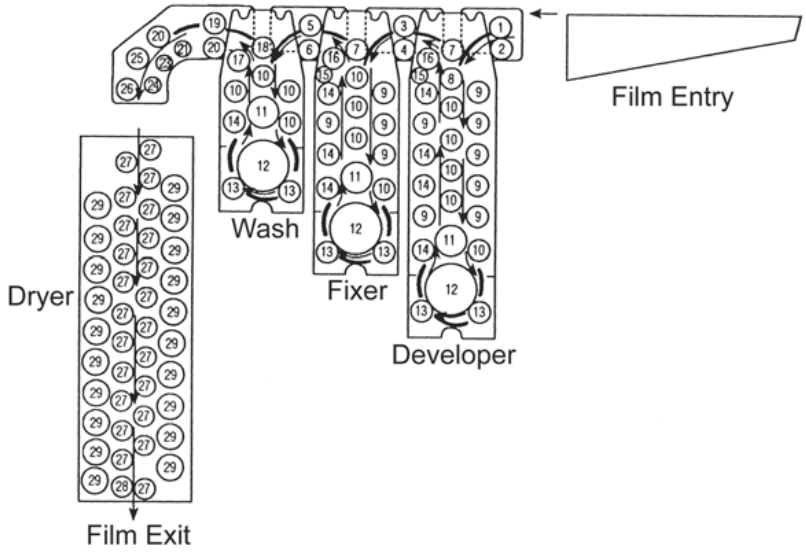


Fig. 3.18. Operation of a typical automatic film processor. Typically, film is manually inserted into the processor transport system from the feed tray. The film is transported through (a) the developer rack, (b) the fixer rack, (c) the wash rack, (d) the dryer section, and (e) exits dry and ready to read. The film path is a "serpentine" route. This enables proper developer agitation, as well as maximum chemical-to-emulsion "coupling," which produces the optimum development for speed and contrast. Developer makes the latent image visible. Fixer essentially "stops" the development process and makes the resultant image "permanent" for archiving purposes. Washing removes chemicals to enable uniform drying and long-term, archival retention of the radiograph (Haus, 1999a).

from approximately 90 to 210 s depending on whether standard- or extended-cycle processing is used. Standard processing cycles are between 90 and 150 s. Developer temperature and replenishment rates are determined by the processing cycle in order to achieve the desired sensitometric characteristics (optical density contrast, speed, base-plus-fog values) for the type of film being used.

Extended-cycle processing has been used for some single-emulsion films (Kimme-Smith *et al*., 1989b; Tabar and Haus, 1989). In extended-cycle processing, the film remains in the developer longer and developer temperature is not altered significantly. For some single-emulsion films, the film contrast is higher and the film speed is increased resulting in a reduction of radiation dose when extended-cycle processing is used.

Recently introduced films for mammography with cubic grain emulsions, which are recommended for standard-cycle processing, provide film contrast comparable to or higher than films designed for extended-cycle processing. The cubic grain emulsions do not benefit from extended-cycle processing. Other benefits of standard-cycle processing over extended-cycle processing include improved productivity and reduced wet-pressure artifacts (Haus, 1999a).

3.2.4.2 *Developer Temperature*. Developer temperatures in automatic film processors range from 33 to 39 °C. The developer temperature depends on film type, chemicals, and transport speed. Figure 3.19 illustrates the effect of developer temperature differences on film speed, film contrast, and fog levels. These variables can be expected to change in similar fashion as a function of development time.

Note that when the developer temperature is lower than the manufacturer's recommendation, film speed is reduced. This may dictate an unnecessary increase in radiation dose to produce mammograms of proper optical density. Similarly, film contrast is reduced when developer temperature is lowered. Conversely, if the developer temperature is higher or development time longer (extended-cycle process), then the manufacturer's recommendation film speed is increased. This may permit a reduction in radiation dose and film contrast may also be increased. However, these changes can be expected to cause quantum mottle and, thus, radiographic noise to increase. In addition, film fog may increase with increased developer temperature. Developer stability may also be affected adversely when higher-than-recommended developer temperatures are used.

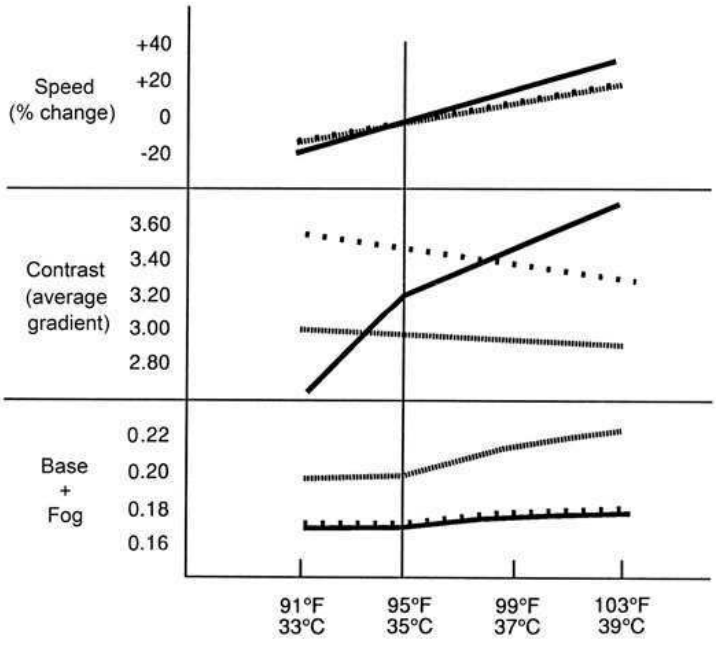


Fig. 3.19. Graph illustrating percent film-speed change, film contrast, and film base-plus-fog values plotted versus developer temperature for the single-emulsion mammographic film [three-dimensional grains (——), cubic grains (. . . .)] and double emulsion [tabular grain film (.....)] using film manufacturer's recommended processor and chemicals. The vertical line represents recommendation for a standard processing cycle (Haus, 1999a).

Mammography films with cubic grain emulsions are less sensitive to temperature change than are three-dimensional grain emulsions. As noted in Figure 3.19 an increase in film contrast occurs for three-dimensional grains but not for tubular or cubic grains with increased developer temperature (Haus, 1999a).

The ACR *Mammography Quality Control Manual* section for radiologic technologists (ACR, 1999), indicates that the developer temperature should be within ±0.3 °C of that recommended by the manufacturer for the specific film-developer combination being used. The measurement accuracy and precision of the thermometer used to monitor developer temperature is most important (ACR, 1993). In the radiology or medical imaging department, a variety of thermometers are used to measure developer temperature. These thermometers vary in accuracy, precision, ease of reading, and cost.

Clinical digital thermometers, which are available in pharmacies and supermarkets, are inexpensive, but accurate devices for measuring the temperature of the developer solution (Wilson *et al*., 1993) are not widely available and are more expensive. These thermometers have a temperature range of 32 to 42 °C and accuracy of approximately ±0.1 °C. It is also recommended that the thermometers used to measure developer temperature be evaluated against a thermometer that has a calibration traceable to the National Institute of Standards and Technology.

It is important to confirm that proper film contrast, film speed, and base-plus-fog values are being obtained for each film type used (according to the manufacturer's specifications and tolerances). This information is available from the film manufacturer (Kimme-Smith *et al*., 1992; Moore *et al*., 1993). To maintain consistent film contrast, film speed, and base-plus-fog values, it is important to implement a processor QC program (ACR, 1999).

3.2.4.3 *Chemicals*. All film manufacturers recommend chemicals for processing their films. Many users consider chemicals from various manufacturers to be interchangeable. However, surveys have documented that film speed, film contrast, and base-plus-fog respond differently to various types of chemicals (Haus, 1999a) (Figure 3.20). These effects also depend on the type of film being processed (Kofler and Gray, 1991).

Chemical manufacturers distribute chemicals as concentrates. Solution service providers add water locally to complete the mixture. In some cases, chemicals are not mixed to the appropriate concentration in accordance with the manufacturer's recommendations. It is also important to avoid the use of chemicals beyond the manufacturers expiration date.

Processing chemical variability can occur in medical imaging due to a number of factors. Although most manufacturers use similar processing chemicals to achieve development and fixing, the concentration of these chemicals can vary, either initially or after being mixed by solution service providers. This concentration variation can result in changes in film response of differing magnitudes depending on the film type. In addition, variability can also result from improper replenishment (Section 3.2.4.4). Either overdevelopment or underdevelopment can occur depending on the degree of replenishment or initial chemical concentration.

For the initial start-up or when fresh chemicals are used, it is important to follow the manufacturer's recommendations by: (1) using the proper chemicals, (2) mixing to the correct concentration, and (3) adding the appropriate amount of starter solution.

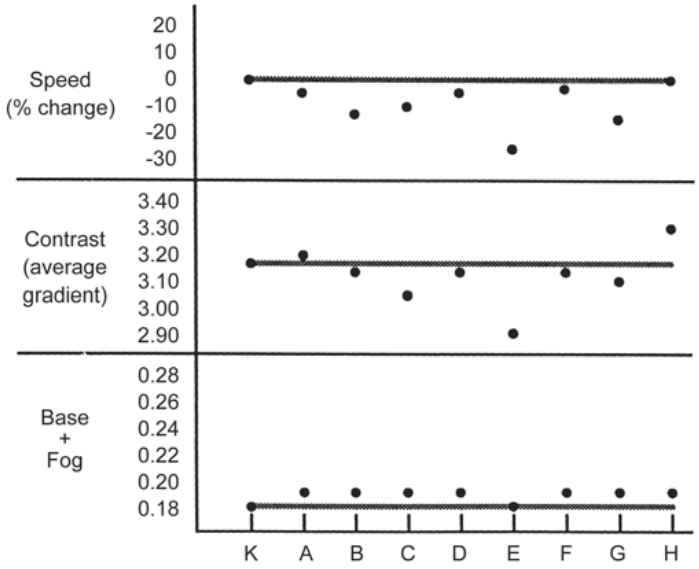


Fig. 3.20. Chart produced from film-processing survey data which shows film-processing variations due to use of different chemicals for single-emulsion mammographic film. The letter "K" indicates processing data (and expected values) using the film manufacturer's processor and chemicals. A horizontal line is drawn at the letter "K" data point. Letters A through H are data for different brands of chemicals. Data were obtained using film strips which were sensitometrically exposed to light that simulates the light spectrum from a mammographic screen. Film speed differences, film contrast (average gradient), and base-plus-fog values were determined from the sensitometry data (Haus, 1999b).

Adding starter solution begins the seasoning process. The developer solution becomes more completely seasoned as more films are processed. This additional seasoning may continue to cause slight changes in film speed and contrast; at some point, film speed and contrast will stabilize. Seasoning effects depend on film type, chemical formulation, and replenishment.

Since both the concentration and composition of chemicals used in film processing can have an effect on the contrast, speed, base-plus-fog, and long-term retention of films used in medical imaging, it is sometimes of interest to attempt to analyze the chemicals used. There are several approaches that are being used to accomplish this. They include: (1) pH measurement, (2) specific gravity measurement, (3) laboratory component analysis, and (4) process control sensitometry.

Determination of pH is a measure of the activity of process chemistry, because development activity generally decreases as pH decreases. This measurement, however, is not very accurate and is useful only for finding trends or large changes in developer concentration. Evaluation of pH is difficult to achieve in solutions (such as developers) containing high concentrations of salt, unless carefully calibrated electrodes are used.

Specific gravity measurements can also be used to determine relatively large changes in concentration. Measurement of specific gravity involves determining the ion and salt concentration of a solution. This same type of measurement is used to measure the acid content of a car battery and is not accurate or specific with respect to any particular chemical. Again, although information about large changes in concentration can be determined, it is not specific enough to determine whether critical components such as developer antifoggants are missing from the developer solution (ACR, 1993; Haus, 1999a; Haus and Jaskulski, 1997).

Analysis of samples of developer solution by an analytical laboratory is the most accurate and predictive approach. However, this approach is costly and time consuming.

The last approach, and probably the most widely used, is to do processor control sensitometry. By monitoring changes in sensitometric response of a processor control film strip, changes due to process chemistry can be detected. If variations in processor control values (speed, contrast, and base-plus-fog) exceed operating tolerances, the chemicals should be changed to insure appropriate and consistent results. Although this approach does not identify the actual cause of sensitometry change, it is probably the most cost- and time-effective approach. Sensitometry must be carried out with the types of emulsion as processed in the film processor. The cost of changing chemistry is small compared to the total cost of doing medical radiography; the down time and investigative time required to identify the cause of a specific change in processor chemistry may not be justified (Haus and Jaskulski, 1997).

3.2.4.4 *Replenishment*. Replenishment is important to maintain stable developer and fixer activity. Proper replenishment: (1) provides stable sensitometric results (film contrast, film speed, and base-plus-fog); (2) reduces or eliminates artifacts such as wet-pressure emulsion pick-off; and (3) enables long-term retention of the films. Replenishment rates are sometimes divided into groups based on daily film volumes. Low film use per day requires higher replenishment per sheet. Processors with very low film volume

(such as surgery rooms) are very difficult to stabilize and it is difficult to maintain consistency. Flooded replenishment is recommended under these conditions (Frank *et al*., 1980). Starter solution is added to the developer replenisher holding tank; the processor is replenished at specific time intervals independent of film volume, in addition to replenishment per sheet of film processed. Flooded replenishment provides a stable fresh process. High film use per day requires a lower replenishment per sheet.

Film throughput (film sheets per day) is the basis for determining replenishment volumes; however, since the typical film sizes for mammography are 18 × 24 cm and 24 × 30 cm, the actual area of the film is less than is used in general radiography. Consult with the manufacturer to correctly adjust and set up the film processor, and replenishment rates to obtain the desired results and to obtain consistency in those results.

3.2.4.5 *Agitation*. Agitation maintains processing uniformity and temperature control. Film surface agitation is provided by roller contact, while tank solution agitation is provided by recirculation pumps.

3.2.4.6 *Drying*. The adjustable range of drying temperatures is from 38 to 71 °C. Drying conditions depend on the environment. This may range from cool and dry to hot and humid. Many users tend to over-dry films, which may cause surface pattern artifacts on the film (*e.g*., water spotting, that may impact the radiologist's ability to read films). The dryer temperature should, therefore, be adjusted as low as possible, while still providing dry films exiting the processor. This will also result in energy savings for the processor operations.

3.2.5 *Maintaining the Darkroom and the Processor*

Optimal processing conditions are more imperative for mammographic quality than for any other type of medical imaging because of the need to identify imaging subtleties, such as fine calcifications inherent in diagnosing breast cancer. The processor itself, the chemicals, the temperature, and the length of the processing time are all crucial elements as discussed previously.

Mammograms often reveal problems associated with film processing. The processor requires properties such as:

- *Correct electrical current.* To avoid problems associated with overloaded circuits and power surges, the processor should have its own electrical circuit.
- *Correct water flow.* A reduced water flow can allow algae to form. In a cold-water processor with metal tanks, too much water flow may lower the temperature in the developer and fixer.
- *Darkroom air, ventilation and temperature.* To make sure that the processor functions correctly, the darkroom needs a constant flow of fresh air. Filtered air should enter the darkroom through an air conditioner. If the processor is not adequately ventilated, streaking and mottling of the film emulsion will result. Without adequate ventilation, not enough air will flow across the rollers to prevent condensation and not enough air will flow into the dryer to dry the films correctly. The air exiting the processor should be adequately ventilated to prevent the buildup of fumes from the developer and fixer fluids because some technologists are sensitive to these vapors.
- *Eliminating dust and artifacts.* Due to the processor's ability to attract dirt which can spot, veil, and obliterate a mammographic image, scrupulous cleaning is essential. Before shutdown, the crossover racks from the developer to the fixer and from the fixer to the wash tank should be cleaned. The processor should be left open until next use. This prevents the chemicals from condensing and crystallizing on the rollers as the processor cools. To be sure that the transport rollers are clean, the technologist must always process the transport roller cleanup film before processing patient films.

  Dust is one of the darkroom's greatest problems. Dust interposed between the screen and the film is more visible on single-emulsion films. Small amounts of dust do not hinder accurate assessment of glandular tissue, but the resulting noise can be distracting for the interpreter. The darkroom should not be carpeted because carpeting creates and harbors dust. Every day, the technologist should wipe the counters in the darkroom with a damp cloth and clean the feed tray of the processor with an antistatic solution. Every week, the air vents should be vacuumed and wiped and the darkroom floor should be vacuumed and mopped. Every month, the air-conditioner filter should be replaced.

- *Humidity.* Controlling the quality of the air is also a necessity. The technologist should check the darkroom's hygrometer at least once a day to be sure that the relative humidity remains at 50 to 55 percent. If the hygrometer registers above 60 percent, which indicates that the darkroom is too humid, the technologist should turn on the dehumidifier. When the hygrometer registers lower than 50 percent, the air is too dry and the technologist should turn on the humidifier not only to prevent static marks, but also to help avoid the electrostatic charging of the cassette that will attract dust.
- *Safelight illumination.* Safelight illumination is an important part of maintaining the darkroom. The adjective "safelight" is only a relative term. Given sufficient time, safelight emissions will expose any film. This exposure, which reduces contrast, is called "fog." It is necessary, therefore, to limit the time that the film is exposed to the safelight and minimize the intensity of the light.

  To prevent film fogging from the safelight:
  - The technologist should process exposed film immediately after removing it from the cassette.
  - The safelight filters should be those recommended by the film manufacturer and must be installed correctly. The identifying marks on the filter should be legible when looking at the lamp. If the filter's orientation is mistakenly reversed, heat buildup inside the lamp's housing may crack the dye layer and cause it to leak "unsafe" light.
  - The wattage of the bulb must be correct based on the film being used. A 110 to 120 volt, 60 Hz source requires no more than a 15 W frosted bulb. Higher wattage will produce excessive illumination and may damage the safelight filters. If the safelight must be placed <4 feet from the work area, the technologist should change the 15 W to a 7.5 W bulb.
  - The position of the safelight should be no closer to the film during processing than the manufacturer recommends. The safelight lamp should be no closer than 4 feet (1.22 m) from the film during processing.
  - Every six months, the technologist should test for fog and check to be sure that the safelight has remained within recommended limits, that the safelight filter has neither faded nor cracked, that it is the recommended filter for

the film, and that nobody has inadvertently replaced the bulb with one of incorrect wattage. The technologist shall verify that the safelight is still located the correct distance from the film. A darkroom fog test is an MQSA (1992) requirement.

The semi-annual test for fog should include examining the darkroom for light leaking in from outside. The technologist should check for light leaks around doors, cracks in the walls, suspended ceilings, junctions between wall partitions, or seams between walls and ceilings. The vibration of an automated processor may disturb a seal or a gasket or the cover may be loose. A darkroom requires white incandescent lights because the afterglow from fluorescent lights can produce fogging. For a darkroom to reflect all the light available from the safelight and illuminate the darkroom better, its walls should be white or light-colored with a white ceiling.

- *Film storage.* Film storage conditions may be brand specific. Unopened boxes of film require a cool, dry spot for storage. Normally the temperature should be no higher than 21 °C and the relative humidity at 50 to 55 percent. The storage area for film should be shielded from chemicals, x rays, and other sources of radiation. Film needs gentle treatment, without any pressing, creasing or buckling. To avoid pressure marks, the technologist should store the boxes of film upright. Films should not be used after the manufacturers expiration date.

3.3 Digital X-Ray Mammography

In screen-film mammography, a phosphor screen in a light-tight cassette absorbs a fraction of the incident x rays. This fraction, typically 60 to 80 percent is known as the *quantum efficiency.* The phosphor also converts the energy to light and has a certain *conversion efficiency* for this process. The light is coupled to a sheet of photographic film by direct contact of the screen and film within the cassette. The signal is recorded in the form of a latent photographic image on the film. This is developed by chemical processing to produce a pattern of optical density on the film, which is then viewed by transillumination. The film itself is both the recording and display device and, in addition, is the archival record of the examination.

In digital mammography, the image acquisition and display operations are separated. The image is acquired by a detector which converts the x-ray signal into electronic form, and then it is digitized or quantized into one of two to the nth power (2^n) intensity levels. Typically, n, the number of bits of digitization, is 12 or 14, giving 4,096 or 16,384 image signal levels. The digital image is also sampled spatially (*i.e.*, either the detector surface is composed of separate x-ray sensitive elements or else the output signal from a continuous detector is broken up into discrete elements each representing the signal from a small area at the detector's entrance).

Screen-film mammography has inherent physical limitations which reduce its effectiveness.

- The film gradient needed for high contrast must be balanced against the need for wide latitude. This is illustrated in Figure 3.21, which is a characteristic curve for a mammographic screen-film combination. The gradient of the curve falls off both at low and high exposures, resulting in a loss of contrast in those regions. If the film gradient is increased, the range of exposures between the minimum and maximum optical densities on the film decreases further.
- Detection of microcalcifications and their portrayal with clarity of the margins of breast masses are reduced due to the presence of film noise and screen blur in the displayed image.
- Film-processing artifacts occasionally degrade the mammographic image.
- The day-to-day variability in performance of automated film processors can produce suboptimal image quality.

In digital mammography, the processes of image acquisition and display are separated so that each can be optimized independently. The image is stored as a matrix of numbers, where each number represents for a specific small square or "pixel" in the image, the number of x rays reaching that point after having been transmitted by the breast (Yaffe, 1992).

3.3.1 *Digital Imaging Detectors*

Detectors for digital mammography can be designed to have a linear response to x rays over a very wide range of exposures (Figure 3.22). After the image data are recorded, it is then possible to apply a transformation to display the image on a high-resolution

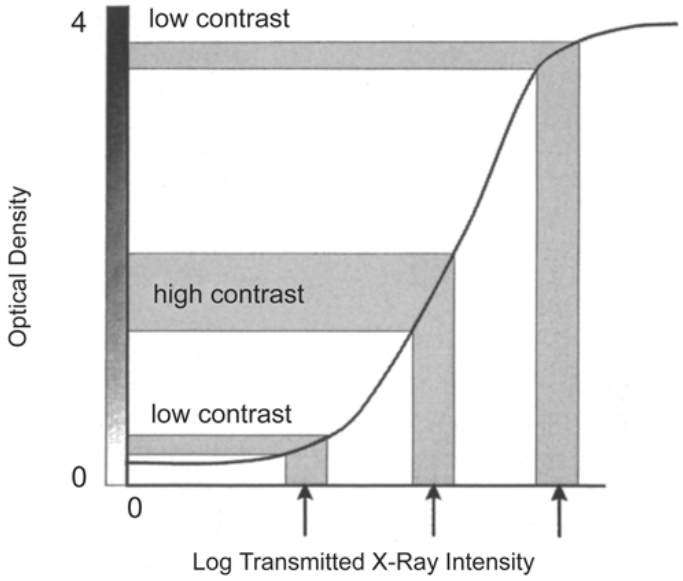


Fig. 3.21. Characteristic curve for a mammographic screen-film combination.

video monitor or print it on laser film. The transformation (inset to Figure 3.22) can be readily adjusted by the user to optimize the presentation of relevant anatomical features in the breast (Yaffe, 1992).

Digital imaging detector element (del) sizes must be adequately small if fine detail in the breast is to be depicted accurately. If it is too large, then the image will be unsharp and the borders of structures will be jagged and poorly defined. Under these circumstances, while the presence of microcalcifications might be evident, details of their shape and edge structure might be inadequate.

The limiting high-contrast resolution of the screen-film image receptor for mammography is on the order of 20 line-pairs per millimeter (lp mm^{-1}). In a digital system, to obtain such resolution, the del would have to be spaced 25 μm apart or less. For a 24 × 30 cm image field, a matrix of 9,600 × 12,000 del would be required.

In practice, screen-film mammography does not resolve 20 lp mm^{-1}, because factors such as the x-ray tube focal-spot size, noise, and inherent low contrast of the image features become limiting factors. In fact, using contrast-detail test objects (Nishikawa *et al*., 1987), it was demonstrated that for subtle soft tissue-like structures, a digital imaging system with modest (10 lp mm^{-1}) limiting resolution could display lower contrast and smaller objects

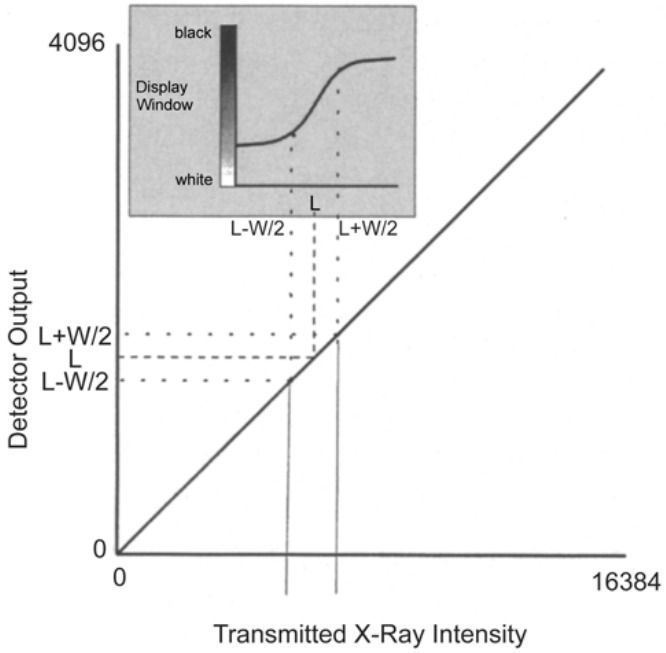


Fig. 3.22. For the digital system, the acquisition and display processes are described by separate curves. The acquisition system has linear response to x-ray intensity, whereas the display curve (insert) can be adjusted by the viewer.

than a state-of-the-art mammography screen-film system. This appears to be supported by early clinical experience with digital mammography systems operating at only 5 lp mm^{-1} limiting resolution (Freedman *et al*., 1995), although the findings are not conclusive (Lewin *et al*., 2001). Freedman *et al*. suggested, however, that although adequate detection of structures may be achieved at 100 μm, smaller del are probably required for shape determination of these structures, often an important feature in the diagnosis of microcalcifications.

In addition to the del determined by the detector, it is also important that the transmitted x-ray intensity be measured to appropriate precision. This is determined, in part, by the number of gray levels of digitization (*i.e*., the number of bits in the analog to digital converter). Use of too few gray levels will cause information to be lost and will give the image a "terraced" appearance with artificial contrast that may be disturbing to the radiologist. For dig-

ital mammography, it appears that between 12 and 13 bit precision is required to accommodate the range of x-ray intensities adequately, unless a logarithmic analog-to-digital converter is employed, in which case, fewer bits are required.

3.3.2 *Digital Mammography System Designs*

Detectors for digital mammography should have the following characteristics: (1) efficient absorption of the incident radiation, (2) linear response over a wide range of incident intensity, (3) low intrinsic noise, (4) spatial resolution on the order of 5 to 10 cycles mm^{-1} (50 to 100 μm sampling), (5) at least an 18 × 24 cm field size and preferably able to handle a 24 × 30 cm field size, and (6) acceptable imaging time and heat loading of the x-ray tube.

3.3.2.1 *Area Detectors—Full Field*. Conventional screen-film mammograms are produced with a single, brief radiation exposure of an area detector. This approach is convenient, allows good throughput, and makes efficient use of the heat loading applied to the x-ray tube. For digital mammography, the area detector must have appropriate spatial resolution, field coverage, and signal-to-noise performance. Some approaches to area detectors, their strengths and weaknesses are described below.

- *Digitization of Film Mammograms*: Conventional film mammograms can be digitized with a high-resolution optical scanner. This allows the image to be acquired quickly, although film processing and digitization require several minutes. The digitized image can then be manipulated to improve display contrast characteristics.

  The quality of the digital image will be limited both by the performance of the digitizer and by the quality of the information initially stored on the film. If conventional mammographic film has been used, then the main limitation in image quality will be associated with the granularity of the film emulsion. This will affect the image most at high spatial frequencies, where the modulation of image information is low compared to the noise. Attempting to achieve a large degree of contrast enhancement, in either the “toe” or “shoulder” regions of the film’s response curve, may cause noise to be amplified to an unacceptable degree. Commercial digitizers typically have reduced performance at high optical densities where their system noise becomes a limiting factor in measuring the low levels of transmitted light.

Because it would require a film to be produced, processed and then digitized with the final processed digital image possibly presented on a second film; it is unlikely that this approach would be acceptable for clinical practice.

- *Demagnification Cameras*: Demagnification cameras for digital mammography are produced by coupling an x-ray absorbing phosphor to a smaller-area photodetector such as, a charge coupled device (CCD) array *via* demagnifying lenses or fiber-optic tapers. The photodetector output can then be digitized to produce a high-resolution digital image.

  Such systems are employed for producing small-area (5 × 5 cm) digital images (Karellas *et al*., 1990) for guiding sterotactic breast biopsy and, typically, provide one million individual images (1,000 × 1,000) with 50 μm del. It is not practical to extend this approach to full breast imaging by employing a larger phosphor surface and increasing the amount of optical demagnification to a factor of about eight. This is very inefficient and causes image noise to be increased to unacceptable levels. On the other hand, a mosaic of multiple small-format detectors, using optics with more modest demagnification factors and acceptable efficiency can be combined to obtain a camera which can cover the full breast. We will refer to this as a Type 1 detector (Figure 3.23). It is important that the subimages from these detectors be combined (stitched) seamlessly to form the complete image so that disturbing artifacts are not introduced at the borders. One manufacturer (Lorad Corporation, Danbury, Connecticut) has received regulatory approval from FDA to market a system based on an array of 3 × 4 CCDs coupled by 12 fiber-optic tapers to a full-area phosphor screen.
- *Photostimulable Phosphors*: Photostimulable phosphors have been successfully developed as an imaging system for general radiography (Kato, 1994), and it is possible to extract the information from such devices in digital form. Energy from absorbed x rays causes electrons in the phosphor to be excited. Rather than decaying immediately to give off light, the electrons are captured and stored in traps in the phosphor crystals. The number of traps filled is proportional to the exposure received by the phosphor. The image is created by scanning the phosphor plate with a finely-focused laser beam. This stimulation releases electrons from the traps, giving rise to emission of light of a shorter wave length (blue), which is collected point-by-point

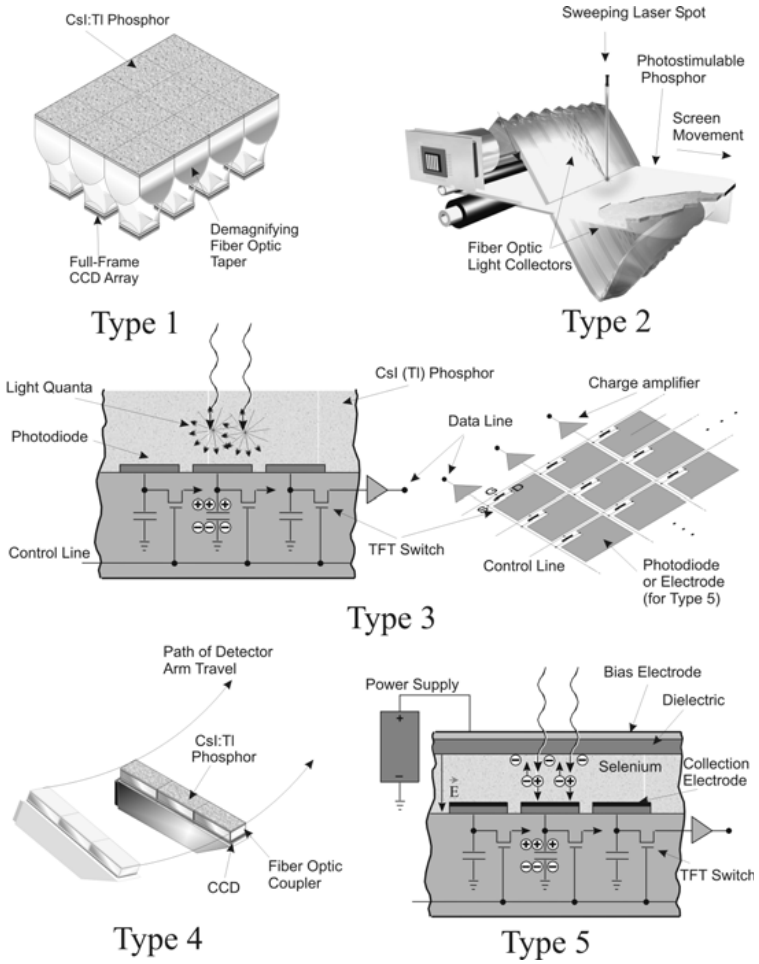


Fig. 3.23. Types of digital mammography systems. Type 1: Scanning system with slot x-ray beam that moves across the breast in synchrony with a long, narrow CsI/fiber optic/CCD detector (Fischer Imaging, Denver, Colorado). Type 2: Photostimulable phosphor plate with laser readout. Type 3: CsI phosphor on large area amorphous silicon plate with active matrix, switched transistor readout. Type 4: Mosaic of modules, each consisting of CsI phosphor coupled to CCD through demagnifying fiber optics (Trex Medical, Danbury, Connecticut). Type 5: Amorphous selenium direct x-ray converter on large area amorphous silicon plate with active matrix, switched transistor readout (Lorad Corporation, Danbury, Connecticut); Instrumentation Imaging, Inc., Milwaukee, Wisconsin; Siemens Medical Solutions, Malvern, Pennsylvania).

as the laser scans over the plate, as illustrated by the Type 2 system in Figure 3.23. A system with 50 μm del has been introduced. The actual spatial resolution of this technology may be determined by the scattering of laser light within the volume of the phosphor, stimulating a larger region of the material than the initial width of the laser beam. A second important factor is that the collection of stimulated light is inefficient, resulting in a loss of signal-to-noise ratio because of a secondary quantum sink in the system (Nishikawa and Yaffe, 1990). This limitation may be offset in part by reading the emitted light from both sides of the phosphor plate. Some researchers have reported positive impressions of the clinical performance of this technology (Freedman *et al*., 1995) although others have found that the performance is inferior to screen-film technology (Kheddache *et al*., 1999).

- *Amorphous Silicon*: Amorphous silicon provides another means for producing area detectors suitable for digital mammography. An array of light sensitive diodes is deposited on a plate of amorphous silicon such that each element provides the signal for one pixel of the image (Type 3 in Figure 3.23). The diodes are covered by a suitable x-ray absorbing phosphor such as thallium-activated cesium iodide. The electric charge stored on the capacitance of each diode after x-ray exposure can be read out through a network of switches (Antonuk *et al*., 1992). Challenges with this technology involve the large number of del in the receptor and the complexity of connecting read-out wires to all of the rows and columns of the matrix, while maintaining minimal loss of coverage at the chest-wall side of the imaging system. A system of this design developed by General Electric Medical Systems (Wankesha, Wisconsin) has received FDA approval for clinical use. In this system, the detector is composed of del that are approximately 100 μm on a side. The detector array resides in a bucky assembly which contains a moving grid.

3.3.2.2 *Scanned-Beam Detectors*. Another way to produce a high-quality mammogram is to use a small-area long, narrow (slot) detector, which is scanned in synchrony with the radiation beam, across the entire breast to build up a full image (Type 4 in Figure 3.23). In this way, images with high spatial resolution, dynamic range, and signal-to-noise ratio (*SNR*) can be produced.

Because the image is acquired sequentially in a scanning system, the acquisition time is longer than for an area detector. A major offsetting advantage of scanned beam systems, however, is that because only part of the volume of the breast is irradiated at any one time; it is much easier and more efficient than in an area system to control the detrimental effects of scattered radiation at the image receptor. Less scattered radiation is created during the time when the detector is measuring x rays from a particular part of the breast. In fact, the scattered radiation contribution to the detected signal is sufficiently low that a grid is not used.

A slot-beam system for digital mammography was proposed by Nelson *et al*. (1987). A prototype slot-beam system was developed (Maidment and Yaffe, 1990; Nishikawa *et al*., 1987; Tesic *et al*, 1999; Yaffe, 1993; Yaffe *et al*., 1996) and designed to operate with an acquisition time that is acceptable for clinical imaging. A clinical system of this type introduced by Fischer Imaging, Inc. (Denver, Colorado) has received FDA approval. After transmission through the breast, x rays are absorbed by a cesium-iodide phosphor, and the emitted light is conveyed *via* fiber-optic couplers to several CCD arrays whose electrical signals are then digitized. This design can provide 50 μm sampling (25 μm for a partial image) referred to the midplane of the breast. The restricted angular acceptance of the optical fibers causes each fiber to collimate the light incident from the screen, thereby increasing the effective resolution. In addition, the high-optical coupling efficiency attainable with fiber optics minimizes signal losses, thereby facilitating an x-ray quantum limited system.

The image is acquired by scanning the fan x-ray beam and the slot detector across the breast in a direction parallel to the short dimension of the detector. To allow a smooth mechanical motion, the images can be acquired using a time-delay integration technique (Holdsworth *et al*., 1989). As the detector is moved across the breast at constant speed, the charge collected in each element of the CCD is shifted down its column at the same speed as the scan, but in the opposite direction, resulting in integration of the signal corresponding to a given image pixel. When the charge packet reaches the last element in the CCD, the charge signals in the columns are read out. Depending on the slot width, a scanning system can acquire a mammogram in 3 to 6 s.

- *Direct Conversion X-Ray Detectors*: In phosphor-based detectors, there are at least two energy conversion stages; x ray to light and light to electronic charge. Because of inefficiencies in energy conversion and/or signal collection, these

systems can be limited in sensitivity and suffer from increased noise (Rougeot, 1993). Several detector technologies in which x-ray energy is directly and efficiently converted to charge are under investigation. Some promising detector materials include cadmium telluride, lead iodide, mercury iodide, and amorphous selenium. In all of these, the direct conversion process provides a much greater electronic charge signal than is available when phosphors are employed.

- *Amorphous Selenium*: Several investigators (Lee *et al*., 1995; Polischuck *et al*., 1999; Rowlands *et al*., 1991; Zhao *et al*., 1995) have investigated amorphous selenium (the same material used as the sensor in xeromammography) as a sensor for digital mammography. Selenium has some important advantages over phosphor-based detectors for imaging. Because it is a photoconductor, it produces an electrostatic image that can provide very high spatial resolution.

  Selenium has very high electrical resistivity in the dark, so that if a plate of selenium is uniformly charged, the charge will remain in place on the surface. When exposed to x rays, the plate will discharge; the degree of discharge being proportional to the amount of radiation striking the plate. For digital mammography, the selenium can be deposited on an array of electrodes where each element contains a collector electrode and thin film transistor or diode switch for readout, in a manner similar to that of the amorphous silicon system described above. A system of this design produced by Lorad Corporation has received FDA marketing approval and is shown schematically as Type 5 in Figure 3.23. Two companies, Instrumentarium Imaging and Siemens Medical Solutions are producing units with amorphous selenium. Note that in both Type 3 and Type 5 detectors, the photoiodide or collection electrode are co-planar with the transistor switches, although for clarity they are drawn at separate levels in the cross-sectional schematic.

3.3.3 *Digital Imaging Display Monitors*

The electronic (soft-copy) display of images on digital mammography systems is limited by the spatial resolution of currently affordable displays (Feig and Yaffe, 2005; Yaffe, 1999). A basic requirement for general use is the ability to portray the entire

breast with sufficiently fine detail so that tiny structures (*e.g.*, microcalcifications) indicative of malignancy are readily visible. Furthermore, since routine mammographic interpretation involves viewing four images of a current examination compared with four images from a prior examination, digital work stations must permit simultaneous display of these eight images, using either eight networked monitors or, a lesser number of monitors providing sufficiently fine detail that two or more whole-breast mammograms are displayed per monitor (Huang and Lou, 1999; Lou *et al.*, 1994). Because soft-copy display technology is currently not able to meet these requirements for systems that provide pixels smaller than 100 μm, the development of innovative methods for rapid image navigation and manipulation is a high priority.

3.3.4 *Exposure Techniques*

The technique (operating potential, filtration, etc.) for screen-film mammography has been established, largely by trial and error, over several decades of the practice of mammography. For digital systems where contrast can be freely manipulated, the optimal spectra may be different than for film. In a digital imaging system, the operating potential and the amount of radiation used to form an image should be defined strictly by signal-to-noise considerations rather than, by contrast or film "blackening." Increased operating potential, compared to screen-film technique, improves efficiency and output of the x-ray tube resulting in images with a higher *SNR*, while allowing reduced patient dose and scan time. It is important to ensure that digital mammography techniques are appropriately optimized for those imaging tasks being considered so as to take advantage of the possible performance gains that digital mammography may provide.

3.3.5 *Digital Mammography Applications*

The evaluation of digital mammography is still underway. Its performance can be properly evaluated only in careful studies that compare its sensitivity and specificity to that of high-quality screen-film mammography. During those studies, the quality of both the conventional and digital imaging must be carefully monitored and controlled (Lewin *et al.*, 2001; 2002). A large clinical study, Digital Mammography Imaging Screening Trial, is currently being carried out in the United States and Canada. In the trial, 49,500 women at 34 sites will receive both screen-film and

digital mammograms and the accuracy of the two methods will be compared (Pisano *et al*., 2000). Screening trials comparing conventional and digital mammography are further discussed in Section 8.

The principal theoretical advantage of digital mammography comes from decoupling image display from image acquisition. This permits the digital image to be acquired, stored electronically, and then manipulated, analyzed and displayed as needed. It is anticipated that digital mammography will provide improved visualization of the structures within the dense breast, thereby increasing the value of mammography in those women. Even if the sensitivity and specificity are only equal to, but not better than screen-film mammography, digital mammography is still likely to play an important role in the detection, diagnosis and management of breast cancer. This statement is based on the potential value of applications that will be greatly facilitated through the availability of mammograms in digital form. These include increased throughput, computer-aided detection/diagnosis (CAD), telemammography, automated QC, image processing, more efficient archiving and retrieval, and the availability of dual energy, stereoscopic and tomographic methods.

3.3.5.1 *Real-Time Image Display.* Real-time image display provides several advantages over conventional screen-film mammography. The waiting time involved in film processing is eliminated, thereby increasing patient throughput and thereby possibly reducing the cost per examination. Day-to-day variability in the performance of automated film processors, which now requires careful monitoring, also will be less of a problem either because the image is interpreted from the soft-copy display (or printed on a laser printer which can automatically monitor its own performance and adjust for any variations). Some diagnostic mammographic workups can be performed in a much faster and more interactive fashion. This is most helpful in quickly and reliably distinguishing summation shadows from true masses and in documenting the dermal location of benign skin calcifications. Finally, it is already apparent that lesion localization procedures are to be facilitated by the ability to visualize localizing needles as they are actually maneuvered within, or immediately adjacent to, suspected lesions.

3.3.5.2 *Post-Acquisition Image Enhancement*. Signal processing techniques can be applied to the digitally acquired mammogram to improve overall image quality or to increase the conspicuity of specific mammographic findings (Smathers *et al*., 1986). Window and

level controls can be manipulated to display the image of the entire breast with optimal intensity and contrast, thereby providing an essentially unlimited gray scale to facilitate visualization of findings that might be obscured by the toe or shoulder of a characteristic film curve. Enlargement and unsharp masking techniques can make such tiny structures as microcalcifications more readily visible (Higashida *et al*., 1992). Noise suppression techniques can render low-contrast objects more readily perceptible. Intensity equalization procedures can be applied to clearly portray in a single-image structures that usually are difficult to see on conventional screen-film mammograms, such as the skin and subcutaneous tissues. Digital systems also have the capability to correct some instances of under- and overexposure, displaying fully interpretable mammograms despite what otherwise would have been considered unacceptable image quality (Bick *et al*., 1996; Byng *et al*., 1997).

3.3.5.3 *Image Archiving and Retrieval*. A major advantage of digital over conventional film imaging is its improved ability to store and retrieve images. This electronic archival process may produce substantial cost savings, especially for high-volume operations, despite an initial large expenditure for digital equipment. Not only are the costs of film and film processing eliminated, but so is the cost of film storage. Since archival and retrieval activities involve electronic rather than hard-copy transfers, costs for file room personnel may also be reduced. Furthermore, digital data storage is much more rapid and reliable than procedures using film images. This is particularly noticeable when prior studies are needed for comparison. Retrieval time is measured in seconds, rather than minutes, hours or days. Finally, most of the problems associated with examinations being misfiled, lost, damaged in storage, or signed out to another location will be averted.

3.3.5.4 *Teleradiology Applications*. Electronic transfer of digital images to remote viewing sites can be accomplished almost as rapidly as between the display workstation and computer storage (Fajardo *et al*., 1990). Numerous activities utilizing teleradiology have been devised, many of which are applicable to mammography practice (Batnitsky *et al*., 1990; Feig and Yaffe, 2005; Lou *et al*., 1997; Shen *et al*., 2001; Sickles, 1992a). Radiologists who work in several different offices or hospitals will be able to monitor and interpret examinations that are carried out in nearby, or distant locations. Mammography screening in mobile units will be made

more efficient, not only by eliminating the need to transport films from the site of examination to the site of interpretation, but also by permitting interpretation while patients are still available for repeat or additional examination. In addition, teleradiology will be used to facilitate second opinion interpretation by providing rapid transfer of images to the second reader's display monitors. This can, in effect, make world-class mammography expertise immediately accessible to community practice radiologists. Finally, digital image transmission can be the cornerstone upon which multi-site teaching conferences are built from applications as simple as the simultaneous conduct of case review sessions among the nearby hospitals that participate in a residency training program, or as complex as intercontinental multilocation conferences supported by satellite or high-speed internet transmission of digital mammograms.

3.3.5.5 *Dual-Energy Subtraction Imaging*. Dual-energy subtraction mammography is based on the principle that if exposures are taken with both high and low operating potentials, using the same radiographic projection, some breast structures will exhibit greater absorption of low-energy compared with high-energy photons. Thus, assuming that there is no patient motion between exposures, one digital image can be electronically subtracted from the other causing most structures (those that do not exhibit differential absorption) to cancel out completely. In this fashion, dual-energy subtraction imaging has the potential to increase the conspicuity of certain subtle findings, not only by portraying some low-contrast objects with increased clarity, but especially by removing the superimposed "clutter" of background breast structures (Asaga *et al*., 1995; Boone, 1991; Johns *et al*., 1985). This can be particularly useful in demonstrating the tiny calcifications that can be the first indicator of a breast cancer, because the relatively high atomic number of calcium results in increased absorption of low-energy photons.

3.3.5.6 *Computer-Aided Image Analysis*. There already has been considerable interest in developing computer-executed algorithms to detect abnormal findings on digitized mammograms. Most such attempts have been directed at the identification of clustered microcalcifications, although several computer programs have been written to detect breast masses as well (Chan *et al*., 1987a; 1988; 1990; Davies and Dance, 1990; Fam *et al*., 1988; Feig and Yaffe, 2005; Karssemeijer, 1993; Kegelmeyer *et al*., 1994; Kupinski

and Giger, 1997; Nishikawa *et al*., 1995; Olson *et al*., 1988; Yin *et al*., 1991; 1993). Current applications are designed to indicate suspect findings by superimposing circles, boxes or arrows in appropriate locations on digitized mammograms. The most successful of these programs, presently, is capable of identifying 85 percent of targeted mammographic lesions, but also falsely indicates an average of 0.2 to 1 suspect area in each image (Bankman *et al*., 1993; Feig and Yaffe, 2005; Nishikawa *et al*., 1995). At current levels of performance, the lesions missed by computer-based applications tend to be those that are most subtle in mammographic presentation, the same lesions that are likely to be missed by radiologists.

These CAD applications can be used by radiologists as second interpretation devices to avoid overlooking identifiable mammographic abnormalities (Chan *et al*., 1990; Giger, 1999). This approach will be much less expensive than a second reading done by another radiologist, but only if the false-positive detection rate of computer-identified findings decreases substantially from current levels. Ultimately, highly sensitive lesion detection applications might be used for the first-pass interpretation of digital mammography screening examinations, forwarding only those cases with suspect findings on to a radiologist for definitive interpretation and, if necessary, for further imaging evaluation.

Numerous clinical studies have shown that the detection sensitivity of CAD is higher for calcifications (83 to 100 percent) than for masses (34 to 95 percent) (Feig and Yaffe, 2005). Masses that do not contain calcifications or spiculation that is not prominent are less likely to be identified by CAD. Cancers in which the mass appears subtle to radiologists or also looks like an architectural distortion or asymmetrical density rather than a mass are also less likely to be flagged by CAD (Vyborny, 2000). Several studies have found that CAD may increase radiologist's cancer detection rates by as much as 20 percent (Destounis *et al*., 2004; Freer and Ulissey, 2001). However, because of the significance of false-negative findings (missed breast cancers) and because it is unlikely that software vendors will assume any medicolegal responsibility for their CAD programs, it is equally unlikely that this software will be used for first-pass interpretation.

Computer-aided interpretation programs also are being developed to further characterize already detected lesions to aid the radiologist in determining whether subsequent management should involve biopsy or less invasive procedures (Ackerman and Gose, 1972). Again, efforts have been directed principally at the

analysis of clustered microcalcifications (Chan *et al*., 1998; Fox *et al*., 1980; Goumot *et al*., 1989; Jiang *et al*., 1999; Magnin *et al*., 1989; Wee *et al*., 1975). Applications operate by quantifying the digital data within suspect lesions that already have been flagged, either by radiologists or by CAD programs. Formulas, then, are used to analyze a wide variety of lesion characteristics for calcifications. These can include not only the standard parameters assessed by radiologists (particle size, number, distribution, density and shape), but also several more complex measures of calcification irregularity (*e.g*., compactness, eccentricity, coefficient of convexity, elongation) (Goumot *et al*., 1989; Magnin *et al*., 1989). Finally, numeric scores calculated for these parameters are weighted by predetermined algorithms and combined to produce a likelihood of malignancy index, upon which management decisions can be based. Currently, the most successful of the calcification characterization programs perform at diagnostic accuracies that approximate, and occasionally even exceed those of expert mammographers (Feig and Yaffe, 2005; Giger, 1999; Giger *et al*., 2000). For breast masses and other types of suspect lesions, today's CAD programs are less fully developed and also somewhat less successful (Huo *et al*., 1998; Kegelmeyer *et al*., 1994; Patrick *et al*., 1991; Yin *et al*., 1993).

Computer analysis of digitized mammograms can also be used to extract other valuable information such as the future risk of developing breast cancer. Boyd *et al*. (1998), have demonstrated a strong correlation between breast density and breast cancer risk by simple thresholding of digitized mammograms.

3.3.5.7 *Computer-Aided Instruction*. Rapid and inexpensive computer-based storage of digital mammography examinations facilitates the creation and utilization of computer-aided instruction packages, since preselected sets of images can be readily catalogued and retrieved for display. The simplest application is the digital counterpart to the conventional film mammography learning file. This consists of an organized library of interesting case material (digitized mammograms), supplemented by hard-copy text descriptions of mammographic findings, suggested interpretations, pathologic correlations, additional discussions, and literature reference material for each case or group of cases. Many mammography cases can be stored on a single CD-ROM. In more sophisticated systems, the text material itself is stored electronically so that cases can be viewed either in random sequence (as unknown cases) or, in sequences ordered either by diagnosis or by specific mammographic finding.

Instructional programs also are being developed to provide the user with response-driven self-instruction courses in which incorrect answers trigger the display of remedial material and additional questions before subsequent cases can be viewed (Cao *et al.*, 1997). These systems can track the progress of individual users, compiling grades and documenting that proficiency has been achieved.

The ultimate instructional package will interface directly with the day-to-day interpretation of digital mammograms. Such a program would be activated either by request of the radiologist or, whenever computer-recorded interpretations indicate specific mammographic findings. In either circumstance, description of particular mammographic findings would call up related image and text materials from expert learning databases to aid in the analysis of the case under consideration (Swett and Miller, 1987; Swett *et al.*, 1989). Thus, the radiologist could simultaneously view pathology-proven cases in which mammograms display similar, if not identical radiographic findings. Embedded text also could suggest predetermined strategies for further evaluation and interpretation of the mammographic findings.

3.3.6 *Future Developments in Digital Mammography*

The principal deficiencies of current digital mammography equipment involve limitation in the capabilities of existing soft-copy display systems to rapidly display images of the present and/or previous examinations with the full acquired spatial resolution. There are also practical challenges in displaying the information in a manner that allows interpretation to be as rapid and efficient as is now possible with current view-box presentation. Cost of the display systems is also a concern. Digital mammograms can also be read from laser-printed films which provide adequate dynamic format and spatial resolution, but do not have adequate dynamic range to depict all of the information in the digital image in a single presentation unless appropriate image processing is performed prior to printing. Teleradiology applications will benefit from improved software techniques to compress and store digital data, as well as from development of more efficient protocols to accelerate image transmission. Computer-aided diagnosis applications also will continue to increase in accuracy as existing algorithms are refined and new ones are developed, driven at least in part by the use of neural networks and other forms of machine intelligence (Wu *et al.*, 1993).

3.4 Stereotactic Breast Biopsy

While mammography provides high sensitivity to the detection of breast cancer, the only definitive test for breast cancer is biopsy. Breast cancers missed by mammography can be minimized only if a diagnostic threshold is used that incurs a reasonable number of false positives. As a result, two-thirds to four-fifths of surgical breast biopsies yield negative results. Over the last decade, stereotactically-guided and ultrasound-guided core needle biopsies have become the standard of care for tissue sampling of suspicious breast lesions. This has been due to pioneering work that has demonstrated that large-core sampling can replace open excisional breast biopsy in most patients. Development and clinical implementation of prone stereotactic biopsy systems with digital image receptors have made the procedure faster, more reliable, more comfortable, and less traumatic for the patient.

Stereotactic breast biopsy uses the principle of parallax: two planar radiographic views acquired at different x-ray source positions are used to determine the location of radiographically visible objects in three dimensions. Dedicated prone biopsy systems place the patient in the prone position with the breast dependent through a hole in the table. The x-ray tube, compression device, image receptor, and biopsy device are mounted under the table, which can be raised to make more working space for the physician conducting the procedure. With the breast compressed, stereotactic views are acquired and targeted lesions are marked in both views to direct needle placement. A precise mounting system (called the punction device or staging unit) is used to hold the core biopsy device and direct sampling to the desired location within the breast.

The development that brought renewed interest to stereotactic localization was the acquisition of core biopsies using prone positioning directed by stereo x-ray images using larger (14 gauge) cutting needles. The cutting needle biopsy consists of a double cannula needle system operated by a biopsy gun. The gun-needle system first deploys the inner needle containing a sampling notch. As the needle is rapidly pushed forward, the beveled tip deflects the needle, opening the sampling notch to tissue. An outer cylindrical cannula then deploys, slicing off a small segment of tissue that is retained in the sampling notch. The deployment (firing) of the two-component needle system is an integral part of tissue sampling in the cutting needle approach. A mounted biopsy device is used to hold and deploy the 14-gauge cutting needle. After each sample

is acquired, the cutting needle must be removed from the breast, the biopsy device removed from the holder, and the needle removed from the biopsy gun to remove the tissue sample. Since multiple tissue samples are required, this process must be repeated. At least five samples are recommended for soft-tissue lesions, and at least ten samples for targeted calcifications.

Core needle biopsies acquired with this system require only a small amount of local anesthetic and a small incision at the point of needle entry into the skin. Core needle biopsies take about one-half hour to perform, are one-fourth to one-half the cost of surgical excisional biopsies, involve minimal risk, and produce no residual scarring of breast tissue. Placing the patient in the prone position rather than upright during biopsy, as with stereotactic devices added on to standard mammography units, minimizes patient motion during localization, eliminates vasovagal reactions (fainting), and provides more working space for the radiologist during the biopsy procedure.

Stereotactic breast biopsy has been improved even further by the development of the vacuum-assisted core biopsy system. The first vacuum-assisted core biopsy system, the Mammotome system, was developed by Burbank and Parker (Burbank, 1997; Burbank *et al*., 1996). The Mammotome system uses a double cannula needle: the outer needle is hollow, with a sampling notch near the end and a vacuum system that pulls tissue into the sampling notch, when open. The inner needle is a hollow cylindrical cannula that can be pulled back to expose the sampling notch, then rotated and advanced to cut off a cylinder of tissue drawn into the sampling notch by the vacuum. A second vacuum line is used to retain the cylinder of tissue at the end of the inner cannula as it is pulled through the outer needle. After the sample is captured, but before it is removed, the sampling notch can be rotated to a slightly different angle to prepare for removal of additional tissue samples. This design permits removal of the tissue sample without having to remove the outer needle from the breast.

The Mammotome system accommodates either 14-gauge or larger 11-gauge needles. The 14-gauge Mammotome system acquires tissue samples that are two to five times larger than 14-gauge cutting needles; the 11-gauge Mammotome system acquires tissue samples that are 5 to 14 times larger than 14-gauge cutting needles. Another advantage of the vacuum system is the removal of blood and fluid, so that samples consistently contain solid tissues. Because of the marked improvement over the cutting needle approach, >90 percent of core biopsies are now performed using the suction biopsy system.

Other vacuum-assisted biopsy systems have recently been introduced. Like the Mammotome system, tissues can be retrieved without having to remove the entire needle device from the breast. Also like the Mammotome system, larger tissue samples are routinely retrieved than with a 14-gauge cutting needle and tissue samples are less likely to consist entirely of blood or fluid.

Prone stereotactic systems now employ digital image receptors based on CCD arrays. A CCD array is a small panel of light-sensitive diodes. CCD arrays are used as the video pickup in modern video cameras. The arrays used are typically 1 × 1 inch arrays with 1,024 × 1,024 matrix elements. X rays are intercepted by a fluorescent screen that converts each absorbed x ray to thousands of visible light photons. A small fraction of the emitted visible light photons is absorbed by the CCD array. Different systems use different methods of directing the emitted visible light photons toward the CCD array. The Fischer system uses a fiber-optic taper with 2:1 demagnification to direct photons emitted from the exit surface of a gadolinium-oxysulfide screen or more recently a cesium-iodide crystal screen to the CCD array. The Lorad system uses a set of mirrors and lenses with approximately 2:1 demagnification to direct photons emitted from the entrance surface of a gadolinium-oxysulfide screen to the CCD array.

The specific steps in stereotactically-guided needle biopsy of breast lesions are listed below:

1. The breast is compressed with the lesion positioned within the window of the compression paddle.
2. A zero degree scout image is acquired to confirm that the lesion is accessible through the window of the compression paddle. Typically, the window on the compression paddle matches the 5 × 5 cm field-of-view of the digital image receptor, so if the lesion of interest is visible and not on the edge of the image, it will be accessible for tissue sampling.
3. A stereo scout image is acquired with the x-ray source positioned 15 degrees to the left (+15 degrees on the Fischer system, –15 degrees on the Lorad system).
4. A second stereo scout image is acquired with the x-ray source positioned 15 degrees to the right (–15 degrees on the Fischer system, +15 degrees on the Lorad system.)
5. The physician uses a cursor to mark the targeted location of the lesion on both the +15 degrees and –15 degrees views. Additional target locations can be marked in one of the two views to specify additional locations to be sampled.

6. The computer calculates the horizontal, vertical and depth coordinates of the targeted lesion based on the targets marked in both views. Additional horizontal, vertical and depth coordinates are calculated for each additional location marked.
7. A sterilized needle is placed in the biopsy device, the device is cocked, and then it is mounted in the device holder on the punction arm. A sterilized needle guide is also placed on the punction arm.
8. The specified horizontal and vertical coordinates are automatically transferred to the needle guidance system and the biopsy device is translated to the correct horizontal and vertical locations. The biopsy device is then advanced so that the tip of the biopsy needle is near the entry point of the breast.
9. A small amount of local anesthetic is injected subcutaneously at the location of the needle entry and a small incision is made to allow the needle to be inserted to specified depth without excessive resistance.
10. The needle is inserted to the specified depth to place the tip of the biopsy needle at the center of the lesion (for 14-gauge cutting needles) or to place the center of the sampling notch at the specified location (for vacuum-assisted biopsy systems).
11. Presampling +15 degrees and –15 degrees views are acquired to verify that the biopsy needle is correctly located.
12. If the position of the needle is correct, the 14-gauge cutting needle is withdrawn slightly (usually about 5 mm) and the biopsy gun is fired, or samples are acquired with the vacuum-assisted biopsy system.
13. Post-fire (for 14-gauge cutting needles) or post-sampling (for vacuum-assisted biopsy systems) +15 degrees and –15 degrees views are acquired to verify that appropriate sampling of the lesion occurred.
14. Additional samples are acquired at slightly different locations, either by repositioning to the newly specified horizontal, vertical and depth coordinates (for the cutting needle approach) or by rotating the direction of the sampling notch (for vacuum-assisted biopsy systems).
15. If calcifications were targeted, specimen radiographs are obtained to verify the presence of calcifications in specimens.

For small lesions, there is a risk that core biopsy will remove all radiographically- or ultrasonically-visible signs of the lesion. To guide surgical removal of the remaining lesion and margins in cases where the removed tissue is analyzed to be malignant by pathology, radiographically or ultrasonically visible markers can be inserted through a larger vacuum-assisted biopsy needle at the time of tissue removal. A number of manufacturers have developed small metallic marking clips for radiographic marking, or gel-markers for ultrasound marking, of biopsy sites.

4. Image Quality

4.1 Introduction

It is widely recognized that high-quality images are imperative for the reliable detection and accurate characterization of subtle lesions in the breast with mammography. The quality of the images depends critically on the design and performance of the x-ray unit and image receptor, and on how that equipment is used to acquire the mammogram. In addition, the type of display and the conditions under which the image is viewed have an important effect on the ability of the radiologist to extract the information recorded in the mammogram.

4.1.1 *Mammographic Image Quality*

In general, the phrase "mammographic image quality" can be considered to indicate the clarity with which radiologically-significant details can be perceived in an image. In turn, high mammographic image quality should contribute to high performance in detecting and diagnosing breast cancer. There is, however, no well-defined standard for specifying mammographic image quality. The relationship between physical properties of the radiographic image (such as contrast, resolution and noise) and the ability of the observer to properly detect and interpret relevant image features is not well understood (Haus and Yaffe, 2000; NCRP, 1986). Currently, probably the most effective tool for inferring this is receiver operating curve (ROC) methodology (Metz, 1979), applied retrospectively to clinical images where the true disease state is known. ROC testing can be used to assess the overall performance of a radiologist in combination with a particular imaging system at detecting or diagnosing breast cancer in terms of sensitivity at varying levels of specificity. This creates a measure that is based on perception of information in the mammogram and is essentially independent of the level of conservatism of the radiologist in calling abnormal findings. Unfortunately, ROC studies are complex, time-consuming experiments, requiring large image databases with known truth data regarding disease. They require many image readings by many observers, and are, therefore, often not practical for routine measurement of image quality.

Logically, mammographic image quality should be related to certain image attributes that can be described technically, such as spatial resolution, contrast, image noise and *SNR* and the absence of artifacts (Haus and Yaffe, 2000; Vyborny and Schmidt, 1994). It is accepted that these are important parameters that will affect the ability to detect or characterize microcalcifications, to visualize fine fibrillar structures radiating from a mass, or to identify the presence of architectural distortion. It is still not known, however, how to define what constitutes "optimal" or "necessary" quality for diagnostic accuracy in terms of technical parameters. At present, about the best that can be done is to attempt to correlate differences in ROC performance with differences in the technical aspects of image acquisition and display. This issue is the subject of continuing research (Bencomo *et al*., 1982; Bunch, 1999; Chan *et al*., 1987b). Nevertheless, there is a strong correlation between radiologist's rejection of mammograms as having inadequate quality and low measured values of resolution, contrast and *SNR*, or the excessive prevalence of artifacts.

In many cases, the optimum values of these parameters are not all simultaneously achievable, at least not at reasonable radiation dose and, therefore, trade-offs must generally be considered. The most acceptable compromise between technical parameters in forming the image to achieve high mammographic quality is likely to be task dependent. For example, the image characteristics required to allow detection of a large lesion in a fatty breast can be very different from those needed to visualize microcalcifications in a rather dense breast.

4.1.2 *Screen-Film and Digital Mammography*

By the early 1980s, screen-film mammography had largely replaced direct-film mammography and xeroradiography as the main technique for producing mammograms. Digital mammography systems have now emerged. There are key differences in the technologies of screen-film and digital mammography. These are discussed in Sections 3.2 and 3.3. These affect both the image quality and the approach to optimization of technique, and therefore, specific reference will be made to digital mammography in this Section where these differences exist.

In the following, the discussion is restricted to those factors that can be quantified objectively. The term, "technical image quality" is used to include those factors that are measurable in the imaging process rather than variables entering into interpretation of the image.

4.2 Factors Affecting Image Quality and Radiation Dose

In this Section, the descriptors of technical image quality and their dependence on the many variables of image acquisition and display in screen-film and digital mammography are discussed. The major parameters describing image quality are: radiographic contrast, spatial resolution (blur), noise (mottle), and the presence of artifacts. These must be considered in relation to the dose to the breast required to produce the mammogram. The technical factors that influence these parameters are listed in Table 4.1 (Haus and Jaskulski, 1997; NCRP, 1986). Image quality, as used here, refers to the aggregate affect of these elements on the appearance of the mammographic image. Inevitably, there are trade-offs among the many components involved (NCRP, 1986). Many of the factors in image acquisition and display can be controlled and optimized so that mammograms having good image quality can be obtained at appropriate radiation dose to the patient.

Using the outline in Table 4.1, the factors affecting technical image quality are reviewed for screen-film and digital mammography image receptors with emphasis on those that can be controlled by the user.

4.2.1 *Contrast*

Radiographic contrast refers to the magnitude of the signal difference between the structure of interest and its surroundings in the displayed image. Radiographic contrast is influenced by two factors: subject contrast and receptor contrast. Contrast is typically considered for larger areas (1 cm^2 or greater) in the image where spatial resolution of the detector is not a limiting factor. Subject contrast is measured in terms of the relative difference in x-ray exposure to the image receptor, transmitted through one part of the breast and through an adjacent part, while overall radiographic contrast is quantified as the optical density difference between two areas on the processed film, or as the relative brightness difference between the corresponding areas in an image displayed on a monitor.

4.2.1.1 *Subject Contrast*. Subject contrast is especially important in mammography because of the subtle differences in the soft-tissue density of normal and pathologic structures of the breast, and because of the importance of detecting minute details such as

TABLE 4.1—*Factors affecting image quality in mammography.*

Factors Affecting Screen-Film Mammography	Factors Affecting Both Screen-Film and Digital Mammography	Factors Affecting Digital Mammography
	Radiographic Contrast	
	Subject contrast	
	absorption differences	
	thickness	
	density	
	atomic number	
	x-ray spectrum	
	target material (molybdenum, rhodium, tungsten)	
	kilovolt potential	
	filter material (molybdenum, rhodium, and so forth)	
	and thickness	
	Scattered radiation	
	beam collimation	
	compression	
	air gap	
	grid	

Film contrast
- film emulsion type
- processing
- chemistry
- replenishment rate
- temperature
- time
- agitation
- optical density of image
- fog
  - storage
  - safelight
  - light leaks

Digital contrast
- detector response
  - linearity
  - number of bits digitization
- display device
  - hard copy (laser film)
    - dynamic range
      - film granularity
      - base-plus-fog
      - maximum density
      - number of bits of printing
  - soft copy (video monitor)
    - dynamic range
      - maximum brightness
      - minimum brightness
      - noise
      - phosphor persistence
      - ambient light
    - characteristic curve of monitor
    - number of displayed bits

Look up table
- shape (linear or nonlinear)
- window-level settings

Enhancement
- edge sharpening
- adaptive contrast enhancement
- thickness compensation

TABLE 4.1—*continued.*

Factors Affecting Screen-Film Mammography	Factors Affecting Both Screen-Film and Digital Mammography	Factors Affecting Digital Mammography
	Resolution (blurring, unsharpness)	
	Motion blurring	
	breast compression	
	exposure time	
	Geometric Blurring	
	focal-spot size	
	focal-spot-object distance	
	object-image-receptor distance	
Screen-film blurring		Digital detector blurring
phosphor thickness		phosphor structure
phosphor particle size		phosphor thickness
light-absorbing dyes and pigments		optical coupling
screen-film contact		detector element aperture
		detector element pitch
		signal transfer efficiency
		electric field strength
		electric field shaping

Image Noise

Quantum mottle
- dose
- phosphor absorption
- phosphor conversion efficiency
- light diffusion
- radiation quality

X-ray-to-light fluctuation (swank noise)
- type of phosphor
- x-ray spectrum

Quantum mottle
- film speed
  - film contrast

Screen structure
Film granularity
Processing "wet pressure"

Quantum mottle
- signal coupling efficiency

Electronic noise
Digitization noise (number of bits)

Artifacts

Machine-related
- filter deterioration
- grid streaks
- tabletop structure
- foreign matter in beam

TABLE 4.1—*continued.*

Factors Affecting Screen-Film Mammography	Factors Affecting Both Screen-Film and Digital Mammography	Factors Affecting Digital Mammography
Screen-film artifacts		Digital artifacts
Handling		flat fielding artifacts
crimp marks		stitching
finger marks		scanning artifacts
scratches		dead pixels
static		persistence
exposure		display artifacts
fog		raster lines (monitor or laser printer)
Processing		nonuniform display brightness or focus
streaks		
spots		
scratches		
dirt		
stains		

microcalcifications and the marginal structural characteristics of soft-tissue masses. Subject contrast is caused by differences in the x-ray attenuation properties of the lesion and those of the surrounding tissue. These differences depend on the thickness of the lesion and that of the compressed breast and the density (defined here as mass per unit volume) and atomic number of the lesion and normal tissue. These differences and, therefore, the contrast also depend on the distribution of x-ray energies (spectrum) used for producing the mammogram. This is often referred to as the radiation quality and is characterized by the HVL of the beam. The x-ray spectrum is determined by the tube target material, operating potential, and filtration (either inherent in the tube or added in its exit port). Figure 4.1 presents the results of a calculation that illustrate how the subject contrast of a tumor and calcification fall as the energy of the x rays increases. Here subject contrast (C_s) is defined by:

$$C_s = \frac{(n_B - n_L)}{(n_B + n_L)} \tag{4.1}$$

where n_L is the number of quanta in a particular area corresponding to a "lesion" or structure of interest in the image and n_B is the number of quanta in the same size area corresponding to the adjacent "background." The curves are calculated for monoenergetic beams. They correspond to the contrast that would be provided by a beam with a spectrum of the same "effective" energy.

Contrast is also dependent upon the amount of scattered radiation recorded by the image receptor. This is influenced by the thickness and composition of the breast, as well as the field of view, degree of compression, and presence of a grid.

For screen-film mammography, high subject contrast is particularly important. Most commonly, molybdenum targeted x-ray units are used. These provide high radiation output at the characteristic emission energies for molybdenum of 17.4 and 19.5 keV. Typical x-ray spectrum from both molybdenum and rhodium target tubes are shown in Figure 4.2. When a molybdenum filter, typically 0.025 to 0.03 mm thick, is used, the spectrum is strongly suppressed at lower photon energies and at energies >20 keV because of the strong increase in x-ray absorption by molybdenum that occurs at its k-shell absorption edge at 20.5 keV. Therefore, the spectrum is rich in photons at and near the characteristic energies. These energies yield high subject contrast, while avoiding the excessive radiation dose for breasts of average thickness that would occur if lower-energy photons were used.

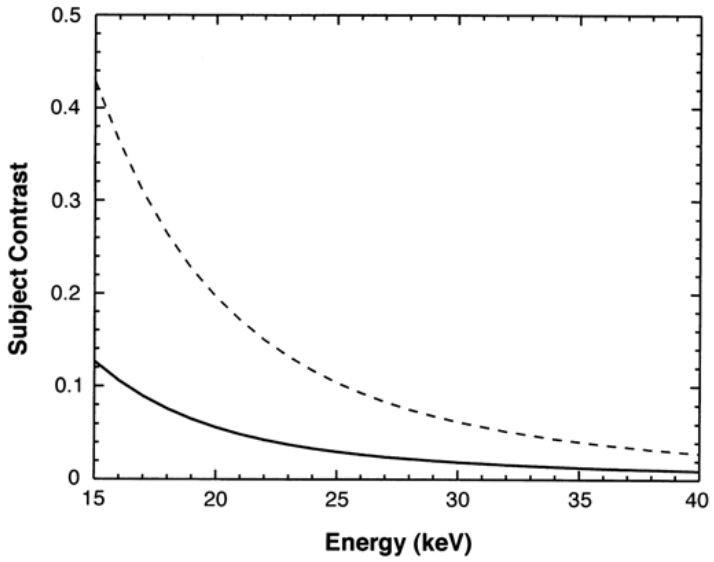


Fig. 4.1. Calculated subject contrast for a 5 mm tumor (solid line) and a small calcification (dashed line) versus energy of the x-ray beam.

For thicker, denser breasts, few low-energy photons are able to pass through the breast, and absorption differences among structures are reduced due to the hardened x-ray beam. Therefore, subject contrast is not as high as with average-sized and fatty breasts. In addition, as a dose-reduction measure, higher energy incident x-ray beams are typically used to image these breasts. Although the effective energy can be adjusted by varying operating potential, the effect on the spectrum is somewhat limited because of the dominance of the fixed-energy characteristic x rays from the target. This motivates the use of targets and filters of different materials to "tune" the spectral shape. Rhodium has a k-absorption edge at approximately 23 keV. Therefore, a rhodium filter will not absorb x rays of energies below 23 keV and will absorb x rays of energies above 23 keV. Used with a molybdenum target in combination with an increase in operating potential, a rhodium filter will give a more penetrating spectrum than that obtained with the Mo/Mo combination. This can be helpful in imaging thick breasts (>5 or 6 cm).

If it is desired to get an even more penetrating beam than available with Mo/Rh, it is possible to use a rhodium target in combination with a rhodium filter (dotted line in Figure 4.2). Rhodium has

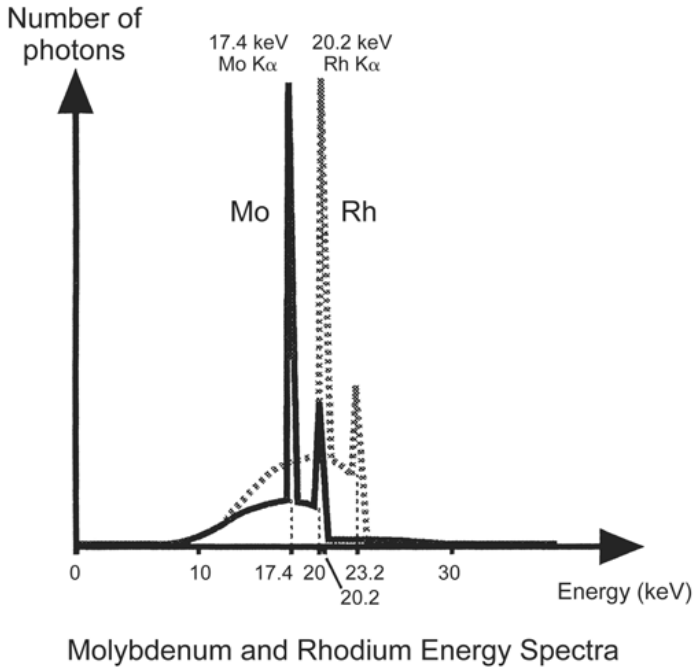


Fig. 4.2. Typical x-ray emission spectra used in screen-film mammography. For the molybdenum (Mo) target, a 0.03 mm molybdenum filter is used and a 26 kVp setting is shown (solid line). For greater penetration, a rhodium (Rh) filter can be used as shown here (dotted line). For very dense breasts, a Rh target and Rh filter x-ray source operated at 30 to 32 kVp may be useful. The dominant characteristic x-ray peaks (Kα) occur at 17.4 keV for a molybdenum target and at 20.2 keV for a rhodium target (Haus, 1999b).

characteristic emissions at 20.2 and 23.2 keV. The Rh/Rh combination is most effective with very dense, difficult-to-penetrate breasts, providing some dose reduction, while preserving as much subject contrast as possible in these difficult to image breasts. It is also possible to provide a suitable spectrum for imaging the dense breast with a tungsten target tube and various metallic filters, such as aluminum or rhodium. While this does not provide the quasi-monoenergetic x rays available with molybdenum and rhodium targets, careful choice of operating potential and filter material and thickness can yield an excellent result in terms of contrast and dose.

For screen-film mammography, operating potentials between 22 and 32 kVp are used depending on breast tissue thickness and composition, the target and filter materials, and exposure time constraints. Hendrick and Berns (1999) have shown that optimum technique factors for screen-film mammography in terms of contrast-detail perceptibility are Mo/Mo with low operating potentials (22 to 25 kVp) for thin breasts (<5 cm), Mo/Rh with intermediate operating potentials (26 to 30 kVp) for thicker breasts (5 to 7 cm) and Rh/Rh or some equivalent harder x-ray beam at 28 to 32 kVp for very thick breasts (>7 cm). At each breast thickness, a sufficiently hard beam should be used to obtain adequate film optical density with exposure times <2 s (Figure 4.3).

For digital systems, it has been found that because of the ability to adjust display contrast, it may be advantageous to employ slightly higher energy x-ray beams than are used with screen film. Except for small breasts, tungsten or rhodium targets with various filters, selected according to breast composition and thickness, appear to provide a better compromise between *SNR* and dose than obtained using molybdenum target tubes (Fahrig and Yaffe, 1994; Venkatakrishnan *et al*., 1999).

4.2.1.1.1 *Scattered radiation*. In soft tissues, even at the low energies used in mammography, scattered radiation is an important mechanism that depletes the primary beam due to Compton interactions of x rays with breast tissue. Scattered x rays that escape the breast and are recorded by the image receptor reduce image contrast. The amount of scattered radiation recorded compared to the useful, directly-transmitted x-ray intensity is characterized by the *S*/*P*. It is not unusual for *S*/*P* to be greater than one (Barnes and Brezovich, 1978).

For screen-film systems, scattered x rays recorded by the image receptor have the following effects: (1) to reduce image contrast, (2) to "use up" some of the available recording range or latitude of the film, and (3) to add noise to the image, thereby reducing its *SNR*, a measure of the information content of the mammogram.

In digital mammography the same factors affecting subject contrast apply. The effect of scattered radiation on the final radiographic contrast, however, is somewhat different. Because of the fact that x rays may scatter multiple times within the breast, their spatial distribution is diffuse [*i.e*., mainly affecting the low spatial frequency part of the modulation transfer function (*MTF*)]. For this reason, in digital systems, much of the contrast can be recovered by viewer adjustment of the computer image display. Similarly, the

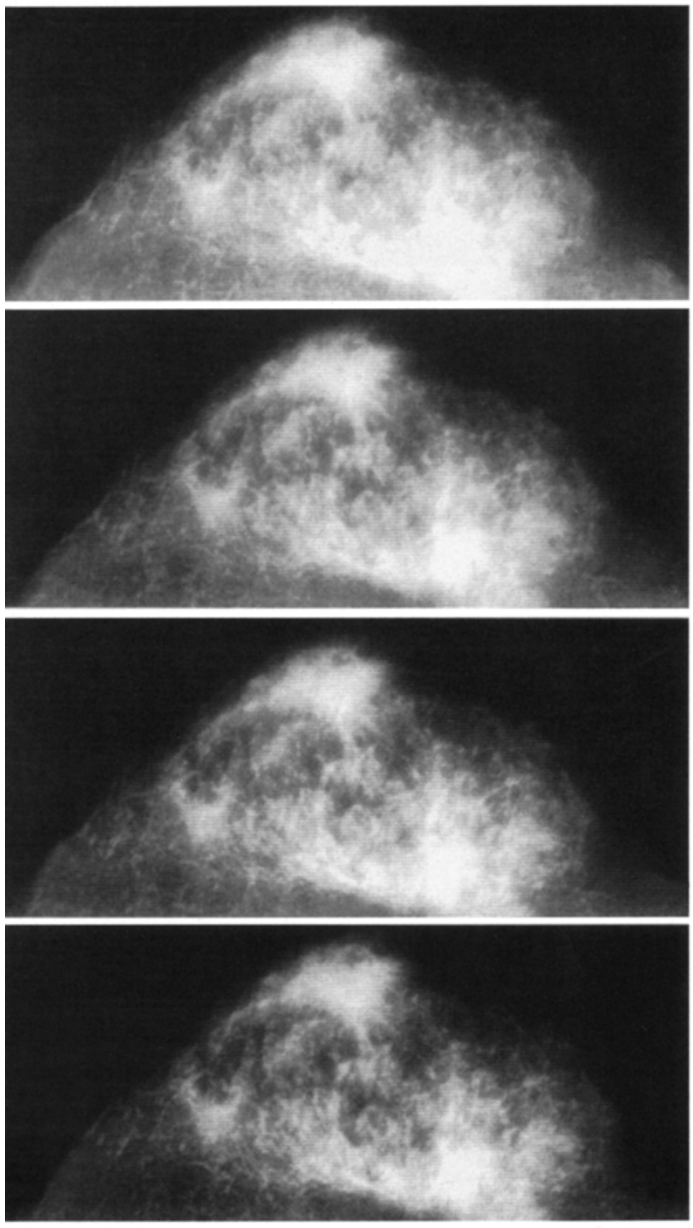


Fig. 4.3. Images of an anthropomorphic breast phantom acquired at varying operating potentials and approximately the same optical density, illustrating a slight dependence of contrast on operating potential (Haus, 1999b).

system can be designed such that the dynamic range of the image receptor is very large so that recording of scattered radiation will not be a limiting factor. Under these conditions, only the third effect, the scatter contribution to random quantum noise, should be of any importance.

4.2.1.1.2 *Grids for mammography.* The use of specifically designed grids for mammography reduces the amount of scattered radiation detected and improves subject contrast. This is especially significant when imaging thick, dense breasts (ACR, 1993; Chan *et al*., 1987b; Sickles and Weber, 1986; Wagner, 1991). Grids are a standard feature of modern mammographic x-ray units. The majority of grids used for mammography consist of lead strips separated by spacers of radiolucent material such as carbon fiber. Virtually, all of these grids are the moving type which blur the grid lines. Moving-type grids are preferred for mammography. Recently, focused rhombic cellular structure air interspaced grids have been introduced (Figure 3.13). These grids improve image contrast and transmission efficiency compared with conventional grids. Grids designed for mammography generally require exposures that are approximately 2 to 2.5 times higher than those used for nongrid techniques. The benefit, in terms of improved image quality, of using a grid in screen-film mammography is considered to be so large that grids are used almost universally for nonmagnification views.

In practice, large-area digital systems require use of a grid, mainly to reduce noise and, consequently, to increase *SNR*. In screen-film mammography, part of the required exposure increase when using a grid is to replace eliminated scattered radiation with sufficient primary exposure to bring the film optical density to the point where the developed film achieves adequate contrast. As will be discussed below, the receptor contrast of the film varies with optical density. With a digital system, detector response is linear with exposure so that receptor contrast is independent of exposure. Therefore, in digital mammography, any exposure increase necessitated by use of a grid will be due only to its incomplete transmission of the primary radiation.

The Fischer digital mammography system uses a narrow scanned beam of x rays which reduces the *S*/*P*. In addition, the long-narrow detector with collimation at its entrance surface rejects much of the small amount of scattered radiation incident on the detector. Thus, a grid is not used with this system.

4.2.1.1.3 *Breast compression*. Good breast compression contributes to image quality in several ways. Compression is an important factor in reducing scattered radiation in screen-film mammography (Barnes and Brezovich, 1978; NCRP, 1986). In a study using phantoms, Barnes and Brezovich (1978) showed that reducing the thickness from 6 to 3 cm by compression reduced the *S*/*P* from 0.8 to 0.4. Use of a mammographic grid further reduced *S*/*P* to 0.14. In addition, compression provides several other technical improvements in image quality that can be achieved without compromising other image-quality factors. These improvements include: (1) immobilization of the breast, which reduces blurring caused by motion; (2) location of structures in the breast closer to the image receptor, which reduces geometric blurring; (3) production of a more uniformly thick breast, which in turn results in more even penetration by x rays and less difference in radiographic density in the image; (4) reduction of radiation dose; and (5) spreading of breast tissue, enabling suspicious lesions to be more easily identified. These benefits apply both to screen-film and digital mammography. Table 4.2 summarizes the relative effect of operating potential, compression and the use of a grid on the contrast, the time required to produce an exposure, and the mean glandular dose to the breast.

4.2.1.2 *Receptor Contrast.* For screen-film mammography, film contrast characteristics determine how the x-ray intensity pattern will be related to optical density in the displayed mammogram. Film contrast is expressed in terms of the gradient of the film, which is defined as the slope of the curve (Figure 4.4a) of optical density versus the log of the exposure (Haus, 1996; 1999b; NCRP, 1986) for that film. The gradient determines how much optical density change is due to variations in x-ray intensity across the breast.

TABLE 4.2—*Relative effect of changes in operating potential, compression and use of grid on contrast, exposure time, and mean glandular breast dose, assuming the same optical density is obtained for screen film.*[a]

Parameter Change	Radiographic Contrast	Exposure Time (motion blur)	Mean Glandular Dose
Operating potential ↑	↓	↓	↓
Compression ↑	↑	↓	↓
Use of grid	↑	↑	↑

[a]Hendrick (1999).

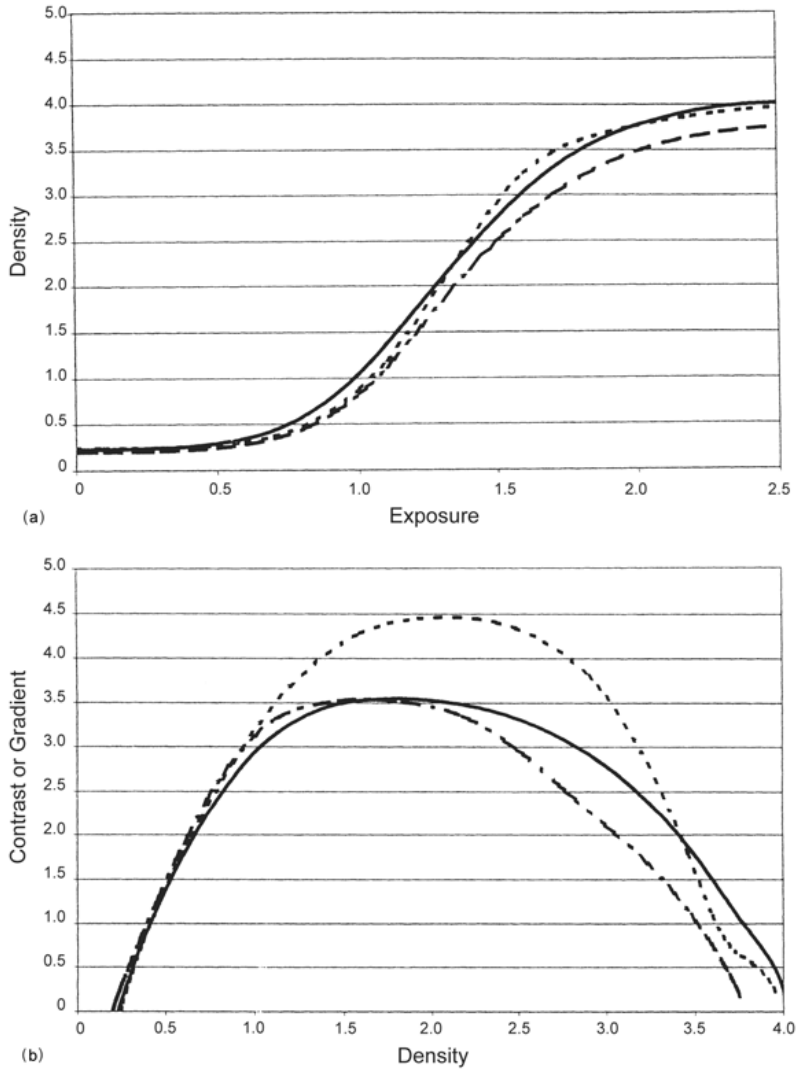


Fig. 4.4. (a) Typical characteristic curves for mammographic screen-film combinations. (b) Contrast or gradient of these systems plotted versus optical density. Note the variation in both the magnitude of the contrast or gradient and also in the latitude or range of optical densities over which near-peak gradient is maintained (Haus, 1999b).

Film gradient is affected by (1) film type; (2) processing conditions (solutions, temperature, time, agitation); (3) fog level (storage, safelight, light leaks); and (4) the optical density. The trend is to use mammographic films with high film gradient (*i.e.*, gradients between 2.8 and 3.7). The maximum gradient occurs at different optical densities for different film types (Figure 4.4a), which may affect optimum exposure for that film. Figure 4.4b illustrates the effect of optical density on mammographic image contrast. To assure adequate contrast in all parts of the breast, the most radio-opaque regions must be imaged with an optical density of 0.80 or greater. This may require an average optical density at the location of the AEC detector of 1.6 to 1.8. Radiation dose may have to be increased to achieve the appropriate optical density when a slower screen-film combination is employed (Table 4.3) (Haus, 1999a). Increasing optical density will reduce the effects of quantum noise or film granularity, as well.

Low film contrast can be the result of using a film with inherently low gradient and processing the film as recommended, or using a film with inherently high contrast and processing the film less than optimally. It is important to note that overall radiographic contrast is influenced by both subject contrast and film gradient. Therefore, a screen-film mammogram of acceptable contrast is best obtained by: (1) use of appropriate beam quality, (2) adequate breast compression, (3) use of a grid, (4) properly processed high-contrast film, and (5) appropriate optical density.

In digital mammography, the signal stored in digital form is linearly (or logarithmically) proportional to the amount of radiation transmitted through the breast and absorbed by the detector over the entire range of intensities, from that of the unattenuated beam outside the breast to that through the densest, thickest part of the

TABLE 4.3—*Effect of optical density of the mammogram on mean glandular dose for a fixed operating potential and breast composition (Haus, 1999b).*

Optical Density	Mean Glandular Dose (mGy)
0.90	1.27
1.10	1.47
1.30	1.70
1.50	2.00

breast (Figure 3.22 in Section 3.3). For this reason, the stored image reflects inherent subject contrast faithfully. To display the image, a "lookup table" (Figure 3.22 inset) is used to transform the recorded intensities either into optical densities on a laser-printed film or brightness on a video monitor. The nature of this transformation can be controlled by the user, and in the case of soft-copy display, it can be varied interactively by the radiologist to facilitate image interpretation. Therefore, provided that the image has been acquired with an adequate number of bits of digitization, there are no overriding limitations related to the characteristic curve of the receptor as there are with screen-film mammography. This is because the image created with a single x-ray exposure can be presented in many ways. On the other hand, there are clearly practical limitations to the number of hard-copy printouts that might be used to display a single exposure and to the amount of time that a radiologist can spend manipulating the soft-copy display. Determination of optimal strategies for display of digital mammograms is an area of active research (Hemminger *et al*., 1999a; 1999b; Kundel *et al*., 1999).

4.2.2 *Spatial Resolution*

Spatial resolution describes the ability of an imaging system to record fine spatial detail. Resolution is degraded in the presence of radiographic blurring. Radiographic blurring refers to the lateral spreading of the image of a structural boundary, that is, to the distance over which the optical density change between the structure of interest and its surroundings takes place. There are three types of radiographic blurring: (1) motion, (2) geometric, and (3) receptor.

Spatial resolution of the image can be assessed by imaging a pattern of evenly-spaced x-ray opaque bars (100 percent contrast) and determining the greatest number of cycles per millimeter (bars and spaces) that can be resolved (Haus, 1996). Unsharpness in the imaging process will eventually make the bars and spaces blur together. This defines the *limiting spatial resolution*. While this measurement is thought of as one of spatial resolution, the reason that the bars fail to be resolved is that the unsharpness causes the contrast between the bars and spaces to become inadequate. In some cases, this is because the contrast between these structures is too small to be detected by the human observer; in others because the difference in the two signal levels is comparable to the fluctuation (noise) of the image, thereby, preventing reliable perception. Thus, while it is often convenient to consider these parameters separately, it is important to realize that spatial resolution, contrast and noise are closely linked.

A more sophisticated measure of resolution is the *MTF*, which describes the relationship between sharpness and contrast in imaging patterns whose x-ray transmission varies sinusoidally with position. This is convenient because any radiologic transmission pattern can be described as a set of sinusoidal patterns of the appropriate amplitudes and spatial frequencies. Low spatial frequency corresponds to coarse detail, while higher frequencies are required to describe the fine details and sharp edges of anatomical structures.

If we know the *MTF*, then we can predict exactly what the imaging system will do to the contrast and sharpness of a specific structure. The *MTF* (Figure 4.5) describes the ability of a mammographic imaging system to transfer the modulation (subject contrast) of a structure to the final recorded image. For example, an *MTF* of 0.5 implies that the inherent contrast of the object will decease by 50 percent because of limitations of the imaging system. If the contrast is low at the outset (say 10 percent), it will be only five percent in the recorded image.

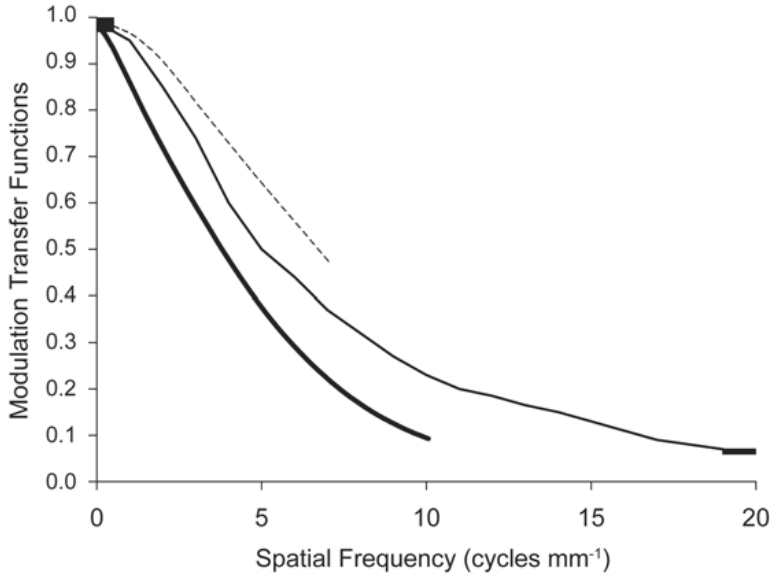


Fig. 4.5. *MTF*s for a direct-conversion x-ray imaging detector (upper curve), a screen-film system for mammography (middle curve), and an indirect, scintillator detector (lower curve). The del sizes of the digital systems differ and the *MTF* curves have been plotted only as far as the Nyquist frequency corresponding to the del size.

As the spatial frequency increases (*i.e.*, for finer detail), most imaging systems will transfer less of the incident contrast to the recorded image. At some point, the contrast becomes so low that it is imperceptible to the eye or "lost in the noise." In other words the *SNR* in the image becomes too low for reliable detection of details. Limiting spatial resolution is sometimes expressed in terms of the frequency at which the *MTF* equals a certain value (*e.g.*, four or five percent level), however, this relationship is not precise (Rossmann, 1963).

4.2.2.1 *Motion Blurring*. The use of long exposure times can result in image blurring caused by motion. In mammography, most motion blurring is caused by movement of the breast during exposure. It can be minimized by using a short exposure time (<2 s) and by compressing the breast. The operating potential may be increased for thick-dense breasts to keep exposure times <2 s. Magnification techniques generally require longer exposure times due to the reduced milliampere rating of the small focus of the x-ray tube. Higher-speed screen-film combinations or higher operating potential can be used to reduce exposure times for magnification mammography.

In digital mammography, the effect of motion blurring is similar to that in screen-film imaging. The amount of blurring depends on the speed of the motion in the patient and the duration of the exposure. It is important to note, however, that for considerations of blur, the exposure time in the case of the large area digital systems is the complete exposure time, while for a scanning system only part of the breast is exposed at any one time. For this reason, even though the overall exposure time is generally longer for a scanning system, the time that x rays expose a particular part of the breast (*i.e.*, the time that affects blurring or dwell time) is only a small fraction of the total exposure time. For scanning systems, sporadic motion will cause blur over a limited region, plus misregistration between anatomy imaged before motion and that imaged after.

4.2.2.2 *Geometric Blurring*. The size, shape and intensity distribution of the x-ray tube focal spot, in combination with focal-spot-to-object and object-to-image-receptor distances, affect geometric blurring (Figure 4.6). Each point in the focal spot casts a sharp shadow of structures within the breast. The size of the shadow increases with the degree of magnification between that structure and the plane of the image receptor. The entire focal spot can be thought of as a large number of adjacent point x-ray emitters. The

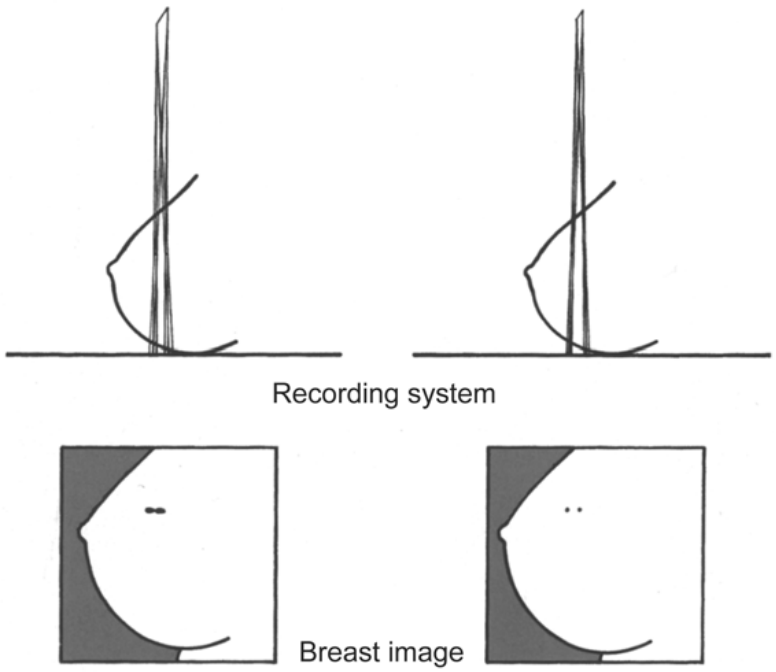


Fig. 4.6. Geometric blurring caused by the finite size of the focal spot and magnification between planes within the breast and the image receptor. At right, a small focal spot produces sharp images of the microcalcifications allowing them to be resolved separately. At left, the larger focal spot causes the images of the two calcifications to be blurred together (Haus, 1999b).

overlap of the shadows from each causes blur. To minimize geometric blurring, the focal-spot size and object-to-image-receptor distance should be minimized, whereas focal-spot-to-object distance should be maximized. The focal-spot-to-receptor distances and the breast support plate-to-receptor distances vary slightly among models of mammography machines causing variation of magnification. Together with variations in the distribution of radiation emission from the focal spot, this results in different spatial resolutions.

At one time, it was common to compress the breast directly on top of the mammographic cassette. The distance between the chest-wall edge of the breast and the screen-film combination was very small. Today, most mammographic procedures are performed with a moving bucky-type grid. With the grid in place, there is a gap of 1 to 2 cm between the edge of the breast and the screen-film

combination. The size of the focal spot, therefore, needs to be smaller in terms of limiting geometric resolution for a given distance from focal spot to surface of breast (Figure 4.7). In modern mammography units, the nominal focal-spot size for most procedures is 0.3 mm. For geometric magnification, a second focal spot with a nominal size of approximately 0.1 mm should be used to avoid unacceptable loss of resolution. It is important to note that the manufacturers' convention (NEMA, 1992) for defining nominal focal-spot size allows the actual distribution of radiation to be considerably larger (1.5 to 2 times) than the nominal value, and that the effective size of the focal spot will vary over the image plane, being largest near the chest wall (Figure 3.3). Therefore, geometric resolution will also vary over the image.

The limit of geometric resolution corresponding to various planes in the breast can be calculated using the focal-spot size, the distance from the focal spot to the receptor, and the distance from the object to the receptor (Haus *et al*., 1978). These values can be compared with a calculation of the limit of resolution for the screen-film combination. Limiting resolution data can be

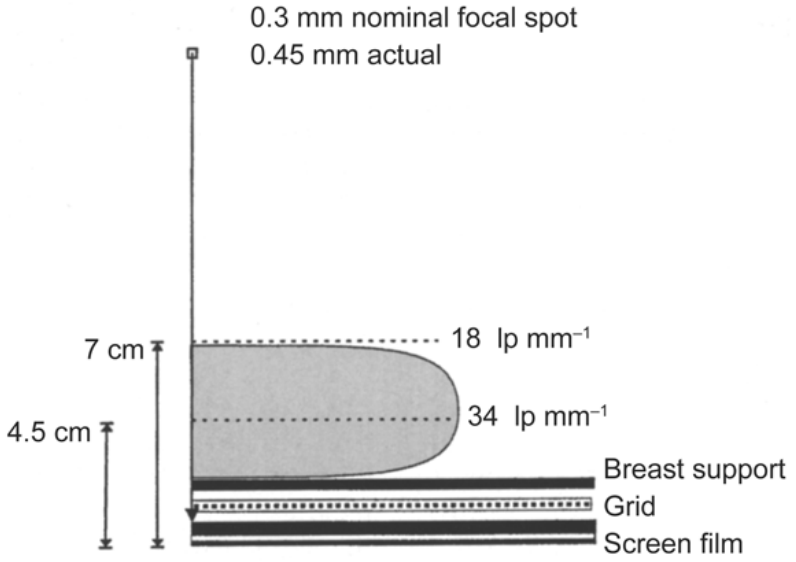


Fig. 4.7. Calculated limiting spatial resolution in line pairs per millimeter due to geometric blurring alone at different planes in the breast for a nominal focal-spot size of 0.3 mm.

obtained from *MTF* data, like that of Figure 4.5, or from bar-pattern resolution test objects. Most mammographic screen-film combinations have resolutions (for high-contrast structures) of at least 20 cycles mm^{-1}. For the lower subject contrast provided by structures within the breast, the detectable resolution is lower because of quantum noise and granularity of the screen and film. In order to achieve a balance between resolution limits caused by geometric unsharpness and receptor blur, ACR has recommended that the limiting resolution (for a high-contrast pattern), in a plane 4.5 cm above the image receptor, due to geometric factors be no <13 cycles mm^{-1} for bars parallel to the anode-cathode axis of the x-ray tube (normally the chest wall to nipple direction) and 11 lp mm^{-1} in the perpendicular direction.

Note that in many cases, for a given image-receptor sensitivity (a specified amount of radiation required at the image plane), there is a trade-off between motion blur and geometric unsharpness. If one attempts to reduce motion blur, then a greater x-ray output must be available.

Short of a radical improvement in the basic x-ray tube performance, this can only be accomplished by either increasing tube current or reducing the distance from x-ray tube to image receptor. The former requires increasing the focal-spot size. In either case, geometric unsharpness will become greater. Reducing the *SID* also makes patient positioning for the examination more difficult.

4.2.2.3 *Receptor Blurring*. For screen-film radiography, light diffusion (spreading of the light emitted by the intensifying screen before it is recorded by the film) causes blurring (Haus, 1991; 1999a). Factors involved include: (1) phosphor layer thickness in the screen, (2) phosphor particle size, (3) light-absorbing dyes and pigments in the screen, and (4) screen-film contact. To minimize receptor blurring, screen-film combinations for mammography use a single high-definition screen in contact with a single-emulsion film.

The single screen is used as a back screen for mammography because x-ray absorption (and emission of screen light) is highest on the side of the screen where the x rays enter. If the screen were used as a front screen, x-ray absorption would be higher in the plane of the screen that is the farthest distance from the screen-emulsion contact surface (Haus, 1991; 1994). This would cause greater light spread (receptor blur) than when a back screen is used. Both parallax and crossover are eliminated in a single-back screen configuration.

Analysis of the *MTF* of system components is helpful in determining which is the limiting factor controlling spatial resolution. In some situations, the x-ray unit may be the major cause of image blur resulting from geometric blur caused by focal-spot size and magnification (Haus, 1991; 1994; NCRP, 1986). In other situations, the main source of blur may be due to longer exposure times coupled with patient motion causing motion blur. In the latter situation, higher speed, slightly less sharp mammographic screen-film combinations may produce mammograms with less overall image blur because shorter exposure times can be selected than with lower-speed high-resolution combinations. For example, a higher-speed screen-film combination may be appropriate for magnification techniques (where geometric blurring may be the dominant factor limiting resolution) to reduce exposure time (minimize motion blur) and to reduce radiation dose.

The factors affecting receptor unsharpness for digital mammography are somewhat more complex. Receptor unsharpness is due to three main factors: (1) signal diffusion between detector elements, (2) the active area of each element (aperture size), and (3) the pitch or center-to-center spacing between elements.

Because some current digital mammography systems employ phosphor-based detectors, there is diffusion of light in those systems that is similar in nature to that which occurs in the screen-film receptor. The aperture dimensions of the detector element determine the maximum possible spatial resolution that the detector can provide. For example, for a square detector element of del = 0.1 mm, the detector can resolve at most $(\text{del})^{-1}$ or 10 cycles mm^{-1}. There is another constraint, however, related to the detector pitch. This determines the number of samples per millimeter that the detector can acquire. If this is not adequately high, it gives rise to a phenomenon called *aliasing*, where artifactual signals, due to undersampling, degrade the quality of the image. The limiting frequency that can be represented correctly without aliasing by a detector with pitch (p) is 0.5 p. For a detector pitch of 0.1 mm, this allows a maximum frequency of 5 cycles mm^{-1}. Because the factors affecting resolution are system dependent, they will be discussed with reference to each of the five current types of digital systems described in Figure 3.23 in Section 3.3.2. Because some detectors have part of their surface occupied by electronic components and conductive leads, only a fraction of the total detector area may actually be sensitive to the incident radiation. To specify this, we define the "fill factor" as the ratio of the effective sensitive area of the aperture to the area defined by the product of the pitch in the "x" and "y" directions.

- *Type 1*: Light produced in the cesium-iodide phosphor is collected by the fiber-optic taper. Light can diffuse laterally and be recorded by detector elements adjacent to that over which the x-ray absorption took place, however, the needle-like structure of the cesium iodide tends to direct the light down the length of the crystal and minimizes lateral spread. There is the potential for some light diffusion in the fiber optics. This can be controlled by the use of extramural absorber (a light absorbing dye) between the individual glass fibers. Possible sources of unsharpness, in addition to light spread within the phosphor and the fibers, are related to imperfections (shear distortion and pincushion) in the optical taper and any mismatch that might occur where the individual detector modules abut one another.
- *Type 2*: The image formed by the trapped electrons is of intrinsically very high quality. When the stimulable phosphor plate is placed in the reader and scanned with a laser beam, the red laser light can scatter from its original path and discharge traps that are laterally adjacent to it. This is a potential source of unsharpness. The sampling aperture is determined by the size of the laser beam. The pitch is determined by the distance that the beam is allowed to move between samples. Both pitch and aperture (del) are approximately 50 μm. The location of a del in the image is determined from the timing of the scanned laser beam. The stimulated blue light is collected by an optical detector which is not spatially localizing, so that scattering of this light is not a source of unsharpness.
- *Type 3*: The desirable properties of cesium iodide were described with respect to Type 1. Possibilities for lateral spread of light are further minimized by the direct application of the CsI to the surface of the amorphous silicon plate containing the photodiode array. The aperture of the detector is slightly smaller than its 100 μm pitch which is determined by the spacing of the photodiode elements on the amorphous silicon plate.
- *Type 4*: X rays are absorbed by a strip of cesium-iodide phosphor. The optical image is transferred to the CCD through a fiber-optic faceplate. If the CCD electronics are not properly synchronized to the motion of the scanning system, this can cause image blur, however, this problem can be avoided by good design. The detector aperture and pitch are determined by the characteristics of the CCD. In this system,

they are approximately 50 μm with the aperture slightly smaller than the pitch.

- *Type 5*: With electrostatic collection of charge in direct-conversion detectors, there should be very little lateral spread of charge between the points of x-ray absorption and charge collection and, therefore, very little loss of resolution due to this factor. Resolution in such systems should then be mainly determined by the del size, together with the unsharpness due to the effective size of the focal spot and any unsharpness due to motion.

Because of cost and other practical considerations, current digital mammography systems are not designed to provide as high a limiting spatial resolution as screen-film mammography. For this reason, the spatial resolution is often determined by the detector aperture and pitch rather than the spreading of light. For the detector pitch of the current systems, it is expected that the useful *MTF* will extend to spatial frequencies of only 5 cycles mm^{-1} (0.1 mm pitch) to 12.5 cycles mm^{-1} (0.04 mm pitch). The underlying hypothesis of digital mammography is that, its improved *SNR* and the ability to enhance the displayed contrast for any region of the breast should provide improved visualization of structures that are too subtle for screen-film mammography to display or that are masked by dense tissue. Some promising evidence that digital mammography will allow improved performance in mammography is given by the comparisons of contrast-detail phantom images obtained with state-of-the-art screen-film mammography and a digital unit. As seen in Figure 4.8, the digital system provides superior visualization of low-contrast structures. In addition, even though it has lower spatial resolution, more low-contrast structures can be seen with the digital system than with screen-film technology.

4.2.3 *Noise*

Radiographic noise or mottle is the unwanted variation in random optical density in a radiograph that has been given a uniform x-ray exposure. For screen-film mammography, major sources of radiographic noise include: (1) quantum mottle, (2) screen structure, (3) film grain, (4) film-processing artifacts, and (5) x-ray-to-light conversion noise (Barnes, 1982).

Quantum mottle is caused by the random spatial variation of the x-ray quanta absorbed in the image receptor. Its effect is reduced as more x rays are used to form the image. Figure 4.9

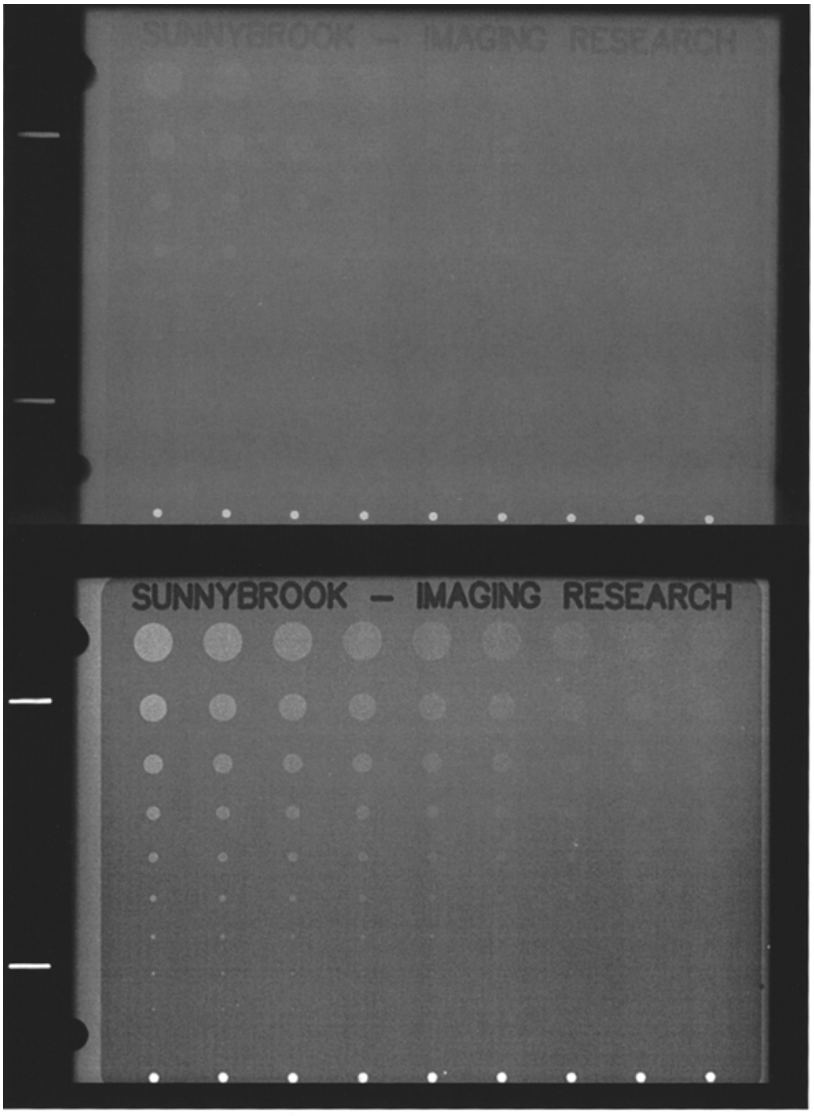


Fig. 4.8. Contrast-detail phantom images obtained on a state-of-the-art screen-film system (top) and on a digital mammography unit (bottom). The superior visibility of both low-contrast structures and small, medium-contrast disks is evident (Haus and Yaffe, 2000).

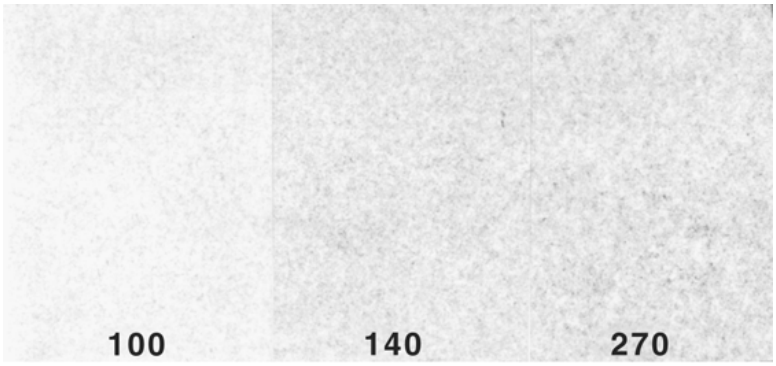


Fig. 4.9. Uniformly-exposed radiographs obtained with screen-film systems of different speed. These images were photographically magnified by 10 to allow the noise levels to be compared. Note that as relative system speed increases from 100 to 270 and fewer x-ray quanta are used, the appearance of quantum noise becomes more noticeable (Haus and Jaskulski, 1997).

shows images obtained with screen-film systems of different speed (Barnes, 1982). For faster (more sensitive) systems obtained by using screens with increased conversion efficiency, faster films or more aggressive processing, fewer x rays must be absorbed by the screen to achieve a given optical density. When fewer x rays are used, the fluctuation in the image (relative to the useful signal) increases, causing the image to appear noisier (Rossmann, 1963). The effect of using fewer quanta on noise and on perception of subtle contrasts can also be seen in Figure 4.10, where digital images have been produced of a contrast-detail phantom.

Generally, screen structure noise and film granularity noise also increase as screens and films are made more sensitive. X-ray-to-light conversion noise results from the statistical fluctuation of the amount of light produced in a phosphor when an x-ray quantum is absorbed.

The simplest characterization of noise is in terms of the standard deviation of the number of x-ray quanta recorded in a given area of the image receptor, or the standard deviation in image signal (optical density or digital image value) over a given area of the image. This says nothing, however, about the spatial characteristics of the noise. The spatial characteristics of noise are better described by the noise power spectrum of the image (Figure 4.11) (Haus, 1991; Rossmann, 1963). The noise power spectrum is basically a graph of how the variance of the image signal is distributed over spatial frequency.

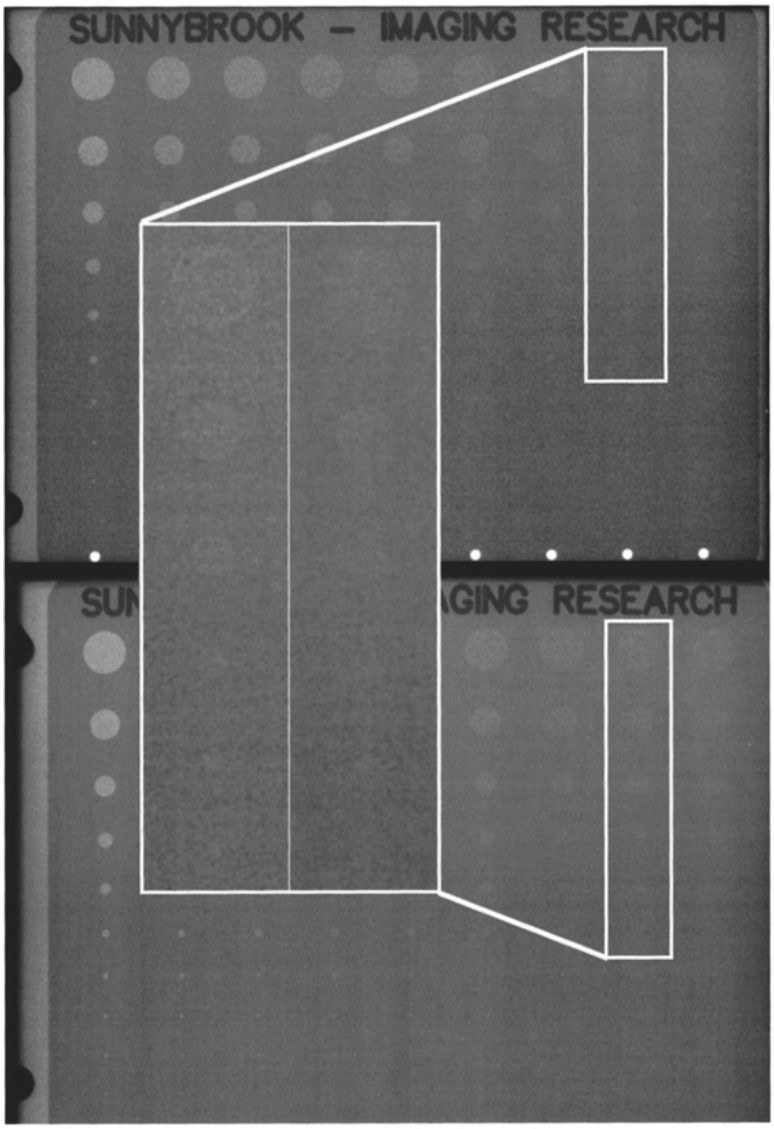


Fig. 4.10. Contrast-detail phantom images obtained on a digital system at exposure levels varying by a factor of three. (Top) low exposure, (bottom) higher exposure. The display characteristics have been adjusted so that the images appear at approximately equal optical density.

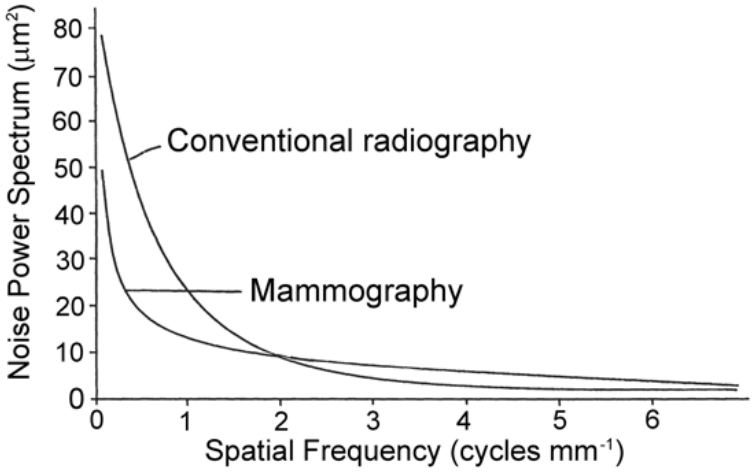


Fig. 4.11. Noise power spectra at an optical density of one for a conventional radiography system exposed at 70 kVp and a mammography system exposed at 28 kVp (Haus, 1999a).

More important than the noise level itself is the consideration of the relative magnitudes of the noise and the useful image signal (difference in image value between two points of interest). This is described by the *SNR* of the image. Often, the square of the *SNR* is calculated. This value can be thought of as the number of x-ray quanta that the imaging system *appears* to be using to produce the image and, for this reason, is termed the number of noise-equivalent quanta (*NEQ*). These measures describe the information content of the image. The higher the *SNR* or *NEQ*, the more reliably subtle details in the image can be detected above the background noise. It is useful to analyze *SNR* or *NEQ* versus spatial frequency (Figure 4.12) to describe the quality of the image for details of different sizes (Haus, 1996; ICRU, 1996; Tapiovaara and Wagner, 1993; Wagner, 1999).

Finally, we can consider the efficiency of the mammographic system in transferring information (in terms of *SNR*), from the x rays transmitted through the breast to the recorded or displayed image. This can be done by considering the ratio of *NEQ* in the final image to the actual number of quanta present in the x-ray image prior to interaction with the image receptor. This quantity is called the detector quantum efficiency (*DQE)* of the imaging system. Again, *DQE* can be analyzed versus spatial frequency to give

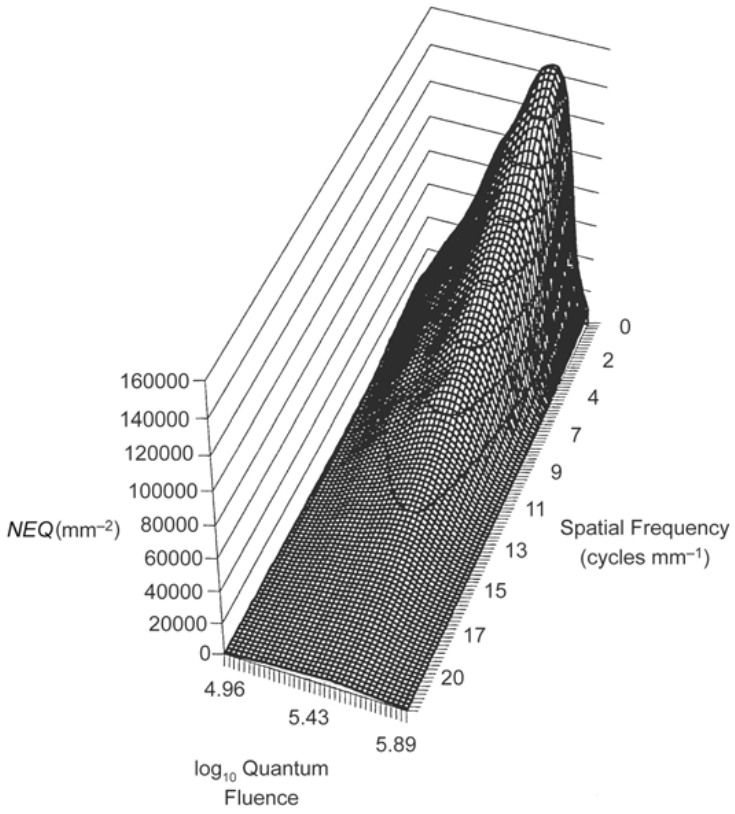


Fig. 4.12. *NEQ* for a screen-film mammography system plotted versus spatial frequency and the radiation exposure incident on the receptor (Bunch, 1999).

a more complete characterization of imaging performance (Figure 4.13). Determination of *DQE* requires three pieces of data: the *MTF* of the imaging system, its noise power spectrum, and a measure of how many x-ray quanta are incident on the receptor. Note that, *NEQ* describes the quality of the image while *DQE* characterizes the efficiency of the imaging system in producing that quality.

Currently, measurement of noise power spectrum, *MTF*, *NEQ*, and *DQE* on screen-film systems require sophisticated microdensitometers to digitize the films and are, therefore, done primarily in manufacturers' laboratories. Because digital mammography systems will provide data in digital form directly, it is much more straightforward to carry out these measurements in the field and to incorporate them in routine QC programs for digital systems.

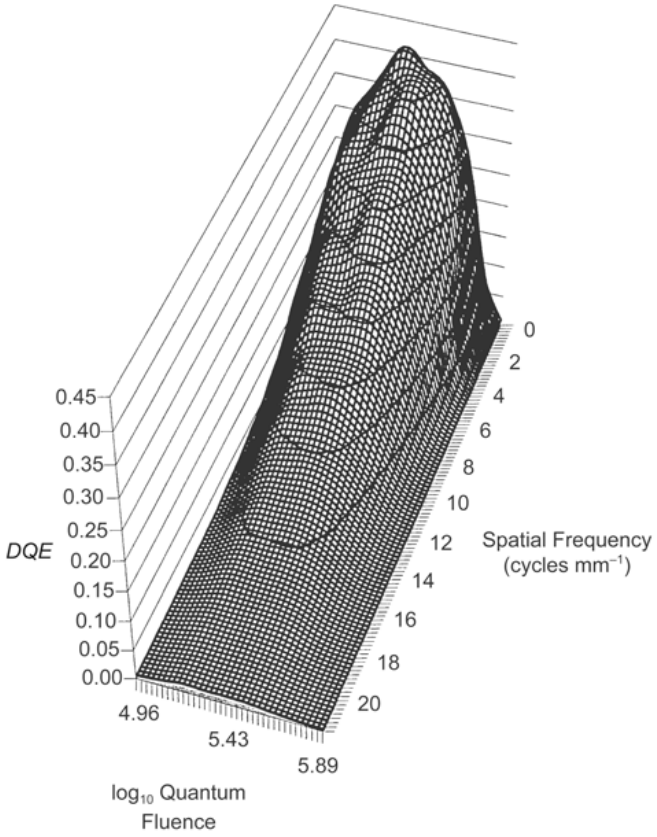


Fig. 4.13. *DQE* of a screen-film mammography system plotted versus spatial frequency and the x-ray exposure incident on the receptor (Bunch, 1999).

In general radiography, quantum mottle is usually the principal contributor to the optical density fluctuation seen in a uniformly exposed radiograph. Factors affecting the perception of quantum mottle include: (1) film speed and contrast, (2) screen absorption and conversion efficiency, (3) light diffusion, and (4) radiation quality. When speed is increased because of increased x-ray absorption (higher quantum efficiency) by the screen for a given film optical density, quantum mottle is not increased. When speed is increased because of increased light output of the screen per absorbed x ray or increased film speed (faster film or increased developer temperature), fewer x rays are used to form the image and, therefore, quantum mottle is increased. Spreading of light in the screen blurs

the recording of quantum noise, so that it becomes less apparent, but also causes a decrease in spatial resolution. Higher energy x rays are more likely to be transmitted through the breast. More importantly, they produce more light per x ray, so that the required optical density can be achieved with fewer quanta, resulting in a higher degree of quantum mottle.

In screen-film mammography, quantum mottle may not be the limiting factor governing noise because of the high quantum efficiency (approximately 70 to 80 percent) of the screen, low average energy of the photons, and the relatively low light emission in the screen (Barnes, 1982; Nishikawa and Yaffe, 1985). In many cases, screen structural noise, variation in the amount of light produced per x-ray and film granularity, due to the random distribution of the finite number of developed silver halide grains, are major noise sources. Film granularity is generally the dominant noise source at spatial frequencies higher than a few cycles per millimeter (Bunch, 1997; Niskikawa and Yaffe, 1985). The graphs of *NEQ* (Figure 4.12) and *DQE* (Figure 4.13) for the screen-film system can be quite instructive in indicating where further improvements might be made. They indicate that the maximum *DQE* is only 35 to 40 percent, suggesting that there is room for at least a 2.5-fold increase in radiation detection efficiency of screen-film systems or an opportunity to produce images of higher information content without an increase in dose. This might be achieved with the use of finer grained film, screens of finer structure, and phosphors that produce a more constant amount of light for each absorbed x-ray quantum (Bunch, 1997). It is also seen that performance falls off in regions of the characteristic curve where the gradient is below its maximum value. This suggests that image quality might be improved by designing characteristic curves that provide a greater range over which the gradient is near maximal.

Higher speed mammographic screen-film combinations resulting in reduced radiation dose can be obtained by using a higher-speed screen or high-speed film. Assuming all other factors are optimized, high-speed systems are generally less sharp or present more noise than images produced using a conventional lower-speed screen-film emulsion combination (Table 4.4). A study (Haus *et al*., 2001) using data from the ACR-MAP on doses and phantom image evaluation showed that phantom failure rates depended on radiation dose (Figure 4.14). Possible reasons for failure at low doses include: (1) excessive noise from use of high-speed screens, high-speed films or overprocessing or (2) lack of contrast due to insufficient optical density. Reasons for failure at high doses include poor contrast due to excessive optical density, possibly

TABLE 4.4—*Speed, dose, gradient and relative noise of various mammographic screen-film combinations (Haus, 1999b).*

Screen	Film	Process[a]	Relative Speed	Relative Dose	Average Gradient[b]	Maximum Density	Relative Noise
1	1	S	1	1	2.95	3.90	Lowest
1	2	S	1	1	3.60	>4.00	
1	3	E	1.4	0.7	3.25	>4.00	
2	2	S	1.5	0.66	3.60	>4.00	
3	1	S	1.7	0.6	2.95	3.90	
1	4	S	1.8	0.56	3.20	4.00	
4	2	S	1.9	0.53	3.60	>4.00	Highest

[a]S = standard cycle
E = extended cycle
[b]Measured between 0.25 and 2.5 optical density units above base-plus-fog optical density.

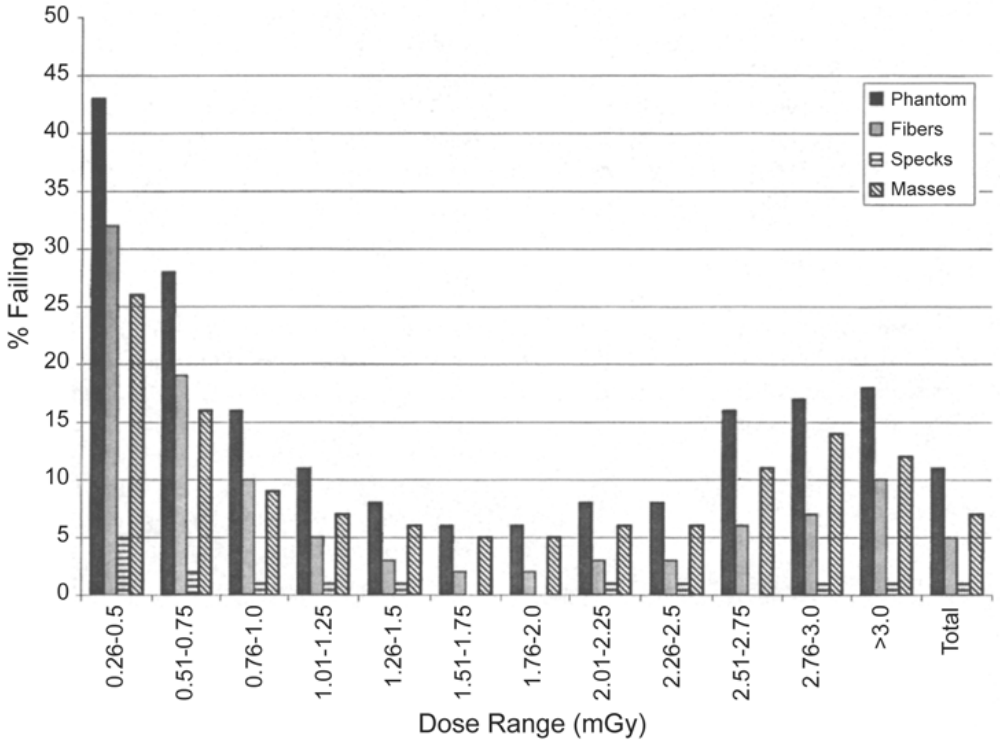


Fig. 4.14. The relationship of the phantom failure rates and failure rates for fibers, specks and masses to the mean glandular dose.

aggravated by inadequate viewbox intensity to allow proper viewing of these very dark films.

For any radiographic imaging system, including digital mammography, quantum noise is a fundamental factor that can never be eliminated, only minimized. This is accomplished by attempting to maximize quantum efficiency and by using an adequate radiation dose. In screen-film mammography for a specified screen and film, the amount of radiation used is largely determined by the need to achieve a given optical density. In digital mammography, the detector and electronics should be designed to have adequate dynamic range and number of bits of digitization to precisely record the entire range of x-ray intensities transmitted through the breast. If this is the case, the electronic image can be amplified as much as desired so that there is really no constraint on image brightness. If an inadequate number of quanta is used, however, the *SNR* will be inadequate. Therefore, it is really the desired *SNR* that should determine the radiation dose used for a given examination (Haus and Yaffe, 2000).

In digital mammography, film granularity is eliminated. However, there may be variations in sensitivity of the receptor which would cause the image to have structure that is unrelated to the tissues in the breast. As long as the system design insures that these variations are temporally stable, this "fixed pattern noise" can be eliminated by imaging a uniform field of x rays and using the recorded image as a correction mask to make the image uniform. This procedure is known as "flat fielding" (Critten *et al.*, 1996).

If flat fielding is not performed properly (*e.g.*, if the mask image itself is noisy), residual noise can result in the digital image. In addition, there can be noise associated with the electronic circuitry that amplifies and digitizes the detector signal. Finally, there will be some level of granularity associated with either the soft-copy display device or with the film used to print the hard-copy digital images. For a digital system to perform well, it must be designed to minimize these nonquantum noise sources such that the *SNR* is determined by the level of radiation used.

4.2.4 *Artifacts*

Artifacts are unwanted contrasts that appear in the image and are unrelated to anatomical structures within the breast. Artifacts have two detrimental effects on mammographic quality: (1) they can mask the detection or impair the characterization of lesions by

adding "clutter" or noise to the image and (2) they can simulate lesions that do not exist. In screen-film mammography, artifacts can be caused by the x-ray source, beam filter, compression device, breast support table, grid, screen, film, processor, and darkroom. These have been well documented in the literature (Haus and Jaskulski, 1997) and their evaluation should be part of any QC program for mammography (ACR, 1999).

In digital mammography, all of the artifacts caused by components before the image receptor are still possible. In addition, there can be artifacts caused by nonuniformities in the detector response over the image area. These may be a result of improper flat fielding, errors in scanning (Type 2 and 4 units), or mismatches in "stitching together" sub-images from detectors that contain multiple modules (Types 1 and 4). Artifacts can also be caused by nonuniformity or miscalibration associated with the hard- or soft-copy display systems (Roehrig *et al*., 1995). With good design, and proper maintenance and system calibration, it should be possible to control or eliminate these artifacts.

4.3 Summary

It is important to remember that the goal in making a mammogram is to obtain as much diagnostic information as possible at the lowest dose compatible with obtaining that information. As noted earlier, this necessitates compromises (*i.e*., an optimization of factors that affect image quality). These include: beam quality, compression, imaging geometry, grids, receptor characteristics, processing of the film or digital image, and display and viewing conditions. If this is done correctly, a high-quality mammogram can be obtained at a reasonably low dose to the patient. The goal is not simply to use as low a dose as possible because, if this is done, there is a risk of degrading the performance of mammography in detecting or accurately characterizing small, node-negative cancers.

5. Dose Evaluation

5.1 Introduction

Mammography is uniquely effective in early detection of breast cancer; however, because this procedure is used for screening asymptomatic women and breast tissue is sensitive to radiation carcinogenesis it is important to monitor the radiation dose delivered to the breast.[7] Although there is ample evidence that the resulting benefits will substantially exceed potential risks (Section 7), the conservatively safe assumption of a linear nonthreshold dose-risk relationship requires that the dose be minimized while necessary image quality is maintained. An early study conducted by the Center for Devices and Radiological Health correlated faulty technique with excessively low, as well as excessively high doses (Jans *et al*., 1979). A recent study discussed the relationship between phantom failure rates and radiation dose in mammography accreditation (Haus *et al*., 2001). Since patient dose levels can, therefore, provide a useful check on the diagnostic adequacy of mammography technique as applied in practice, dose values are useful for assessing and monitoring risk, selecting techniques, and verifying their proper clinical application.

5.1.1 *Requirements of a Dosimetry Method*

There should be a suitable dose index for each radiographic procedure to help in selecting among alternatives. In addition, dose values should characterize the probable risk of radiation carcinogenesis in the female population studied. Finally, to be practical, the dose-evaluation procedure must be easily applied in a clinical setting. Investigators did not always consider *all* of these requirements; for this reason, the literature has shown a significant range of doses for the same techniques. Previous work has been carefully reviewed in preparation of this Report in order to determine a preferred approach to dose evaluation.

[7]The term "dose" in this Report is used generically when not referring to a specific quantity, such as "mean glandular dose."

5.1.2 *Coverage*

Section 5.2 explains why the *mean glandular dose* most appropriately characterizes radiation risk from mammography and discusses several other dose quantities that have been widely used. A brief review is also included of x-ray exposure, air kerma, and absorbed dose concepts.

Section 5.3 discusses the basic approach of the recommended method and explains how mean glandular dose is determined. Section 5.4 presents a summary of current dose recommendations, doses measured in nationwide surveys, and also the relationship of phantom dose determinations to actual dose delivered in clinical examinations. Section 5.5 summarizes the recommended dose-evaluation procedure.

5.2 Risk-Related Dose

5.2.1 *Radiation Risk*

Three considerations must be kept in mind in estimating the potential carcinogenic radiation risk of mammography. First, glandular tissue is the most vulnerable in the breast as compared to adipose, skin and areolar (nipple) tissues (Hammerstein *et al*., 1979). (In this context "glandular tissue," which includes acinar and ductal epithelium and associated stroma is assumed to have equal sensitivity throughout.) Second, the *mean* rather than maximum dose to the glandular tissue most usefully characterizes risk of carcinogenesis and is consistent with an assumed linear dose-response relationship. Third, the population of primary interest is women 40 y and older since younger women are likely to have only diagnostic mammographic examinations because of physical findings (or a single baseline screening study); it is therefore, reasonable to assume that the dose calculations apply primarily to breasts containing a larger fraction of adipose tissue found primarily in older women (Section 5.3.1).

5.2.2 *Variables Affecting Dose*

The major variables that affect the breast dose per view delivered in a mammographic examination are: the choice of image receptor, the x-ray beam energy (HVL and kilovolt peak), the degree of breast compression, and the breast size and adiposity (Table 5.1). Xeroradiography systems are not considered since their

TABLE 5.1—*Variables affecting breast dose.*

- Breast size and adiposity
  - Thickness: Exerts great effect.
  - Field size: Exerts minimal effect.
  - Adiposity: Only a moderate effect.
- X-ray beam energy (HVL)
  - Breast dose is reduced when beam energy is increased. This may be at the cost of reduced image contrast.
  - There is a slight variation of breast dose for constant HVL, but varying tube potential.
  - The use of rhodium filters or targets can reduce breast dose for thicker or more glandular breasts. This may be at the cost of reduced image contrast.
- Types of image receptor
  - Optimum beam HVL for screen-film technique is 0.3 to 0.4 mm Al.
  - Breast dose is determined by required optical density.
  - Optimum settings for digital systems are individually determined for each type of system. Breast dose is determined by required *SNR*.
- Grid versus nongrid
  - The bucky factor for most mammography grids is about 2 to 2.5 leading to an increase in breast dose by this factor for grid versus nongrid techniques.
- Degree of breast compression
  - Firm compression reduces breast dose as much as 50 percent and is *indispensable* for best image quality with all techniques.

manufacture has been discontinued. It should be noted here that the dose associated with any digital technique is not governed by the need to obtain a proper image density or brightness, since that may be obtained for almost any dose with appropriate manipulation of the window and level controls. Doses for those techniques are normally determined by the need to obtain an acceptable *SNR* in the image.

Increasing the x-ray beam energy tends to reduce breast dose but at the cost of image contrast. As a result, there is an optimum and quite narrow range of beam quality for screen-film breast imaging. In recent years, special target-filter combinations, such as Rh/Rh or Mo/Rh, have been introduced to obtain high-quality images of breasts of greater thickness or with a higher percentage of glandular tissue.

Firm compression greatly reduces the dose (Figure 5.1). The effect of firm compression is to spread the breast volume laterally, thereby significantly reducing the x-ray path through the breast. Possible dose reductions as a result of breast compression can exceed 50 percent for screen-film techniques. Compression also greatly modifies the breast shape. By making the sagittal and transverse cross-sections of the breast and its glandular component more nearly rectangular (Figures 5.2a and 5.2b), the compression simplifies the geometric configuration of breast structures and permits use of the computational model of Figure 5.2c in dose determinations (Section 5.3).

Female breasts vary greatly in size and adiposity resulting in a significant range of dose values for a given technique. The compressed breast thickness affects dose to a great degree and, hence, must be specified to obtain accurate dose values. Although the breast area when compressed also varies greatly, the effect on dose is relatively small. For example, an increase from 35 to 270 cm^2 changes the dose to the breast by <10 percent (Dance, 1980). Finally, a breast containing a high fraction of adipose tissue is more readily penetrated than one containing a high fraction of fibroglandular tissue, and thus, a fatty breast receives a lower dose per view from the same technique. However, simple dose-evaluation procedures can yield mean glandular dose values reasonably independent of moderate differences in breast composition so that simple corrections can be applied (Stanton *et al*., 1984).

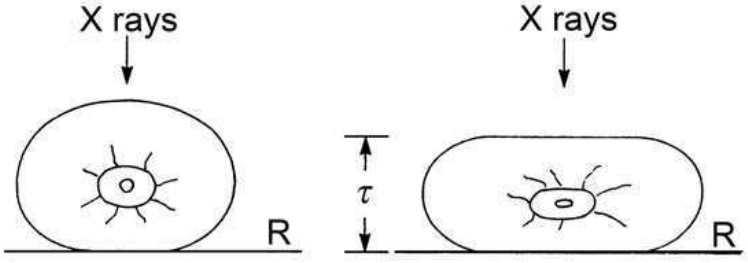


Fig. 5.1. Effect of firm compression on breast contour. Breast is essentially spread out laterally (right) and made more uniform in thickness, so that x rays traverse less thickness (τ) (centimeters). Consequently, a shorter exposure is required with corresponding dose reduction. Scatter to the image receptor R is also reduced, significantly improving image contrast. The resulting image improvement is *indispensable* in screen-film mammography.

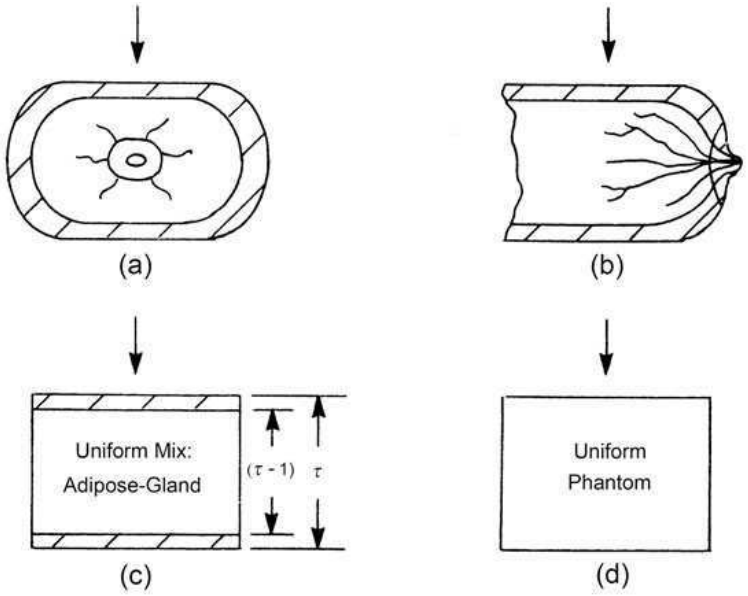


Fig. 5.2. By making the sagittal (a) and transverse (b) cross sections of the breast more nearly rectangular with compression, computational model (c) can be utilized for estimating the mean glandular dose ($\overline{D}_g$) (Hammerstein *et al.*, 1979). The computational model for mean whole breast dose is (d). Outer hatched area in a, b and c represents skin and outer adipose layer thickness of 0.5 cm (Stanton *et al.*, 1984).

A reference breast composition must be used when comparing doses from different techniques. By common usage, 50 percent water, 50 percent fat by weight has been an unofficial standard since 1976 for "average breast." The synthetic mix BR-12® closely matches the radiological properties of this composition (Hammerstein *et al.*, 1979; ICRU, 1989) and is used extensively in dosimetry phantoms. Geise and Palchevsky (1996) have suggested that 30 percent glandular, 70 percent adipose might be a better match to the average patient. Although this suggestion has not been widely adopted in the radiological community, this Report contains data to calculate dose to a breast of this composition for the Mo target-Mo filter combination. (Table 5.2d). Other publications that indicate there is a lower glandular tissue content (*e.g.*, less than 50 percent grandular tissue) in the average breast are those of Heggie (1996), Klein *et al.* (1997), and Kruger and Schueler (2001).

5.2.3 *Why "Mean Glandular Dose?"*

The mammography literature has frequently used the term "dose" when x-ray exposure was actually measured, usually free-in-air (i.e., no backscatter) or at the skin (with backscatter). Moreover, absorbed doses have often referred to the breast mid-plane value or to the average for the entire breast. To explain why mean glandular dose ($\bar{D}_g$) is the preferred quantity, a brief conceptual discussion of x-ray exposure and absorbed dose is given below; this is followed by a comparison of the dosimetric quantities of most interest for mammography.

5.2.3.1 *Absorbed Dose, X-Ray Exposure, and Air Kerma*. Radiation effects result from the deposition of energy in tissue. Absorbed dose (D) is the energy imparted by ionizing radiation to matter in a volume element, divided by the mass of matter in that element. The International System (SI) special name for the quantity absorbed dose is the gray (Gy), where 1 Gy is an energy absorption of one joule per kilogram.

Although absorbed dose is the quantity most directly related to biological effects, it cannot be directly measured in the breast. However, x-ray exposure can be measured in suitable phantoms for given spectra and the result used to estimate absorbed dose (Hammerstein *et al*., 1979). X-ray exposure (X), is related to the ion concentration (number of ion pairs per gram) produced in a tiny volume of air at the location of interest, under specified conditions. More complete discussions of radiation quantities and their measurements are available in various radiological physics texts.

In practice, the distribution of x-ray exposure in suitable homogeneous phantoms is measured by thermoluminescent dosimeters or ionization chambers. The measurements can then be used to estimate the exposure distribution in a simplified model of the human breast, such as that of Figure 5.2c (Hammerstein *et al*., 1979). From that result, the desired absorbed dose (D) (in rad) from exposure (X) (in roentgen) at any location of interest can be directly computed using the appropriate exposure to absorbed dose conversion factor ($\bar{f}_m$) in a given material (m) (in rad per roentgen):

$$D = X\bar{f}_m . \tag{5.1a}$$

In the SI system of quantities and units, Equation 5.1a would be:

$$D = K_a\bar{f}_m \tag{5.1b}$$

where $\bar{D}$ is absorbed dose in milligray, K_a is air kerma in milligray, and $(\bar{f}_m)$ is an air kerma to absorbed dose conversion factor in milligray per milligray air kerma for the material (m) of concern (adipose tissue, glandular tissue, etc.).

Published $(\bar{f}_m)$ values for 10 to 40 keV x rays range from 0.58 to 0.65 and 0.90 to 0.92 mGy per milligray air kerma (0.51 to 0.57 and 0.79 to 0.81 rad per roentgen), respectively, for adipose (ad) and breast glandular tissue (g), respectively (Hammerstein *et al*., 1979). Because of the small change in $(\bar{f}_m)$ over this energy range, single values of 0.62 mGy per milligray air kerma (0.54 rad per roentgen) $(\bar{f}_{ad})$ and 0.90 mGy per milligray air kerma (0.79 rad per roentgen) $(\bar{f}_g)$ have been used for mammographic dose calculations (Stanton *et al*., 1984).

5.2.3.2 *Depth Dose Distributions.* Figure 5.3 illustrates how x-ray exposure, air kerma, and absorbed dose values change with depth in the simplified breast model of Figure 5.2c, when the latter receives a nominal x-ray exposure (free-in-air) at the entrance surface of the breast of 1 R (8.76 mGy air kerma), and the beam HVL is 0.37 mm Al. Such a beam would be representative of a screen-film technique with grid. With the breast in place, some of the incident x-ray energy is scattered back to the entrance location increasing the surface skin exposure (or air kerma) by about 10 percent. The light solid curve (top curve) in Figure 5.3 shows the relative depth-dose distribution for exposure (or air kerma) from the skin entrance to the exit surface.

The adipose tissue absorbed dose (dashed line, bottom curve in Figure 5.3) is given by Equation 5.1, using the $\bar{f}_{ad}$ value of 0.62 mGy per milligray air kerma (0.54 rad per roentgen exposure). In the central volume, glandular and adipose tissue elements lie adjacent to each other. They can, therefore, receive the same exposure (or air kerma) at a given depth, but quite different absorbed doses. For example, the midplane exposure (or air kerma) at 2.25 cm depth is the same for both tissues but the absorbed dose to glandular tissue is about 30 percent higher than that for the adjacent adipose tissue. The single quantity most relevant to radiation risk is the mean glandular dose $(\bar{D}_g)$, which is obtained as described in Section 5.3.1 and Equation 5.2.

5.2.3.3 *Mean Glandular Dose and Other Dose Terms Compared.* The mean absorbed dose to the glandular tissue [mean glandular dose $(\bar{D}_g)$] is the preferred measure of potential carcinogenic risk from mammography. This quantity can be readily estimated with

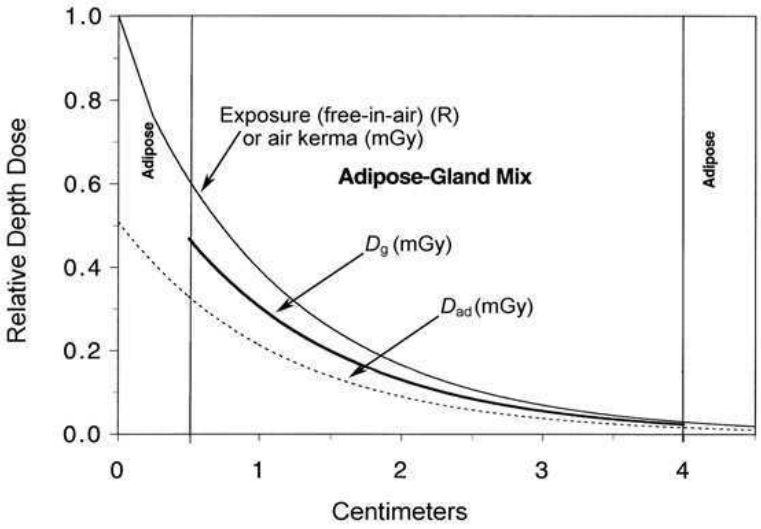


Fig. 5.3. Variation of x-ray exposure, air kerma and absorbed dose with depth in the breast. For the 4.5 cm thick breast model of Figure 5.2c, normalized to 8.76 mGy air kerma (1 R) (free-in-air at the entrance skin surface) for a 0.37 mm Al HVL beam. The top curve of exposure (or air kerma) versus depth (light solid line) applies to both adipose and glandular tissue, but two separate absorbed dose curves result. The absorbed dose to glandular tissue (dark solid line, D_g) is consistently greater at a given depth than that for adjacent adipose tissue (dashed curve, D_{ad}). The D_g curve is limited to the central region where glandular tissue is present.

good accuracy, so it has become the standard "mammographic dose" quantity. However, some comment is in order regarding three other widely used quantities: skin dose, midplane glandular dose, and average whole-breast dose. (The latter is approximated by the absorbed dose to a uniform breast phantom of the same thickness in Figure 5.2d).

The skin dose (D_s) has been widely quoted in the past, probably because it is most easily determined. However, it is a poor choice because skin is not the tissue at risk for radiation carcinogenesis, and the ratio D_s per $\overline{D}_g$ varies greatly with both beam quality and breast thickness. Midplane dose to the glandular tissue (D_{mg}) can be confused with $\overline{D}_g$, and the latter may be substantially greater for screen-film techniques. The mean whole-breast absorbed dose ($\overline{D}$) is reasonably close in value to $\overline{D}_g$, for an "average breast" composition of 50 percent water, 50 percent fat by weight. There have been many publications on evaluation of $\overline{D}$. However, $\overline{D}$ varies

much more with changes in breast adiposity than does $\overline{D}_g$ (Stanton *et al.*, 1984). The practical result is that estimates for $\overline{D}$ for patients with very dense or fatty breasts tend to involve much greater errors than those for $\overline{D}_g$. Consequently, Section 5.3 describes evaluation of mean glandular dose ($\overline{D}_g$) only.

5.3 Dose-Evaluation Principles

5.3.1 *Introduction*

Direct evaluation of mean glandular dose ($\overline{D}_g$) is complicated by the many variables on which x-ray exposure depends. Fortunately, $\overline{D}_g$ can be computed from the simple relationship:

$$\overline{D}_g = \overline{D}_{gN} X_a \tag{5.2}$$

Here $\overline{D}_{gN}$ is the mean glandular dose (in millirad) resulting from an incident exposure (free-in-air) of 1 R, and X_a is the incident exposure (free-in-air) needed to produce a proper density image.[8] To good accuracy, the value of $\overline{D}_{gN}$ depends on only four quantities: the beam energy (HVL and operating potential), the x-ray tube target material (molybdenum, tungsten and, most recently, rhodium) and filter materials (molybdenum, rhodium, and sometimes aluminum), breast thickness, and breast composition. When breast composition is known, it is possible to construct simple working curves or tables to evaluate $\overline{D}_{gN}$ (Dance, 1980; Stanton *et al.*, 1984). Tables 5.2a through 5.2j give values of $\overline{D}_{gN}$ for Mo target-Mo filter, Mo target-Rh filter, and Rh target-Rh filter for 50 percent glandular-50 percent adipose tissue, 100 percent adipose tissue, and 100 percent glandular tissue (Wu *et al.*, 1991; 1994). In addition, values of $\overline{D}_{gN}$ for Mo target-Mo filter and 30 percent glandular-70 percent adipose are also provided by Wu.[9] The effect on $\overline{D}_{gN}$ of moderate departures from this composition is not great (NCRP, 1986). The exposure (free-in-air) required for proper image density (X_a) is

[8]In the SI system of quantities and units, Equation 5.2 would be expressed as: $\overline{D}_g = \overline{D}_{gN} K_a$, where $\overline{D}_{gN}$ is the mean glandular dose (in microgray) resulting from an incident air kerma (K_a) (free-in-air) of 1 mGy, and K_a is the incident air kerma (free-in-air) (in milligray) needed to produce a proper density image.

[9]Wu, X. (2000). Personal communication (University of Alabama Hospitals and Clinics, Birmingham, Alabama).

determined from x-ray output measurements (Sections 5.3.3 and 5.3.4). Parameterization of these data has been published by Sobol and Wu (1997).

5.3.2 *Determination of Mean Glandular Dose (in millirad) per 1 R Entrance Skin Exposure (free-in-air)*

Both experimental and computational methods have been employed to evaluate $\bar{D}_{gN}$. An earlier method begins with measurements of exposure versus depth and backscatter factors, using a breast phantom. Refer to Figure 5.3, from which glandular tissue dose as a function of depth (z) [$D_g(z)$] can be determined as follows:

$$D_g(z) = \bar{f}_g X_s \left[\frac{X_g(z)}{X_s}\right], \tag{5.3}$$

where $\bar{f}_g$ is the exposure-to-dose conversion factor for glandular tissue, essentially a constant in mammography (Section 5.2.3.1), X_s is the incident skin surface exposure (with backscatter) (in roentgen), $X_g(z)$ is the exposure to glandular tissue at depth z cm (in roentgen), and $X_s = B\,X_a$, where B is the backscatter factor. Therefore:

$$D_{gN}(z) = \frac{D_g(z)}{X_a} = \bar{f}_g B \left[\frac{X_g(z)}{X_s}\right] \tag{5.4}$$

Since $\bar{f}_g$ is essentially independent of depth in the breast, the mean value of D_{gN} over the central glandular region ($\bar{D}_{gN}$) is:

$$\bar{D}_{gN} = \bar{f}_g B \left(\frac{X_g}{X_s}\right)_{av} \tag{5.5}$$

where $(X_g/X_s)_{av}$ is the mean value (over z) of the ratio $[X_g(z)/X_s]$ in this glandular region. Values of B for low atomic number materials have been published (Johns and Cunningham, 1983; Stanton *et al*., 1984). Additional data on backscatter factors for HVLs in the mammography range are available in Bewley *et al*. (1983). In addition, x-ray exposure versus depth data are available (Hammerstein *et al*., 1979; Stanton *et al*., 1984) from which the ratio $[X_g(z)/X_s]$ versus depth z can be computed. For a given x-ray tube target material, $\bar{D}_{gN}$ can be computed with good accuracy from the breast thickness and the HVL.

$\bar{D}_{gN}$ can also be computed directly by Monte Carlo methods, starting with mammography x-ray beam spectra (Dance, 1980; Wu *et al*., 1991; 1994). Tables 5.2a through 5.2j provide data from

TABLE 5.2a—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Mo filter and 100 percent glandular breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
23 kVp						
0.24	136	100	78	63	53	46
0.26	146	107	84	68	58	50
0.28	157	115	90	73	62	53
0.30	167	123	96	79	66	57
0.32	177	131	102	84	70	61
0.34	188	139	109	89	75	64
25 kVp						
0.26	151	112	87	71	60	52
0.28	161	119	93	76	64	55
0.30	171	127	99	81	68	59
0.32	181	134	105	86	73	63
0.34	191	142	111	91	77	66
0.36	201	149	117	96	81	70
27 kVp						
0.28	165	122	96	78	66	57
0.30	174	130	102	83	70	61
0.32	184	137	108	88	74	64
0.34	194	144	114	93	78	68
0.36	203	152	119	98	83	71
0.38	213	159	125	103	87	75
29 kVp						
0.30	177	132	104	85	72	62
0.32	187	139	110	90	76	66
0.34	196	147	116	95	80	69

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
0.36	205	154	121	100	84	73
0.38	215	161	127	104	88	76
0.40	224	169	133	109	92	80
31 kVp						
0.31	184	138	109	89	75	65
0.33	193	145	115	94	80	69
0.35	203	152	120	99	84	72
0.37	212	160	126	104	88	76
0.39	221	167	132	109	92	80
0.41	231	174	138	113	96	83
33 kVp						
0.32	190	143	113	93	79	68
0.34	200	150	119	98	83	72
0.36	209	158	125	103	87	75
0.38	218	165	131	108	91	79
0.40	228	172	137	113	96	83
0.42	237	179	143	118	100	86
35 kVp						
0.33	197	148	118	97	82	71
0.35	206	156	124	102	86	75
0.37	215	163	130	107	91	79
0.39	225	170	136	112	95	82
0.41	234	178	142	117	99	86
0.43	243	185	148	122	104	90

[a]To convert values of $\overline{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in milligray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1991).

TABLE 5.2b—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Mo filter and 50 percent glandular-50 percent adipose breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
23 kVp						
0.24	166	126	100	82	69	60
0.26	179	135	107	88	75	65
0.28	191	145	115	95	80	69
0.30	203	155	123	101	86	74
0.32	216	164	131	108	91	79
0.34	228	174	139	114	97	84
25 kVp						
0.26	184	140	112	92	78	67
0.28	196	149	119	98	83	72
0.30	207	159	127	104	89	77
0.32	219	168	134	111	94	81
0.34	231	177	142	117	99	86
0.36	242	186	149	123	104	90
27 kVp						
0.28	199	153	122	101	85	74
0.30	211	162	129	107	91	79
0.32	222	171	137	113	96	83
0.34	234	180	144	119	101	88
0.36	245	189	152	125	107	92
0.38	256	198	159	132	112	97
29 kVp						
0.30	214	164	132	109	93	80
0.32	225	173	139	115	98	85
0.34	236	182	146	121	103	89

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
0.36	247	191	154	127	108	94
0.38	258	200	161	134	114	99
0.40	269	209	168	140	119	103
31 kVp						
0.31	221	171	137	114	97	84
0.33	232	180	145	120	102	89
0.35	243	189	152	126	107	93
0.37	254	197	159	132	113	98
0.39	265	206	166	138	118	102
0.41	276	215	174	144	123	107
33 kVp						
0.32	229	177	143	119	101	88
0.34	239	186	150	125	106	92
0.36	250	195	157	131	112	97
0.38	261	203	164	137	117	102
0.40	272	212	172	143	122	106
0.42	282	221	179	149	127	111
35 kVp						
0.33	236	183	148	123	105	91
0.35	246	192	155	129	110	96
0.37	257	201	163	136	116	101
0.39	268	210	170	142	121	105
0.41	279	218	177	148	126	110
0.43	289	227	185	154	132	115

[a]To convert values of $\overline{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from *Wu et al*. (1991).

TABLE 5.2c—*Values of* $\overline{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Mo filter and 100 percent adipose breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
23 kVp						
0.24	207	163	132	110	94	82
0.26	221	175	142	119	102	89
0.28	236	187	152	128	109	95
0.30	251	199	163	136	117	101
0.32	265	211	173	145	124	108
0.34	280	223	183	153	131	114
25 kVp						
0.26	227	180	147	123	106	92
0.28	241	192	157	132	113	98
0.30	255	203	166	140	120	104
0.32	268	214	176	148	127	111
0.34	282	226	186	156	134	117
0.36	296	237	195	164	141	123
27 kVp						
0.28	245	195	160	135	115	101
0.30	258	206	170	143	122	107
0.32	271	217	179	151	129	113
0.34	285	229	188	159	136	119
0.36	298	240	198	167	143	125
0.38	311	251	207	175	150	131
29 kVp						
0.30	261	209	172	145	125	109
0.32	274	220	181	153	132	115
0.34	287	231	191	161	138	121

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
0.36	299	242	200	169	145	127
0.38	312	253	209	177	152	133
0.40	325	263	218	185	159	139
31 kVp						
0.31	269	217	179	151	130	114
0.33	282	227	188	159	137	120
0.35	295	238	197	167	144	126
0.37	307	249	206	175	150	132
0.39	320	259	215	182	157	138
0.41	332	270	224	190	164	144
33 kVp						
0.32	277	224	185	157	135	118
0.34	290	234	194	164	142	124
0.36	302	245	203	172	149	130
0.38	315	256	212	180	155	136
0.40	327	266	221	188	162	142
0.42	339	277	230	196	169	148
35 kVp						
0.33	285	231	191	162	140	122
0.35	297	241	200	170	147	129
0.37	310	252	209	178	154	135
0.39	322	262	219	186	161	141
0.41	334	273	228	194	167	147
0.43	347	284	237	201	174	153

[a]To convert values of $\overline{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in milligray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from *Wu et al*. (1991).

TABLE 5.2d—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Mo filter and 30 percent glandular-70 percent adipose breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
23 kVp						
0.24	181	139	111	92	78	68
0.26	194	150	120	99	84	73
0.28	208	160	129	107	91	79
0.30	221	171	137	114	97	84
0.32	234	181	146	121	103	89
0.34	247	192	155	128	109	95
25 kVp						
0.26	200	155	124	103	88	76
0.28	213	165	133	110	94	81
0.30	225	175	141	117	100	87
0.32	237	185	149	124	106	92
0.34	262	205	166	138	118	102
27 kVp						
0.28	216	168	136	113	96	84
0.30	228	178	144	120	102	89
0.32	240	188	152	127	108	94
0.34	253	198	160	134	114	99
0.36	265	208	168	140	120	104
0.38	277	217	176	147	126	109
29 kVp						
0.30	231	181	146	122	104	91
0.32	243	190	154	129	110	96
0.34	255	200	162	136	116	101
0.36	267	210	170	142	122	106

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
0.38	278	219	178	149	127	111
0.40	290	229	186	156	133	116
31 kVp						
0.31	239	188	153	127	109	95
0.33	251	197	160	134	115	100
0.35	262	207	168	141	120	105
0.37	274	216	176	148	126	110
0.39	285	226	184	154	132	115
0.41	297	235	192	161	138	120
33 kVp						
0.32	247	194	158	132	113	99
0.34	258	204	166	139	119	104
0.36	270	213	174	146	125	109
0.38	281	223	182	153	131	114
0.40	292	232	190	159	137	119
0.42	304	241	198	166	142	124
35 kVp						
0.33	254	201	164	137	117	102
0.35	265	210	172	144	123	108
0.37	277	220	180	151	129	113
0.39	288	229	188	158	135	118
0.41	300	238	196	164	141	123
0.43	311	248	204	171	147	129

[a]To convert values of $\overline{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu, X. [(2000), personal communication (University of Alabama Hospitals and Clinics, Birmingham, Alabama)] and Wu *et al*., 1991).

TABLE 5.2e—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Rh filter and 100 percent glandular breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	177	132	104	85	72	62
0.32	187	140	110	90	76	66
0.34	197	147	116	95	81	70
0.36	207	155	122	101	85	73
0.38	216	163	129	106	89	77
0.40	226	170	135	111	93	81
27 kVp						
0.34	200	150	119	98	83	71
0.36	209	158	125	102	87	75
0.38	219	165	131	107	91	79
0.40	228	172	137	112	95	82
0.42	237	180	143	117	99	86
0.44	247	187	149	122	104	90
29 kVp						
0.38	220	166	132	108	92	79
0.40	229	173	138	113	96	83
0.42	238	181	144	118	100	87
0.44	248	188	150	123	104	90
0.46	257	195	156	128	109	94
0.48	266	203	162	133	113	98

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	230	175	139	114	97	84
0.42	240	182	145	119	101	88
0.44	249	189	151	124	105	91
0.46	258	197	157	129	110	95
0.48	267	204	163	135	114	99
0.50	277	212	169	140	119	103
33 kVp						
0.42	241	183	146	121	102	89
0.44	250	191	152	126	107	92
0.46	259	198	158	131	111	96
0.48	268	206	164	136	116	100
0.50	278	213	171	142	120	104
0.52	287	221	178	147	125	109
35 kVp						
0.44	251	192	153	127	108	93
0.46	260	199	160	132	112	97
0.48	270	207	166	137	117	101
0.50	279	215	172	143	122	106
0.52	289	223	179	149	127	110
0.54	298	231	186	155	132	115

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b] Adapted from Wu *et al*. (1994).

TABLE 5.2f—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Rh filter and 50 percent glandular-50 percent adipose breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	213	164	132	109	93	81
0.32	225	174	140	116	98	85
0.34	236	183	147	122	104	90
0.36	248	192	155	128	109	95
0.38	259	201	162	135	115	99
0.40	270	210	170	141	120	104
27 kVp						
0.34	239	186	150	125	106	92
0.36	250	195	157	131	111	97
0.38	261	204	165	137	117	101
0.40	272	212	172	143	122	106
0.42	283	221	179	149	127	110
0.44	293	230	187	156	133	115
29 kVp						
0.38	262	205	166	138	118	102
0.40	273	214	173	144	123	107
0.42	284	222	180	150	128	111
0.44	294	231	187	156	133	116
0.46	305	240	195	163	139	121
0.48	315	249	202	169	144	126

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	274	215	174	145	124	108
0.42	285	223	181	151	129	112
0.44	295	232	189	158	135	117
0.46	306	241	196	164	140	122
0.48	316	250	203	170	146	127
0.50	326	259	211	177	151	132
33 kVp						
0.42	286	225	183	153	130	113
0.44	296	233	190	159	136	118
0.46	307	242	197	165	141	123
0.48	317	251	205	172	147	128
0.50	327	260	212	178	153	133
0.52	338	269	220	185	159	138
35 kVp						
0.44	297	234	191	160	137	119
0.46	308	243	199	166	142	124
0.48	318	252	206	173	148	129
0.50	328	261	214	180	154	134
0.52	339	270	222	186	160	140
0.54	349	279	230	194	166	145

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1994).

TABLE 5.2g—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Mo target-Rh filter and 100 percent adipose breast tissue.*[a,b]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	260	209	172	145	125	109
0.32	274	220	182	154	132	115
0.34	287	232	191	162	139	122
0.36	300	243	201	170	146	128
0.38	313	254	210	178	153	134
0.40	326	265	220	186	161	140
27 kVp						
0.34	290	234	194	165	142	124
0.36	302	245	204	172	149	130
0.38	315	256	213	180	156	136
0.40	327	267	222	188	162	142
0.42	340	277	231	196	169	148
0.44	352	288	240	204	176	155
29 kVp						
0.38	316	257	214	181	157	137
0.40	328	268	223	189	163	143
0.42	340	278	232	197	170	149
0.44	352	288	241	205	177	155
0.46	364	299	250	213	184	162
0.48	376	309	259	221	191	168

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	329	269	224	190	165	144
0.42	341	279	233	198	171	150
0.44	353	289	242	206	178	156
0.46	365	300	251	214	185	163
0.48	376	310	260	222	192	169
0.50	388	320	269	230	199	175
33 kVp						
0.42	342	280	234	199	172	151
0.44	354	290	243	207	179	158
0.46	365	301	252	215	186	164
0.48	377	311	261	223	193	170
0.50	388	321	270	231	201	176
0.52	400	331	279	239	208	183
35 kVp						
0.44	354	291	244	208	180	159
0.46	366	302	253	216	187	165
0.48	378	312	262	224	195	171
0.50	389	322	271	232	202	178
0.52	400	332	280	240	209	184
0.54	411	343	290	249	217	191

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1994).

TABLE 5.2h—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Rh target-Rh filter and 100 percent glandular breast tissue.*[a]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	178	134	106	87	74	64
0.32	189	143	113	93	79	68
0.34	200	151	120	99	84	72
0.36	210	159	127	104	88	77
0.38	221	168	133	110	93	81
0.40	231	176	140	116	98	85
27 kVp						
0.34	207	158	126	104	88	76
0.36	217	166	133	110	93	81
0.38	227	174	139	115	98	85
0.40	237	182	146	121	102	89
0.42	247	190	152	126	107	93
0.44	257	198	159	131	112	97
29 kVp						
0.38	232	179	144	119	101	88
0.40	242	187	150	124	106	92
0.42	252	194	156	130	110	96
0.44	261	202	163	135	115	100
0.46	270	209	169	140	119	103
0.48	279	217	175	145	124	107

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	246	191	154	128	109	94
0.42	255	198	160	133	113	98
0.44	264	205	166	138	118	102
0.46	273	213	172	143	122	106
0.48	282	220	178	148	126	110
0.50	291	227	184	153	131	113
33 kVp						
0.42	258	201	163	136	116	100
0.44	267	208	169	141	120	104
0.46	276	216	175	146	124	108
0.48	285	223	181	151	128	112
0.50	293	230	186	156	133	115
0.52	302	237	192	160	137	119
35 kVp						
0.44	270	211	171	143	122	106
0.46	278	218	177	148	126	110
0.48	278	225	173	153	130	113
0.50	295	232	189	158	135	117
0.52	304	239	194	162	139	121
0.54	312	246	200	167	143	124

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1994).

TABLE 5.2i—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Rh target-Rh filter and 50 percent glandular and 50 percent adipose breast tissue.*[a]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	214	166	134	111	95	82
0.32	226	176	142	118	101	88
0.34	239	186	151	126	107	93
0.36	251	196	159	133	113	98
0.38	263	206	167	140	119	104
0.40	275	216	175	147	125	109
27 kVp						
0.34	246	193	157	132	113	98
0.36	257	203	165	138	118	103
0.38	269	212	173	145	124	108
0.40	280	222	181	152	130	113
0.42	291	231	189	159	136	118
0.44	302	240	197	165	142	123
29 kVp						
0.38	274	217	178	150	128	112
0.40	284	227	186	156	134	117
0.42	295	236	193	163	140	122
0.44	306	244	201	169	145	127
0.46	316	253	208	176	151	132
0.48	326	262	216	182	156	136

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	288	230	190	160	137	120
0.42	298	239	197	166	143	125
0.44	309	248	204	172	148	130
0.46	319	256	212	179	154	134
0.48	329	265	219	185	159	139
0.50	338	273	226	191	164	144
33 kVp						
0.42	301	242	200	169	145	127
0.44	311	251	207	175	151	132
0.46	321	259	214	181	156	137
0.48	331	267	221	187	161	141
0.50	340	275	228	193	167	146
0.52	350	284	235	199	172	150
35 kVp						
0.44	313	253	210	178	153	134
0.46	323	261	217	184	158	139
0.48	333	270	224	190	164	143
0.50	342	278	231	195	169	148
0.52	351	285	237	201	174	152
0.54	360	293	244	207	179	157

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1994).

TABLE 5.2j—*Values of* $\bar{D}_{gN}$ *[mean glandular dose (millirad) for 1 R entrance skin exposure (free-in-air)] for Rh target-Rh filter and 100 percent adipose breast tissue.*[a]

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
25 kVp						
0.30	260	209	173	147	127	111
0.32	274	222	184	156	135	118
0.34	289	234	194	165	142	125
0.36	303	246	205	174	150	132
0.38	316	258	215	183	158	139
0.40	329	269	225	192	166	145
27 kVp						
0.34	295	241	201	172	149	131
0.36	308	252	211	180	156	137
0.38	321	264	221	189	164	144
0.40	334	275	231	197	171	151
0.42	346	286	240	206	179	157
0.44	358	296	250	214	186	164
29 kVp						
0.38	325	268	226	194	168	148
0.40	337	279	235	202	176	155
0.42	349	290	245	210	183	161
0.44	361	300	254	218	190	167
0.46	372	310	263	226	197	173
0.48	383	320	271	233	204	180

Operating Potential and HVL (mm Al)	Compressed Breast Thickness (cm)					
	3	4	5	6	7	8
31 kVp						
0.40	340	283	239	205	179	158
0.42	352	293	248	213	186	164
0.44	363	303	257	221	193	170
0.46	374	313	266	229	200	176
0.48	385	323	274	236	206	182
0.50	396	332	283	244	213	188
33 kVp						
0.42	354	296	251	216	189	167
0.44	365	306	260	224	196	173
0.46	376	315	268	231	202	179
0.48	387	325	277	239	209	185
0.50	397	334	285	246	215	191
0.52	408	344	293	254	222	196
35 kVp						
0.44	367	308	262	226	198	175
0.46	378	317	270	234	204	181
0.48	388	327	279	241	211	187
0.50	399	336	287	248	217	192
0.52	409	345	295	255	224	198
0.54	419	354	303	263	230	204

[a]To convert values of $\bar{D}_{gN}$ from millirad per roentgen to the SI system of quantities and units (in microgray mean glandular dose per milligray incident air kerma), multiply table entry by 1.14.

[b]Adapted from Wu *et al*. (1994).

Wu *et al*. (1991; 1994) and X. Wu,[10] which include the effects of operating potential, as well as HVL and values for different targets and filters.

5.3.3 *Needed Measurements*

Evaluation of the mean glandular dose ($\bar{D}_g$) for a given mammographic view requires knowledge of the x-ray exposure (free-in-air) (X_a), the x-ray beam HVL, operating potential, and the compressed breast thickness. Both ionization chambers and thermoluminescent dosimeters have been used for this purpose. The ionization chamber response should be constant to ±10 percent for beams of 0.3 to 1.5 mm Al HVL, and have a National Institute of Standards and Technology traceable calibration. In addition, the ionization chamber-instrument system must provide accurate, reproducible readings, with at least 99 percent of saturation ionization chamber current for the highest measured exposure rate levels, negligible chamber leakage current, and electrometer zero drift. Additional information is given in ICRU (1973), Johns and Cunningham (1983), NCRP (1981), and Stanton *et al*. (1984). Ionization chambers designed for mammography are normally calibrated for free-in-air exposure or air-kerma measurements.

Accurate determination of the HVL for mammography x-ray beams requires great care (Wagner *et al*., 1990). Generally, the same ionization chamber used for exposure measurements may also be used for HVL measurements, which must be performed using proper geometry (Johns and Cunningham, 1983). The added aluminum filters must be high-purity aluminum and the thickness verified by micrometer. Type 1145 aluminum, which is 99.99 percent pure, is now commercially available in 0.1 mm thick sheets. For very low-energy measurements, uniformity of absorber material thickness should be checked radiographically and determination of thickness by precision weighing is recommended.

Lithium fluoride thermoluminescent dosimeter extruded ribbons ("chips") have been used successfully for measurement of x-ray exposure (free-in-air), at the entrance surface (with backscatter), and at depth in a phantom. Achievement of accurate results requires careful initial selection, handling and annealing of thermoluminescent dosimeter ribbons; also, multiple ribbons must be used for each measurement and corrections made for energy

[10]Wu, X. (2000). Personal communication (University of Alabama Hospitals and Clinics, Birmingham, Alabama).

dependence to insure accuracy (Hammerstein *et al*., 1979). Other corrections may also be required for residual signal after readout and for short-time fading. More extensive technical information on thermoluminescent dosimetry is available in specialized references (Robertson, 1974).

5.3.4 *Application to Patient Dosimetry*

The discussion in Sections 5.3.1 and 5.3.2 has dealt with the dose to a breast of reference composition (radiologically equivalent to 50 percent water, 50 percent fat by weight). The results are directly applicable to the comparison of dose levels from different techniques. A second important need is to monitor the patient dose. This Section explains in more detail how each of these important tasks may be accomplished.

5.3.4.1 *Comparing Techniques*. Values of $\overline{D}_{gN}$ from Tables 5.2a through 5.2j may be used for comparing doses from different techniques. The value of X_a is determined using a BR-12® breast phantom, consisting of a stack of 1 cm thick BR-12® slabs of total thickness appropriate to the degree of compression used and the phantom surface location. Radiographs of the phantom are then made, varying the exposure time. The desired X_a value is the product of the measured exposure rate and the exposure time in seconds that yields the desired image optical density. Density of film images may be checked by densitometer. The mean glandular dose ($\overline{D}_g$) can then be computed by Equation 5.2.

5.3.4.2 *Monitoring Patient Dose*. When screening programs are being established, the primary concern is the potential carcinogenic risk to a large group of women examined, rather than to specific individuals (Section 7). The average value of the mean glandular dose $\overline{D}_g$ for the group is hence most important, and the average breast thickness and composition most relevant. In a reasonably large population of women 40 y and older, this average composition differs only moderately from the composition of a reference phantom.

When there is concern by an individual woman about the dose received from a given mammography examination, dose calculations should be modified to account for the actual breast tissue composition of that patient, when possible.

5.4 Published Dose Recommendations and Surveys

5.4.1 *Recommendations*

Recommendations for acceptable mean glandular dose ($\overline{D}_g$) delivered for a single view to a standard thickness (4.5 cm) compressed breast of average composition have been issued by various national organizations, as well as national and state regulatory agencies. These groups now all agree that for a single view of a 4.5 cm compressed breast of average composition, the $\overline{D}_g$ should not exceed 3 mGy.

5.4.2 *National Surveys*

Both ACR, through MAP, and the FDA Center for Devices and Radiological Health have gathered data on $\overline{D}_g$ delivered to a standard thickness acrylic phantom which simulates a compressed breast of average thickness and composition. A summary of these data is presented in Table 5.3.

TABLE 5.3—*Typical values of* $\overline{D}_g$ *from nationwide surveys*.[a]

ACR-MAP (1992) Image Receptor	Number of Facilities	$\overline{D}_g$ (mGy)
Screen-film, grid	5,054	1.28 (Range: 0.15 – 7.45)

CDRH/NEXT (1992)[b] Image Receptor	Number of Facilities	$\overline{D}_g$ (mGy)
Screen-film, grid	187	1.8 ± 0.05

MQSA/NEXT (1988 – 1997)[c]

	Year				
Parameter	1988	1992	1995	1996	1997
X_a, entrance skin exposure (free-in-air) (mR)	683	N/A	910	943	965
HVL (mm Al)	0.38	0.35	0.33	0.33	0.33
$\overline{D}_g$ (mGy)	1.33	1.49	1.50	1.56	1.60

[a]Quantities and units are as given in the original publication of the data.
[b]Conway *et al*. (1994).
[c]Suleiman *et al*. (1999).

5.5 Summary

Table 5.4 lists steps for two dose-evaluation approaches. Approach I is employed for determining the mean glandular dose ($\overline{D}_g$) delivered to a breast of reference composition by the equipment at a particular facility. This may then be compared to published national averages (Table 5.3). Approach II is required for determining $\overline{D}_g$ for a range of actual patients at a facility. The demographics for patient populations may differ greatly from one mammography facility to another.

TABLE 5.4—*Dose-evaluation procedures* (for $\overline{D}_g$).

Approach I

1. Application: Comparing mean glandular dose ($\overline{D}_g$) from various techniques and comparing facility equipment performance to national averages.

2. Procedure:
   a. Note tube target and filter materials, operating potential (kVp), and breast thickness
   b. Measure HVL (mm Al)
   c. Use these data to obtain $\overline{D}_{gN}$ value from Table 5.2
   d. Measure incident x-ray exposure rate (per *mAs*) (no phantom)
   e. Determine required *mAs* for proper image density in radiographing standard phantom
   f. Calculate X_a as the product of results of Steps d and e.
   g. Determine mean glandular dose using $\overline{D}_g = \overline{D}_{gN} X_a$

Approach II

1. Application: Determination of the average value of $\overline{D}_g$ for a specific population of patients.

2. Procedure: Same as above, except Step e: *mAs* is instead determined from an average for a large representative sample of patients with varying compressed breast thicknesses.

6. Quality Assurance

Quality assurance (QA) in mammography is defined as those planned and systematic activities that monitor and improve the early detection of breast cancer and the evaluation of breast disease. Those activities include the employment, training, and continuing education and experience of qualified personnel. They also include the selection of appropriate mammography equipment, acceptance testing and regular evaluation of equipment performance, and the evaluation of positioning and compression. QA also includes the evaluation of patient interactions, reporting of results, diagnostic accuracy, patient tracking, and follow-up.

QA activities may be subdivided into two major categories: quality-control (QC) procedures and quality administration procedures. QC includes the technical components of QA: equipment selection, equipment performance evaluation and routine equipment monitoring, technique factor selection, and evaluation of breast positioning and compression. Quality administration includes monitoring methods that assess interactions and communications between the mammography provider and the patient, and between the interpreting physician and the referring physician. Quality administration also includes steps that assess the skills of the interpreting physician by comparing screening or diagnostic results with patient outcomes and other administrative monitors of quality.

6.1 The Current Status of Quality Assurance in the United States

During the 1980s, the quality of mammography improved through the replacement of conventional x-ray units used for mammography by dedicated mammographic units and by the improvement of image receptors designed specifically for screen-film mammography (Bassett *et al*., 1992). During the mid-1980s, it was commonly believed that the use of a dedicated mammography unit with appropriate screen-film image receptors was adequate to insure high-quality mammographic images at low radiation dose.

During the latter half of the 1980s, several studies revealed that the use of dedicated mammography equipment alone was insufficient to insure the production of consistently high-quality images

at uniformly low radiation doses. The Nationwide Evaluation of X-Ray Trends conducted in 1985 (NEXT-85) evaluated radiation dose and image quality at 232 mammography sites in the United States. The NEXT-85 study found a wide variation in image quality and radiation dose from site-to-site (Conway *et al*., 1990; Reuter, 1986). Similar results were found in a survey of 29 dedicated screen-film mammography sites in the Philadelphia area in 1986 (Galkin *et al*., 1988). The study found that the film processors at 41 percent of sites varied in film mid-density by more than ±0.10 over a 15 d period, suggesting that short-term processor variations might be a common source of variation in mammographic image quality.

Data collected during the first six months of the ACR-MAP, which began in August 1987, confirmed the wide variations in image quality and dose observed in the NEXT-85 study (Hendrick, 1990; Hendrick *et al*., 1987). Data collected as part of ACR-MAP site applications indicated that most sites were not performing QC tests at adequate frequencies. For example, on ACR applications collected during 1987 and 1988, approximately one-half of sites claimed to perform daily processor sensitometry and less than one-third of sites claimed to perform, at least, monthly evaluation of image quality using a phantom (Hendrick *et al*., 1998). Data collected from ACR-MAP applicants over the first 6 y of the program indicated increased performance and improved performance frequencies of QC tests at mammography sites. In 1992, 88 percent of sites stated that they were performing daily processor sensitometry and 61 percent of sites stated they were performing, at least, monthly evaluations of image quality using a phantom (Hendrick *et al*., 1998). A 9 y study of film processing in radiology conducted by the Center for Devices and Radiologic Health found a high rate of underprocessing among hospitals (33 percent in 1987) and private practices (42 percent in 1989), but a surprisingly low rate of underprocessing among mammography sites (seven percent in 1988). This improved and significantly lowered the rate of poor processor performance in mammography (seven percent underprocessing in 1988 versus 18 percent underprocessing in 1985) was attributed to increased attention to QC practices at mammography sites (Suleiman *et al*., 1992).

The improvement in QC practices over time can be attributed to a number of factors including the advent of ACR-MAP in 1987, publication of the ACR *Mammography Quality Control Manual* (ACR, 1999); publication of AAPM Report No. 29 on *Equipment Requirements and Quality Control for Mammography* (AAPM, 1990); the ratification of the *ACR Standards for the Performance of Screening*

Mammography (ACR, 1990b); the ACR-MAP requirement that accredited mammography sites perform QC tests according to the ACR QC manuals beginning in January 1992, and the passage of MQSA in October of 1992 and its subsequent implementation.

Even though QC practices have improved over the last decade and a half, there is still room for improvement.

Quality administration of mammography practices is a newer concept than QC. While effective quality administration has been conducted and described in several model mammography practices (AHCPR, 1994; Bird, 1989; Linver *et al*., 1992; Sickles, 1990; 1992b), it is more recently becoming widespread among United States mammography sites. Prerequisites to an effective quality administration program are standardized reporting and recording of mammography results, a patient follow-up system, and a method to monitor outcomes of screened women or patients who receive both positive and negative results.

Comparison of screening results among sites, additionally, requires similarity of screened populations and a reporting and monitoring system standardized across mammography sites. Standardized reporting systems and computerized monitoring and follow-up systems have recently been introduced in the United States mammography market (ACR, 1998; Kopans, 1992a), but data comparing identically compiled results from different sites using a standardized reporting and tracking system have not yet been reported.

6.2 Essential Elements of an Effective Quality-Control Program

An effective QC program should begin with the selection of appropriate equipment for mammography and the use of qualified personnel, including the interpreting physician, radiologic technologist, and medical physicist, each of whom must participate actively in mammography QC.

An interpreting physician experienced in mammography should be designated to oversee, monitor and motivate the QC program at each mammography site. A radiologic technologist who is experienced in mammography and trained in mammography QC should be designated as the mammography QC technologist, performing the regular technologist QC tests. One technologist should be designated so that tests are performed consistently; the primary QC technologist should then train another technologist to perform the tests in a similar manner when the primary QC technologist is

absent. A medical physicist experienced in mammography and mammography QC should perform acceptance testing of new mammography equipment, perform annual equipment surveys, and review the site's ongoing QC program and records.

6.2.1 *Selection of Mammography Equipment*

The type of equipment used for mammography is crucial to obtaining images of consistently high quality (see also Section 2). A dedicated x-ray unit, designed specifically for mammography, is a requirement for both screening and diagnostic mammography. The unit should be equipped with low-attenuation parallel-plate compression devices, a foot-activated motorized compression drive, image-receptor holders and removable grids for both 18 × 24 cm and 24 × 30 cm image-receptor sizes, and AEC. The x-ray generator should be capable of <10 percent kilovolt peak ripple (<20 percent exposure ripple) to minimize excess patient dose. The system should be capable of generating an x-ray output of at least 7 mGy air kerma (800 mR) per second at the entrance surface of the breast in contact mode at 28 kVp. The system should be able to sustain this radiation output rate for at least 3 s (ACR, 1993). For diagnostic mammography, the system should have both large and small focal spots, and the small focal spot should be used for magnification mammography. Diagnostic mammography equipment should be equipped to obtain coned, compressed views in magnification mode.

Rather than specifying maximum focal-spot sizes, which has been traditional but problematic for measurement, there is growing consensus that system specifications should be given in terms of the limiting spatial resolution of the system. For example, a suggested performance specification is that the limiting spatial resolution should be measured using a high-contrast resolution bar pattern oriented parallel to the plane of the image receptor, centered left-to-right and at the chest wall, and 4.5 cm above the breast support surface. In this location, the limiting spatial resolution should be no less than 13 cycles mm^{-1} (lp mm^{-1}) with the pattern oriented with bars parallel to the anode-cathode axis, and no less than 11 cycles mm^{-1} (lp mm^{-1}) with the pattern oriented with bars perpendicular to the anode-cathode axis. Such a performance specification would eliminate the difficulties inherent in accurately measuring focal-spot sizes using different devices and different measurement methods (ACR, 1993; Kimme-Smith, 1992).

More detailed specifications for mammography x-ray units are available in two documents [*i.e.*, AAPM Report No. 29 lists both

general and specific mammography equipment requirements (Yaffe *et al*., 1990), and the ACR *Recommended Specifications for New Mammography Equipment* lists recommended specifications for newly manufactured screening x-ray equipment (ACR, 1993; Yaffe *et al*., 1995)].

6.2.2 *Selection of Screens and Films*

Fluorescent screens and films used in mammography should be those designed specifically for mammography. Screens and films should be matched to one another for spectral characteristics. Typically, green light-emitting screens are used with green light-sensitive films in mammography. Single-emulsion films should be used only with single-screen cassettes, with the emulsion of the film facing the fluorescent screen. However, higher speed receptors may be useful for magnification mammography where their faster speed helps reduce the effects of patient motion and breast radiation dose, both of which tend to be greater in magnification mammography. Additional information and recommended specifications for mammography screen-film image receptors are available in the published literature (Law and Kirkpatrick, 1989; 1990) and in the ACR Minimum Specifications for Mammography Image Receptors (ACR, 1993; AHCPR, 1994).

Screen-film combinations used for mammography should be capable of achieving a limiting spatial resolution (0.05 *MTF*) of at least 15 cycles mm^{-1} (lp mm^{-1}). Many current screen-film combinations can achieve limiting spatial resolutions of approximately 20 cycles mm^{-1} (lp mm^{-1}) or more.

6.2.3 *Selection of Film-Processing Conditions*

Mammography films should be processed in a processor suitable for, or designed specifically for, mammography and processed under conditions optimized for the mammography film. The processor should be operated with the chemistry, replenishment rate, processing time, and temperature specifically recommended by the film manufacturer for the film used. Typically, higher replenishment rates are required for mammography films due to the higher densities attained (ACR, 1993). A prolonged delay between film exposure and processing is not desirable due to loss of resultant film speed, a loss that can range from 6 to 46 percent over a 24 h period, depending on the mammography film (Kimme-Smith *et al*., 1991). If delayed processing is necessary, the length of delay should be kept constant and as short as possible (ACR, 1993).

6.2.4 *Quality-Control Procedures*

Regular quality-control (QC) procedures are essential to ensuring consistent mammography equipment performance. QC procedures may be subdivided into those tests conducted by the mammography QC technologist and those procedures conducted by the medical physicist.

Procedures that should be conducted by the QC technologist, recommended minimum frequencies, and the purpose of each test are listed in Table 6.1. Complete descriptions of the technologist QC tests are contained in the ACR *Mammography Quality Control Manual* (ACR, 1999) including required test equipment, step-by-step procedures, data recording forms, action limits, and corrective actions that should be taken if action limits are exceeded (ACR, 1999). Each site should have a technologist conducting QC tests according to the technologist's tests in the ACR (1999) manual.

Quality control (QC) requires consistent monitoring of quality. It is important to continue QC testing even if problems do not occur in the first few months of testing. QC is not just monitoring of quality, but also includes identifying that systems are "out-of-control" and taking appropriate actions when problems are identified. It is especially important that appropriate actions be taken when action limits are exceeded and before image quality and patient safety are compromised.

QC procedures that should be conducted by the medical physicist are listed in Table 6.2, and correspond to the tests for the medical physicist listed by ACR (1999). These tests should be conducted annually or after major equipment changes, including relocation of fixed mammography equipment. An independent evaluation of mammography image quality and artifacts by the medical physicist is important, since the medical physicist is in a position to compare image quality among a number of mammography sites. The medical physicist should also review the procedures and records of the technologist's QC tests at least annually and preferably on a more frequent basis, such as quarterly.

The ultimate responsibility for QC at each mammography site rests with the interpreting physician, who should take an active role in motivating, supporting and overseeing the QC activities of the radiologic technologist and medical physicist. The interpreting physician should insure that appropriately qualified and trained people are chosen for these important jobs, that adequate time and test equipment are made available to the QC technologist, and that QC records are properly maintained. The interpreting physician should review the QC records and reports of the QC technologist at

TABLE 6.1—*QC tests for the technologist listed in ACR QC manual (ACR, 1999).*

QC Test	Frequency	Purpose
Processor	Daily	To insure consistent film processing
Darkroom cleanliness	Daily	To minimize film artifacts caused by dirt and dust
Mobile unit	Daily	To insure consistency
Screen cleanliness	Weekly	To free cassettes and screens of dirt and dust
Viewboxes and viewing conditions	Weekly	To insure that film viewing conditions are appropriate
Phantom images	Weekly	To insure that film density, contrast, uniformity and image quality are adequate
Visual checklist	Monthly	To insure that x-ray system lights, displays, locks and detents work properly
Repeat analysis	Quarterly	To determine the numbers and causes of repeated mammograms
Analysis of fixer retention	Quarterly	To determine the residual fixer in processed film, as a measure of film storage life
Darkroom fog	Semi-annually	To insure minimal film fogging
Screen-film contact	Semi-annually	To insure that each cassette maintains adequate contact between screens and film
Compression force	Semi-annually	To insure that motor-driven compression yields adequate, but not excessive, breast compression force

TABLE 6.2—*QC tests for the medical physicist listed in the ACR QC manual (ACR, 1999).*

QC Test	Frequency	Purpose
Mammographic unit assembly evaluation	Annually	To insure that x-ray equipment locks, detents, indicators and mechanical supports for x-ray tube and image-receptor holder assembly work properly
Collimation assessment	Annually	To insure that the radiation field matches the light field and image receptor, and that the compression paddle is properly aligned
System resolution	Annually	To insure a sufficiently small focal spot to maintain image sharpness
Operating potential accuracy and reproducibility	Annually	To insure that the indicated tube potential is accurate and reproducible
Beam quality assessment	Annually	To insure that the HVL of the x-ray beam is adequate to minimize breast dose without contrast loss
AEC system performance	Annually	To insure that the AEC system performs properly across the full range of breast thickness
Uniformity of screens	Annually	To insure each cassette produces the same film optical density
Breast exposure and AEC reproducibility	Annually	To insure reproducible exposures
Mean glandular dose	Annually	To insure that breast radiation doses are appropriate
Image-quality evaluation	Annually	To insure that image quality is consistently high
Artifact evaluation	Annually	To isolate the sources of artifacts and insure that artifacts are eliminated
Radiation output rate	Annually	To insure adequate radiation output rate to obtain reasonable exposure times
Measurement of viewbox luminance and room illuminance	Annually	To insure appropriate viewing conditions

least quarterly, and the QC reports of the medical physicist each time a report is received. Interpreting physicians should also provide frequent and consistent feedback to all technologists about technique selection, clinical film quality, positioning and compression, as evaluated from clinical images.

6.2.5 *Acceptance Testing Procedures*

Acceptance testing of new mammography x-ray equipment shall be conducted by a qualified medical physicist prior to patient use. Acceptance testing should include the procedures performed by the medical physicist for QC testing (Table 6.2), plus additional tests to insure that all aspects of equipment performance are acceptable (Rossi and Hendrick, 1985; Yaffe *et al*., 1990). These include testing the equipment in all clinical modes (contact mode with the large focal spot and all available image-receptor sizes and holders, including grid and nongrid; magnification mode with the small focal spot at all available magnification factors without a grid), a range of milliampere second and kilovolt peak stations, density control settings, and all target-filter combinations. AEC reproducibility and phototimer performance should be checked in all modes for which it is used clinically, and for the clinical range of breast thicknesses and operating potential settings.

Acceptance testing is aided by previously obtaining a set of manufacturer-provided performance specifications. This permits direct comparison of acceptance test results with performance specifications. Complete manufacturer-provided performance specifications for mammography equipment are best obtained prior to purchase of equipment in a competitive process in response to a set of carefully prepared purchase specifications sent to manufacturers by the prospective purchaser. A medical physicist experienced in mammography is best qualified to prepare purchase specifications on behalf of the mammography site.

6.3 Quality Administration (Medical Audit)

A comprehensive mammography quality-assessment program not only evaluates equipment, image quality, and image processing, but also evaluates the appropriateness and accuracy of image interpretation. Although these latter assessments, collectively known as a medical audit, can be tedious and time consuming, they are especially important because they demonstrate one's success or failure in detecting otherwise occult breast cancer, the ultimate

indicator of mammography performance (AHCPR, 1994; Murphy *et al*., 1990; Sickles *et al*., 1990; Spring and Kimbrell-Wilmot, 1987). This Section describes the data collection procedures and statistical analyses involved in the conduct of such an audit, provides examples of the current audit results from an expert mammography screening practice, and concludes by discussing how to interpret and effectively use audit results.

6.3.1 *How to Conduct an Audit*

The first step in conducting an audit involves deciding which data to collect. Attempts at achieving completeness must be tempered by the realization that some data have relatively little importance, that other data are very difficult to acquire, and that the gathering of each additional data item requires extra time and expense. The core information basic to an audit includes the following:

- For each patient, a cancer risk profile (*e.g*., age, personal and family history of breast cancer), whether symptomatic, and whether the current mammography examination is interpreted in comparison with a prior examination.
- The exact number of true-positive (TP) and false-positive (FP) interpretations. This requires one to determine the ultimate clinical outcome of all positive cases; fortunately, this is not onerous for screening examinations because only a small percentage of screening cases are read as being positive.
- An estimate of the number of true-negative (TN) and false-negative (FN) interpretations. It is too costly to track all these cases because of the large numbers of normal examinations involved, the geographic mobility of women in the United States, and the need to assess breast health status at least 1 y after mammography (to include interval cancers). The best method to estimate the number of FN cases is by linkage of mammography data with those stored in a regional tumor registry that maintains a listing of almost all women in the region who are diagnosed as having breast cancer (Clark *et al*., 1995). A somewhat less accurate method is to calculate the number of FN cases by extrapolation from known results among reliably followed patients. The calculation is based on the percentage of examined women who are known to be followed in this reliable fashion (*e.g*., if approximately 50 percent of women

examined in a practice have further evaluation including biopsy within an institution at which all biopsy results are available, then one may estimate that twice that number of FN cases actually occurred at that institution).

- The cause of all known FN interpretations. This involves retrospective review of the images for these cases and determination of whether the cancers were not identified because of poor quality images (underexposure, overexposure, motion, etc.), improper patient positioning (deep lesions not included on the films), inaccurate interpretation, ineffective communication of accurate interpretation, or because benign fibroglandular tissue obscured visualization of noncalcified tumor masses.
- The cytologic or histologic diagnosis for all biopsied lesions. It is now generally accepted that lobular carcinoma *in situ*, along with atypical lobular and ductal hyperplasia, should be classified into a nonmalignant high-risk category, thereby limiting the definition of cancer to ductal carcinoma *in situ* (DCIS) and invasive ductal and lobular carcinoma (Burhenne *et al*., 1992; Dershaw *et al*., 1992; Page, 1986; Sickles, 1992b). In addition, cases of DCIS should be reported separately from those of invasive carcinoma (Tabar *et al*., 1992).
- The size, nodal status, and stage of all cancers. Most audits use the tumor-nodes-metastases staging system of either the American Joint Committee on Cancer (Greene *et al*., 2002) or the Union Internationale Contre le Cancer (Hermanek and Sobin, 1987). Definitions of the various tumors, nodes and metastases categories within these two classifications are identical, although the wording in the text of the American Joint Committee on Cancer and the Union Internationale Contre le Cancer documents is somewhat different (Beahrs, 1991).

Once data collection is complete, one then must decide which statistics to derive in analyzing the data.

- Most widely reported are calculations of sensitivity and specificity. However, these usually represent approximations of the true values, in part because TN and FN data are estimates rather than exact determinations and also for other reasons (Schmidt and Metz, 1990). Standard formulas calculate estimated sensitivity = TP/(TP + estimated FN), and estimated specificity = estimated TN/(FP + estimated TN).

- Positive predictive value (PPV) is derived using the formula PPV = TP/(TP + FP). Because the clinical outcome of every positive case should be determined during data collection, the exact PPV will be obtained rather than an estimate. Despite the use of exact data, however, there often is considerable variation in reporting PPV statistics, in part due to the differing methods that are used to define a "positive" interpretation (Kopans, 1992b; Linver *et al*., 1992; Sickles *et al*., 1990). For problem-solving mammography examinations, positive cases usually are limited to those for which biopsy is recommended; however, some radiologists also include cases where periodic short-term follow-up is suggested as a substitute for biopsy, thereby producing a different PPV. The situation is even more confusing for screening examinations. Radiologists who restrict their screening procedure to standard mammographic views may define as "positive" any examination for which they request additional imaging to further characterize detected findings, even if extra studies rule out the presence of a true lesion (Sickles *et al*., 1990). This approach produces a PPV that reflects the likelihood of malignancy for an abnormal screening interpretation, but such a PPV will be of considerably lesser magnitude than the PPV reported for problem-solving examinations, especially when positive cases are defined as those sufficiently abnormal to require biopsy.
- Biopsy yield of malignancy is calculated as number of cancers per number of biopsies.[11] The biopsy yield, which actually represents the PPV for breast biopsy, must be distinguished from the previously described definitions of PPV for mammography interpretations because biopsy will not always be done when recommended by the radiologist.
- Calculations characterizing the nature of the cancers detected at mammography should be reported. Most commonly reported are percentages of nonpalpable cancers and Stage 0 plus 1 cancers expressed in terms of total number of mammography examinations, total number of abnormal interpretations, or total number of cancers detected. As will be discussed, subsequently, these statistics in combination with the calculation of exact PPV, provide insight into

[11]All biopsies, whether obtained by percutaneous sampling (fine-needle aspiration or core biopsy) or by surgical excision, should be included in this calculation.

whether interpretations are in the mainstream of practice or whether they represent over- or underreading.

- All of the calculations described previously should be made not only for an entire mammography practice, but also for each participating radiologist in order to determine whether one or several of these individuals are reading below acceptable levels of performance (Linver *et al*., 1992; Murphy *et al*., 1990; Sickles *et al*., 1990).

The first medical audit of a given mammography practice will be tedious and time-consuming, whether conducted on paper or by computer. The bulk of this effort involves establishing the audit protocol itself, documenting the completeness of data collection procedures, verifying the accuracy of statistical analyses, and making an initial interpretation of audit results.

Subsequent audits are much easier to perform and take considerably less time, especially if data accrual occurs on an ongoing basis *via* a computerized data management program which then carries out the audit protocol on command without further human interaction. Indeed, such a computer program can gather the required data from its own databases, track unresolved abnormal cases automatically (when needed, generating letters requesting follow-up information from referring physicians), calculate the audit statistics, and print out the final report (Sickles, 1990). Once properly programmed, a computerized audit is far preferable to labor-intensive paper-based procedures, being much more rapid, reliable, reproducible and inexpensive.

Established computer software that performs medical audits is available commercially. Alternatively, a local programmer can be commissioned to write software customized to the specific needs of a mammography practice. Whichever type of program is selected, it is important that the auditing software interfaces with continually updated computer databases that store appropriate data on demographics, film interpretation, disposition of cases, biopsy results, and cancer staging. Furthermore, auditing software also should be compatible with the data format described in the Breast Imaging Reporting and Database System (BI-RADS®) established by ACR (1995; 1998; 1999). When data are stored according to this widely-accepted format, audit results can be pooled with results from many other practices that also use the same data format. In this manner, each mammography practice can compare its own audit results with those of a pooled national standard.

6.3.2 *Medical Audit Results from an Expert Mammography Screening Practice*

Although the audit results described herein come from a mammography practice that is restricted to screening examinations, audits also should be conducted for practices limited to problem-solving examinations and for practices that offer both screening and problem-solving examinations.

The mammography practice supplying the following audit data provides rapid-throughput screening for nominally asymptomatic physician-referred women. Screening is done using mammography alone with reliance on referring physicians to provide breast physical examination. Details of the principles behind the day-to-day operation of the practice have been reported previously (Sickles, 1988; Sickles *et al*., 1986a). In short, it utilizes streamlined procedures designed to provide high-quality mammography screening at low cost.

An integral part of this streamlined operation involves limiting screening to two standard mammographic views per breast. As a result, characterization of screening-detected findings is accomplished only after additional imaging at a later date. The data reported in this Section are based on initial screening interpretations, not those derived from subsequent problem-solving examinations. Specifically, screening cases are read as either "normal" or "abnormal" with abnormal interpretations classified as follows: "needs additional assessment" (those lesions requiring more imaging tests or fluid aspiration before deciding whether biopsy is indicated), "suspicious for malignancy" (those lesions fulfilling mammographic criteria for biopsy), and "highly suggestive of malignancy" (those lesions displaying characteristic mammographic features of malignancy).

All screening data are collected and stored on an ongoing basis in a computerized data management program, also described previously (Monticciolo and Sickles, 1990; Sickles, 1987b; 1990). Thus, the built-in auditing software provides statistical information about every aspect of the practice ranging from the demographics of the patient population to detailed analyses of the breast cancers that are detected.

6.3.2.1 *Patient Demographics*. As of August 1997, 88,346 women have been examined in the mammography screening practice. Table 6.3 indicates the age distribution of screenings (mean age, 51 y). Only 2,145 women (2.4 percent) underwent mammography prior to examination in the screening practice; of the remainder,

TABLE 6.3—*Age distribution of screenees.*

Age	Number of Examinations	
<40	12,584	(14.2%)
40 to 49	29,671	(33.6%)
50 to 59	22,042	(24.9%)
60 to 69	15,053	(17.0%)
70+	8,996	(10.2%)

42,014 examinations were baseline screenings, while 44,187 were performed on women already screened in the practice at least once. Despite a concerted effort to screen only asymptomatic women, 3.9 percent of screening examinations were done on women with palpable breast masses (Table 6.4).

Since the practice accepts only physician-referred women, the screening population probably does not represent a true cross section of women in the service area. Therefore, it is especially pertinent to describe the frequency with which known breast cancer risk factors are found in those screened. Table 6.5 shows that 10,465 examinations (11.8 percent) were done on those having a strong or very strong family history of breast cancer; 857 examinations (one percent) involved women who had a personal history of breast cancer. Among risk factors of lesser importance, typically not reported in medical audits, 33,088 examinations (37.5 percent) were done on nulliparous women, 4,307 (4.9 percent) on women who were 35 y or older when their first child was born, 910 (one percent) on women with menarche before age 10 y, 1,716 (1.9 percent) on women who went through menopause after age 55 y, and 12,307 (13.9 percent)

TABLE 6.4—*Palpable breast masses among screenees.*[a]

Palpable Mass	Number of Examinations	
None	84,861	(96.1%)
Right breast	1,536	(1.7%)
Left breast	1,718	(1.9%)
Both breasts	231	(0.3%)

[a]Palpable mass considered present if screenee gave history of palpable mass or if technologist detected palpable mass on a correlative physical examination.

TABLE 6.5—*Family history of breast cancer among screenees.*

Family History	Number of Examinations	
None	67,981	(76.9%)
Minor[a]	9,900	(11.2%)
Strong[b]	6,982	(7.9%)
Very strong[c]	3,483	(3.9%)

[a]Only distant relatives with breast cancer.
[b]First-degree relative (mother, sister, daughter) with unilateral postmenopausal breast cancer.
[c]First-degree relative with either premenopausal or bilateral breast cancer, or more than one first-degree relative with any breast cancer.

on women who had undergone prior breast surgery. Slightly more than half of the screening examinations involved women who were >10 percent overweight, based on calculations made from standard height-weight tables (Kowalski, 1987); 12,345 examinations (14 percent) were done on women overweight by 25 to 39 percent, and 12,081 examinations (13.7 percent) involved women overweight by 40 percent or more.

6.3.2.2 *Radiologist Demographics*. The majority of screening examinations were interpreted by one board-certified diagnostic radiologist who specializes in breast imaging with four other board-certified general diagnostic radiologists reading approximately equal numbers of the remaining cases. An additional board-certified diagnostic radiologist joined the practice 7 y after its inception, having just completed a 1 y breast imaging fellowship.

Table 6.6 indicates the frequency with which each radiologist made abnormal interpretations. Strikingly, fewer examinations were read as being abnormal when prior mammograms were available for comparison, especially if these films came from previous screenings (which were obtained using the same x-ray equipment, mammography technique, and breast positioning procedures). In addition, the most experienced radiologist had the lowest rate of abnormal interpretations, ranging from 6.1 percent for baseline examinations to 2.4 percent for studies that were compared with at least one prior screening examination.

TABLE 6.6—*Frequency of abnormal mammography screening interpretations.*[a]

Radiologist	No Prior Mammograms		Prior Nonscreening		Prior Screening[b]		Total	
A	1,544/25,472	(6.1)	49/1,298	(3.8)	628/26,222	(2.4)	2,221/52,992	(4.2)
B	318/4,462	(7.1)	15/239	(6.3)	143/4,675	(3.1)	476/9,376	(5.1)
C	354/4,619	(7.7)	19/221	(8.6)	171/5,112	(3.3)	544/9,952	(5.5)
D	333/3,939	(8.5)	15/173	(8.7)	193/4,489	(4.3)	541/8,601	(6.3)
E	296/2,033	(14.6)	16/141	(11.3)	5/61	(8.2)	317/2,235	(14.2)
F	196/1,489	(13.2)	7/73	(9.6)	182/3,628	(5.0)	385/5,190	(7.4)
Total	3,041/42,014	(7.2)	121/2,145	(5.6)	1,322/44,187	(3.0)	4,484/88,346	(5.1)

[a]Data are expressed as number of abnormal interpretations per total cases, with percentage of abnormal interpretations in parentheses.
[b]Prior screening mammograms done by mammography screening program. Prior nonscreening mammograms done elsewhere.

6.3.2.3 *Disposition of Abnormal Interpretations.* Of the 4,484 abnormal interpretations, management outcomes have been cataloged for those 4,428 cases for which more than three months have elapsed since screening (Table 6.7). Almost 25 percent of screening-detected abnormalities are found to be normal after further problem-solving imaging evaluation. The majority of these cases involve summation shadows created by superimposition of normal fibroglandular structures, simulating breast masses on only one of the two standard screening views. About 10 percent of abnormal screening cases are determined to be simple benign cysts either by aspiration (if palpable) or by breast ultrasound examination. Slightly more than one-third of screening abnormalities are judged to be "probably benign" after complete imaging evaluation (Brenner and Sickles, 1989; Sickles, 1991; Varas *et al*., 1992). These cases then require periodic mammographic follow-up to demonstrate radiographic stability (hence implied benignity). Finally, slightly <30 percent of abnormal screening interpretations result in percutaneous or surgical biopsy for diagnostic purposes. Minor variations in the frequencies of these outcomes are found when data are broken down by selected subcategories. For example, in

TABLE 6.7—*Disposition of abnormal mammography screening interpretations.*

Outcome	Number of Cases	
Unknown	22	(0.5%)
No follow-up done	127	(2.9%)
Further tests[a] normal	1,027	(23.2%)
Further tests[a] cyst	455	(10.3%)
Further tests[a] follow-up mammography[b]	1,569	(35.4%)
Any procedure biopsy	1,228	(27.7%)
Total	4,428[c]	

[a]Further tests include problem-solving mammography examination, breast ultrasound examination, and aspiration for fluid.

[b]Follow-up mammography includes periodic follow-up mammography examinations at six months to 1 y intervals for at least 3 y.

[c]Disposition for 56 abnormal interpretations (currently within three months of screening) was not ascertained.

this study, the rate at which abnormal interpretations are reclassified as normal decreases to only 17 percent and the biopsy rate increases to almost 35 percent, if the most experienced radiologist reads the images.

Determination of TP, FP, FN and TN cases are based on those 86,536 examinations for which at least three months have passed since screening. Among the 4,428 abnormal interpretations, breast cancer was found in 425 women (TP cases) leaving the other 4,003 to be called FP. Among the normal interpretations based on linkage with a regional tumor registry and (for those examinations done in the last 2 y) based on extrapolation from known results among reliably followed patients, the number of FN cases is estimated to be 61. The remaining cases, therefore, are estimated to be TN. These statistics form the basis for the following calculations of screening performance: estimated sensitivity = 87.4 percent, estimated specificity = 95.3 percent, and screening PPV = 9.6 percent.

6.3.2.4 *Biopsy Results.* There were 441 malignancies found in 425 screening examinations. Breast cancer was detected in 289 of the 41,490 baseline screenings (prevalence of seven per 1,000 examinations) and in 126 of 42,928 screenings done after at least one normal screening (incidence of 2.9 per 1,000 examinations). The remaining 10 screening examinations with cancer had undergone prior nonscreening examinations.

The histologic diagnoses from biopsies of all screening-detected abnormalities are summarized in Table 6.8. Slightly, more than one-third of biopsies resulted in a diagnosis of breast cancer. This 34.8 percent biopsy yield must be distinguished from the 9.6 percent screening PPV described previously. The biopsy yield indicates

TABLE 6.8—*Overall biopsy results.*

Histologic Diagnosis	Number of Screenees		Number of Biopsies	
Benign	722	(58.8%)	743	(58.6%)
Premalignant[a]	81	(6.6%)	85	(6.7%)
Malignant[b]	425	(34.6%)	441	(34.8%)
Total	1,228		1,269	

[a]Premalignant is defined as epithelial hyperplasia with cellular atypia, lobular carcinoma *in situ*.

[b]Malignant is defined as DCIS and any invasive carcinoma.

the probability of malignancy at biopsies prompted by screening, whereas the screening PPV states the likelihood of breast cancer for abnormal screening interpretations (prior to full problem-solving imaging evaluation).

Table 6.9 demonstrates the relationship of biopsy yield to age; the percentage of biopsies showing cancer increases progressively from 16.2 percent in women younger than 40 y to 57.1 percent in women 70 y of age and older. An even more pronounced progression from low to high cancer yield is found when biopsy data are subclassified according to degree of abnormality at initial screening interpretation (Table 6.10). Only 25.9 percent of biopsies show malignancy for examinations read as indicating the need for additional assessment with the biopsy yield increasing to 67.5 percent among cases called suspicious for malignancy, and increasing further to 95.2 percent for cases read as highly suggestive of malignancy.

6.3.2.5 *Characteristics of Breast Cancers*. Among the 441 cancers detected at mammography screening, 120 were DCIS, 287 were invasive ductal carcinoma, and 34 were invasive lobular carcinoma. The sizes of these cancers are indicated in Table 6.11, with a median size of 11 mm (9 mm for DCIS, 13 mm for invasive carcinoma). Among all cancers, 376 (85.3 percent) were clinically occult prior to mammography, according to the criteria listed in the footnotes to Table 6.8. Some of these tumors were palpated in retrospect, but 304 (68.9 percent) still remained nonpalpable and required biopsy with the aid of mammographic needle localization.

Axillary lymph node sampling or dissection was done for 311 of the 321 invasive cancers. There were 265 (85.2 percent) node-negative tumors. Systemic tumor spread was found for only two malignancies, the remaining 439 (99.5 percent) showing no

TABLE 6.9—*Biopsy results as a function of patient age.*

Age (y)	Benign		Premalignant		Malignant		Total
<40	120	(77.9%)	9	(5.9%)	25	(16.2%)	154
40 – 49	253	(65.2%)	28	(7.2%)	107	(27.6%)	388
50 – 59	184	(57.3%)	25	(7.8%)	112	(34.9%)	321
60 – 69	128	(51.2%)	14	(5.6%)	108	(43.2%)	250
70+	58	(37.2%)	9	(5.8%)	89	(57.1%)	156

TABLE 6.10—*Biopsy results as a function of mammography screening interpretation.*

Interpretation	Benign		Premalignant		Malignant		Total
Needs additional assessment	697	(67.0%)	74	(7.1%)	269	(25.9%)	1,040
Suspicious for malignancy	44	(26.5%)	10	(6.0%)	112	(67.5%)	166
Highly suggestive of malignancy	2	(3.1%)	1	(6.1%)	60	(95.2%)	63

TABLE 6.11—*Size of breast cancers detected at mammography screening.*

Tumor Size[a]	Intraductal	Invasive	Total
1 – 5 mm	36	31	67
6 – 10 mm	47	93	140
11 – 20 mm	20	131	151
>20 mm	17	66	83
Mean size	13 mm	15 mm	15 mm
Median size	9 mm	13 mm	11 mm

[a]When tumor size was not stated in the pathology report, it was estimated to be the greatest tumor diameter measured on preoperative mammograms.

evidence of metastasis at chest radiography, by the presence of elevated serum liver enzyme levels, or (if done) at scintigraphy, skeletal radiography, computed tomography (CT), or more invasive procedures.

All breast cancers detected at mammography screening were classified according to the American Joint Committee on Cancer staging system (Beahrs, 1988) (Table 6.12); 78.5 percent of tumors were Stage 0 or 1. It also has become commonplace to report an additional staging category called "minimal" cancer, defined as *in situ* carcinomas, as well as invasive cancers smaller than a given size. According to the criteria used in the Breast Cancer Detection Demonstration Project (BCDDP) (invasive cancers smaller than 10 mm) (Baker, 1982), 213 (48.3 percent) of screening-detected

TABLE 6.12—*Stage of breast cancers detected at mammography screening.*

Tumor Stage	Number of Cases	
Stage 0	120	(27.2%)
Stage 1	226	(51.2%)
Stage 2	88	(20.0%)
Stage 3	5	(1.1%)
Stage 4	2	(0.5%)

cancers were minimal; using the more rigorous Martin-Gallager criteria (invasive cancers smaller than 6 mm) (Martin and Gallager, 1971), there were 150 (34.2 percent) minimal cancers.

Table 6.13 summarizes selected mammography screening results separately for each radiologist in the practice demonstrating considerable variability in performance. These data indicate that the most experienced radiologist generated more biopsies, and identified more nonpalpable and early-stage cancers per abnormal screening interpretation.

6.3.3 *How to Interpret Audit Results*

For the first medical audit of a mammography practice, interpretation of audit results is based primarily on comparison with parallel data from previously published reports. However, there are pitfalls inherent in such an exercise because substantial variations in results can arise due to differences in the patient populations studied and due to differences in the methods and definitions used to compile the data.

By far the most confusing situation occurs when comparing audit results derived from screening and problem-solving examinations. As stated previously, the definitions basic to data analysis may vary widely for these two types of examination. Furthermore, the likelihood of finding breast cancer is much greater for problem-solving examinations, which often involve women having palpable masses. Either or both of these factors may cause substantial differences in observed audit statistics (Dee and Sickles, 2001). Therefore, results of any audit must be interpreted in the context of (1) the percentage of symptomatic women examined and (2) whether (and to what extent) problem-solving examinations are intermixed with screening studies. Problem-solving and screening data should be segregated during auditing. If this is not possible, analysis of combined results should be based on known differences between problem-solving and screening examinations (Sohlich *et al*., 2002).

There also are pitfalls in the interpretation of audit data when results of seemingly similar types of examinations are compared. For example, the rates of detecting prevalent and incident cancers are higher in the expert screening practice than in large population-based screening studies (Tabar *et al*., 1984). It might be tempting, albeit misleading, to conclude that the screening practice results indicate superior performance.

TABLE 6.13—*Overall screening results for each radiologist expressed in terms of number of abnormal interpretations.*

Radiologist	Abnormal Interpretations	Biopsies Performed[a]		Cancers Detected[a]		Nonpalpable Cancers Detected[a]		Stage 0 + 1 Cancers Detected[a]	
A	2,184	797	(36.5)	288	(13.2)	201	(9.2)	235	(10.8)
B	475	118	(24.8)	42	(8.8)	28	(5.9)	30	(6.3)
C	544	118	(21.7)	38	(7.0)	26	(4.8)	27	(5.0)
D	541	118	(21.8)	36	(6.7)	23	(4.3)	29	(5.4)
E	317	67	(21.1)	17	(5.4)	11	(3.5)	14	(4.4)
F	367	51	(13.9)	20	(5.4)	15	(4.1)	11	(3.0)
Total	4,428	1,269	(28.7)	441	(10.0)	304	(6.9)	346	(7.8)

[a]Percentages (in parentheses) indicate the number of cases divided by the number of abnormal interpretations.

Disposition for 56 abnormal interpretations (currently within three months of screening) was not ascertained. Rather, the discrepancy probably is due to self-selection bias in the expert screening practice, causing women at high risk of developing breast cancer to be examined with greater frequency, thereby resulting in detection of more breast cancers than would be found in a true cross section of women.

Audit results from the expert screening practice also indicate a very high proportion of FP cases and a PPV of only 9.6 percent, primarily because all initially abnormal screening interpretations are defined as "positive." However, an alternative, more commonly used definition of positive cases includes only those still considered abnormal after completion of problem-solving imaging evaluations. Applying this latter, more restrictive definition would produce results similar to those reported by others (Table 6.7). For example, by considering as positive, only those problem-solving interpretations that recommended either biopsy or periodic mammographic follow-up, 1,631 FP cases would be reclassified as TN with an increase in PPV to 15.2 percent. By further narrowing the definition of positive cases to those problem-solving interpretations for which biopsy actually was done, 1,569 more FP cases would be converted to TN status producing a biopsy yield (PPV for biopsy) of 34.6 percent.

Several factors may contribute to differences in the frequency of FN cases between the expert screening practice series and those reported by others:

- In the screening practice, most women already known to have palpable breast masses are systematically excluded from screening. This policy effectively eliminates a major source of FN interpretation: palpable cancers not detected by mammography because they are obscured by surrounding dense fibroglandular tissue. Thus, the screening practice series should report fewer FN cases than series whose patient populations are more heavily weighted with symptomatic women.
- Another screening practice policy is to rely on the referring physician to provide a breast physical examination for each woman. It is possible that some women never receive this examination at all, and probable that some physical examinations are done with less than optimal skill and attention to detail. Since the vast majority of breast cancers missed by mammography are detected by physical examination, the

number of FN mammography interpretations depends substantially on the quality and frequency of physical examination actually done. As a result, practices that screen with mammography alone are likely to report fewer than the expected number of FN cases simply because high-quality physical examination may not be done concurrently.

- Estimation of the total number of FN cases based on extrapolation methods (Section 6.4.1) is inherently imprecise. Although the ultimate effect that this has on FN case ascertainment is potentially substantial, the extrapolation method itself is not biased toward either over- or underestimation of FN cases.
- FN cases are defined as those in which breast cancer is identified within a specified time interval after normal mammography examination. This time interval varies among published reports ranging from four months to several years (Bird, 1989; Margolin and Lagios, 1987; Spring and Kimbrell-Wilmot, 1987). The most widely used time interval is 1 y (Linver *et al*., 1992). In the screening practice series, an interval of variable length is defined as the time actually observed between current and next screening examinations. This approach incorporates some degree of individual flexibility based on patient age, other breast cancer risk factors, and compliance with screening guidelines. Studies using longer time intervals can be expected to count more FN cases. Because the interval in the screening practice series is intermediate between those used in previous reports, there should be little, if any, bias favoring identification of either more or fewer FN cases; however, since a small percentage of the cases eligible for analysis were followed for intervals as short as three months, there should be a slight tendency to underestimate the number of FN cases.

Once a mammography practice completes its first medical audit, interpretation of subsequent audit results becomes much less complex. Emphasis shifts from comparing current results with those published by others to making comparisons with results obtained previously in its own audits. Thus, most of the pitfalls in interpreting audit data are avoided since similar, if not identical, audit protocols are employed and since the patient population of a mammography practice rarely changes.

Finally, in assessing the ultimate success or failure of mammography performance, it may be inadequate to consider observed results only in the context of the specific patient population examined and as a function of the definitions used for data compilation; one also should factor in the size and palpability of the breast cancers actually detected. This is especially important if, as often will be the case, calculation of exact (nonestimated) audit results is restricted to TP, FP and PPV, or biopsy yield statistics. In this circumstance, apparently favorable—but truly misleading, results can be produced by underreading the practice of interpreting as abnormal only those lesions that are fairly characteristic of malignancy by standard mammographic criteria (Moskowitz, 1989). To use an extreme example, among the 63 lesions interpreted as highly suggestive of malignancy in the expert screening practice described previously, 60 (95.2 percent) actually were breast cancers (Table 6.10), a very high PPV that suggests a highly successful outcome. However, only 25 (41.7 percent) of these cancers were nonpalpable in retrospect and only 33 (55 percent) were Stage 0 or 1 tumors indicating unsatisfactory performance because there were so few small, good-prognosis cancers. On the other hand for the screening practice as a whole, although only 9.6 percent of abnormal interpretations eventually led to the diagnosis of malignancy, 68.9 percent of these 441 cancers were clinically occult and 78.5 percent were Stage 0 or 1 tumors, a much more favorable outcome. High PPV (indicating relatively few FP cases) is desirable to decrease morbidity and cost, but such a result should not be achieved by underreading. Rather, the ultimate success in mammography screening should come from detecting invasive cancers when they are nonpalpable and early in stage, thereby preventing these tumors from becoming locally advanced or systemically disseminated (Sickles *et al*., 1990; Tabar *et al*., 1992).

Audit results also can indicate the extent to which radiologists are overreading [*i.e*., producing a greater number of positive (abnormal) interpretations without an accompanying increase in detection of favorable-prognosis cancers]. One method of assessing overreading is presented as follows. Table 6.14 contains selected results for the radiologists in the expert screening practice expressed as percentages in terms of examinations interpreted. These data should be compared with the data in Table 6.13, in which the same results are expressed as percentages in terms of abnormal interpretations. Note that the indicators of superior performance for the most experienced radiologist suggested in Table 6.13 are not as readily apparent in Table 6.14, which shows that all radiologists identify clinically occult and early-stage

TABLE 6.14—*Overall screening results for each radiologist expressed in terms of number of examinations interpreted.*

Radiologist	Total Number of Interpretations	Biopsies Performed[a]		Cancers Detected[a]		Nonpalpable Cancers Detected[a]		Stage 0 + 1 Cancers Detected[a]	
A	52,992	797	(1.50)	288	(0.54)	201	(0.38)	235	(0.44)
B	9,376	118	(1.26)	42	(0.45)	28	(0.30)	30	(0.32)
C	9,952	118	(1.19)	38	(0.38)	26	(0.26)	27	(0.27)
D	8,601	118	(1.37)	36	(0.42)	23	(0.27)	29	(0.34)
E	2,235	67	(3.00)	17	(0.76)	11	(0.49)	14	(0.63)
F	5,190	51	(0.98)	20	(0.39)	15	(0.29)	11	(0.21)
Total	88,346	1,269	(1.44)	441	(0.50)	304	(0.34)	346	(0.39)

[a]Percentages (in parentheses) indicate the number of cases divided by the number of examinations interpreted.

cancers at fairly similar rates. This apparent discrepancy is best understood by observing that the most experienced radiologist makes fewer abnormal interpretations while still identifying a relatively high percentage of favorable-prognosis cancers. However, viewed from a different perspective, it also is evident that radiologists B, C, D and F are overreading because they produce higher rates of abnormal interpretation without any increase in detection of nonpalpable, early-stage cancers. Analysis of overreading is less clear-cut for radiologist E, who records 30 to 40 percent higher cancer detection rates than radiologist A, but achieves this modest improvement at the expense of a very large (344 percent) increase in rate of abnormal interpretation.

6.3.4 *How to Use Audit Results Effectively*

Medical audits are useful to everyone involved in the operation of a mammography practice, including those who request, deliver, receive, and pay for the service. The best reason to conduct an audit is for the benefit of the mammography staff, the radiologists, and technologists actually performing the examination (Murphy *et al*., 1990; Sickles, 1992b). Circulation of successful audit results among these workers builds morale and maintains enthusiasm, providing positive reinforcement that keeps the mammography team focused on the challenging task of detecting nonpalpable breast cancer. This is especially important because mammography, at times, can be both demanding and stressful. Should an audit uncover an area of deficiency, it not only indicates the existence of the problem but also provides clues to aid in identifying the source of difficulty, thereby, leading to appropriate corrective action. Repeat audits limited to the area of deficiency then can be used to demonstrate improvement in performance and, ultimately, complete resolution of the problem.

Audit results also can be used to educate patients and referring physicians by indicating that successful clinical results actually are being achieved. This is, in fact, the most meaningful information that consumers can utilize to decide whether and where to obtain mammography services. Dissemination of successful audit results through the medical and public media: (1) boosts confidence in accuracy of interpretation, thereby, increasing the likelihood of compliance with recommendations for subsequent management, (2) stimulates new referrals to a mammography practice helping to build a referral base, and (3) encourages women and their physicians to follow established guidelines for periodic mammography screening. This is especially important, because to be effective,

screening must be done at regular and reasonably short intervals (Moskowitz, 1986; Sickles, 1987b; Tabar and Dean, 1987; Tabar *et al*., 1992). A particularly effective method of informing patients about audit successes is to provide lay-language displays and handouts in the mammography suite. In similar fashion, regularly updated newsletters highlighting successful audit results can be sent to referring physicians.

Publication of audit statistics also has had considerable impact on third-party payers, who for many years had been opposed to paying for mammography screening. Although this opposition was based partially on economic considerations, there also was uncertainty about whether successful audit results previously reported by mammography specialists in academic centers truly could be achieved by community practice radiologists as well. However, several articles now have been published by private practitioners confirming their ability to produce good clinical results (Bird, 1989; Margolin and Lagios, 1987; Moseson, 1992; Robertson, 1993). This has dispelled most of the concern held by the insurance industry and government agencies, thereby, helping to build the political consensus that has produced enactment of legislation in most states and in Congress to mandate insurance coverage for mammography screening. Continued demonstration of successful audit results should reinforce the decision of third-party payers to maintain, perhaps even expand, this coverage.

The medical audit can be put to one final use: to help a radiologist's defense in selected malpractice lawsuits. No protection will be provided when the facts in a specific case prove substandard image quality or interpretation, but the great majority of malpractice actions do not involve such egregious errors. In these circumstances, a medical audit documenting successful results is the best available evidence to indicate the high performance level of a mammography practice (Brenner, 1989; Potchen *et al*., 1991). The defendant radiologist can use such an audit to support the argument that his or her interpretation of many mammography examinations, similar to the case in question, has produced clinical results similar to those published in the medical literature, thereby establishing that the standard of care has been met.

6.4 Mammography Interpretive Skills Assessment

Although a properly performed medical audit provides substantial insight into the clinical performance of a medical practice, there is another approach that enables radiologists to evaluate their mammography interpretive skills more directly and more rapidly.

In 1992, ACR formed its Committee on Mammography Interpretive Skills Assessment (COMISA) charged with designing a voluntary program to be of tutorial assistance to practicing radiologists. Committee members were experienced, knowledgeable, mammography specialists from both academic and community practices throughout the United States. Over the next several years, they created a paper-and-pencil, multiple-choice self-assessment test that utilized high-quality copies of original mammograms and a case management approach (ACR, 1995). The COMISA test was built around the following categories: detection (ability to perceive unsuspected findings, 30 percent); validation (determination of whether a finding is real versus summation artifact, and if real, where it is located, 20 percent); analysis (description and assessment of findings, 15 percent); management (planning the next step in the workup, 15 percent); image quality (10 percent); physics (five percent); and general information (five percent). During this process, which was conducted under the supervision of a professional educational test development expert, COMISA test items (questions) were reviewed, field tested, analyzed, and revised. The field testing took place at numerous regional and national mammography seminars attended by practicing radiologists. Testing conditions were carefully monitored to mimic the clinical setting (darkened reading rooms, viewboxes, magnifying lenses, etc.). Each test administration involved approximately 100 to 125 questions, taking approximately 1.5 h to complete. The complex process of test question creation, review and revision helped to insure that the wording of a question was unambiguous, that the question tested underlying skills, rather than the examinee's success in understanding the meaning of the question, that there was one best or correct answer to the question and that the question was neither too easy to be answered correctly by all examinees, nor too difficult to be answered correctly by any. Ultimately, each individual question was accepted for use in the COMISA test only after (1) demonstration that examinees who score high on the overall examination answer the question correctly more frequently than low scorers (item discrimination), (2) determination that substantial numbers of low-scoring examinees select the incorrect choices (distractor analysis), and (3) an independent determination of the clinical relevance of the question. By 1998, there was a pool of approximately 500 fully validated COMISA test questions; many hundreds of radiologists had taken at least one version of the test.

In 1999, ACR decided to convert the paper-and-pencil COMISA examination to computerized format, employing digital images.

New image-based material was collected, specially selected to take advantage of the digital display format. Many test items were of the traditional multiple-choice variety, but others took advantage of CD-ROM-based computer technology by requiring users to move the mouse to point at and click on specific image-based findings. In this way, the computerized version of the COMISA examination combines the strength of multiple-choice testing to assess radiologist's knowledge and understanding with image-based performance assessment to evaluate radiologist's ability to detect breast abnormalities with mammography. An interactive response-driven approach was built into the examination. Using carefully structured questions and detailed text explanations of why provided answers were correct or incorrect, radiologists were prompted to make their own observations (detection of findings), then assessments, and finally management decisions just as if an imaging evaluation were being performed at the time, closely approximating the real-life workup of a mammography examination. The computer-based version of the ACR examination was field tested at several national breast imaging seminars, producing reliable and valid scores for performance assessment of mammography detection, analysis and management skills (ACR, 2000a). Examinee response to the computerized version also was extremely positive, in fact outstanding. Those radiologists who have taken both versions of the ACR examination uniformly prefer the computerized version over the paper-and-pencil version, primarily because of the interactive nature of the test process and the immediate feedback provided by display to text explanations for why each question was answered correctly or incorrectly. The computerized version of the COMISA test was first released for general use in 2001, in CD-ROM format; a completely different set of cases and questions has been developed each year, so as to encourage annual use.

6.5 Legislative Issues Relating to Quality Assurance

Quality assurance (QA) is essential to maintaining optimized mammography image quality at low radiation dose. Recognition of this has led to the inclusion of QA requirements for mammography sites in federal legislation (Hendrick, 1992).

Two bills passed by the U.S. Congress contain important mammography QA provisions. The Omnibus Budget Reconciliation Act, passed on November 28, 1990 and effective January 1, 1991, provided federal funding for breast cancer screening of Medicare-eligible women, with the provision that Medicare sites meet

prescribed quality standards (OBRA, 1990). Medicare quality standards for screening mammography sites included the use of dedicated mammography equipment, annual physics inspections by a qualified medical physicist, acquisition of images by qualified technologists, and interpretation of images by qualified physicians (OBRA, 1990). MQSA (1992), passed in October 1992 and effective on October 1, 1994, included similar QA standards. MQSA (1992) quality standards apply to all mammography sites and superseded Medicare quality standards.

MQSA (1992) requires all mammography sites to be accredited through a private, nonprofit organization or state agency that meets the requirements of the Secretary of the U.S. Department of Health and Human Services (DHHS). In addition, all mammography providers are required to have annual equipment surveys by a qualified medical physicist, to have an ongoing QA program, and to have annual inspections by an inspector acting on behalf of DHHS (MQSA, 1992).

Specific MQSA quality standards for accrediting bodies and for mammography sites have been developed by DHHS. The development of complete quality standards, known as the Final Rules, was done by the FDA with the assistance of a National Mammography Quality Assurance Advisory Committee. The Final Rules were published in October 1997, and went into effect April 28, 1999. Since October 1, 1994, all mammography sites have been required to meet the requirements of MQSA (1992) in order to perform mammography. Mammography sites are subject to annual inspections by qualified inspectors designated by the FDA to insure that sites are properly accredited and meet standards of MQSA (1992).

7. Benefits and Risks of Mammography

7.1 Benefits

7.1.1 *Introduction*

In medical practice, mammography may be used for diagnosis, surveillance and screening. Diagnostic mammography is performed to evaluate a woman with a sign or symptom of breast disease such as a mass, or to provide further workup of a finding detected at screening (DHEW, 1977). Surveillance mammography provides follow-up of a breast that has been treated for cancer. With diagnostic and surveillance mammography the issue of risk versus benefit does not arise since the immediate need for diagnostic information is compelling and the risk from an examination is negligible. By comparison, the use of mammography for screening may be subject to benefit/risk analysis because a very small fraction of the population is likely to benefit and because the cumulative radiation risk from numerous periodic multiple examinations is higher.

Screening is the periodic examination of a population to detect previously unrecognized disease. The major goal of breast cancer screening is to reduce breast cancer mortality through detection of earlier-stage disease. Earlier detection also provides a wider choice of therapeutic options. Mammography can frequently detect breast cancer at a relatively early stage when tumors are too small to be palpable.

The benefit of screening mammography has been called into question over the last decade. This occurred first for the application of screening mammography to premenopausal women (Fletcher *et al*., 1993), then more recently for the application of screening mammography to all age groups (Gotzsche and Olsen, 2000; Olsen and Gotzsche, 2001). In light of these criticisms, it is important to review the benefits and risks of screening mammography.

7.1.2 *Comparative Detection Sensitivity of Mammography and Physical Examination*

The relative accuracy of mammography and physical examination received a large scale assessment by the American Cancer Society through the National Cancer Institute (NCI) supported BCDDP. Over 280,000 women between the ages of 35 and 74 were offered five annual screenings with both modalities at 29 centers throughout the United States from 1973 to 1980.

Mammography was the sole method of detection for 41.6 percent of cancers (*i.e.*, only 58.4 percent were detected by physical examination). As earlier cancers are considered, the sensitivity of mammography (alone or with physical examination) remains high while the sensitivity of physical examination (alone or in combination with mammography) declines (Table 7.1). Nevertheless, 5.5 percent to 8.7 percent of cancers in each category were found by physical examination alone (Baker, 1982).

Data from a number of studies have shown that the sensitivity of mammography is highly dependent on technical quality of the mammographic examination (Beahrs *et al*., 1979; Feig, 1995; 2002; Kopans and Feig, 1993; Roberts *et al*., 1990; Sickles and Kopans, 1993; Tabar *et al*., 1993; Taplin *et al*., 2002; Young *et al*., 1994;

TABLE 7.1—*Breast cancer detection by the BCDDP according to lesion size and modality findings.*[a]

	Breast Cancer Size[b]			
Detection Modality[c]	Noninfiltrating	Infiltrating <1 cm	Infiltrating >1 cm	Total
Mammography only	59% (461/782)	52.6% (195/371)	33.7% (63/1,871)	41.6% (1,481/3,557)
Mammography and physical examination	33% (258/782)	36.4% (135/371)	55.3% (1,033/1,871)	47.3% (1,683/3,557)
Physical examination only	5.5% (43/762)	8.4% (31/371)	8.6% (161/1,871)	8.7% (308/3,557)
Total	100%	100%	100%	100%

[a]Baker (1982).
[b]Size not specified in 537 cancers.
[c]Detection modality unknown in 2.2 to 2.6 percent of cancers in each category.

1997). Because mammography techniques have improved continuously over the past 20 y (Conway *et al*., 1990; 1994; Suleiman *et al*., 1999), it is likely that if a study similar to the BCDDP were conducted today, sensitivity of mammography relative to physical exam would be even greater.

7.1.3 *Breast Cancer Survival Rates*

Survival rates among breast cancer patients depend in large part on two related factors: tumor size and stage at time of diagnosis. Smaller cancers with no histologic evidence of spread to the regional lymph nodes have the best prognosis. The 20 y relative survival rates in the BCDDP were 80.5 percent (overall), 85.1 percent for cancers detected by mammography alone, 82.4 percent for cancers detected by physical examination alone, and 74.1 percent for cancers detected by both mammography and physical examination. Twenty-year relative survival rates were highly dependent on lesion size. For *in situ* carcinomas and for invasive cancers measuring 0.1 to 0.9 cm, 1 to 1.9 cm, 2 to 4.9 cm, and 5 to 9.9 cm, 20 y survival rates were 95.8 percent, 88.1 percent, 78.4 percent, 68.3 percent, and 58 percent, respectively (Smart *et al*., 1997). These rates can be compared with survival data from the Surveillance Epidemiology and End Results (SEER) Program of NCI, a population-based network of cancer registries that monitors cancer trends throughout the United States. Women with breast cancer entered into the SEER database during the BCDDP era, consisting largely of women who were not being screened, had a 20 y relative survival rate of 53 percent (Ries *et al*., 2000).

7.1.4 *Limitations of Survival Rate Data*

There are several reasons why "improved" survival rates among women who volunteer to be screened do not necessarily establish benefit from screening. These include selection bias, lead-time bias, length bias, and interval cancers (Feig, 1996a). Thus, differences in survival rates may be influenced by variables other than the screening process itself.

Selection bias refers to the possibility that women who volunteer for screening differ from those who do not volunteer in ways that may alter the outcome of their disease.

Lead-time bias implies that screening may advance the time of diagnosis, but not postpone the date of death from breast cancer. Therefore, a measured "improvement" in length of survival may not actually prolong the patient's life span.

Length bias postulates that cancers detected at screening contain a disproportionate number of slow-growing, less-aggressive lesions. Even if undetected, some of these tumors might never kill.

Finally, more favorable survival rates for screen-detected cancers may be negated by lower survival rates for faster growing interval cancers that are undetected by mammography and surface clinically between screens.

The validity of survival rates as an index of benefit from screening depends on the extent of influence of selection bias, lead-time bias, and length bias on screen-detected cancers, as well as the frequency and characteristics of interval cancers. Consequently, benefit from screening cannot be proved by observation of "improved" survival rates in a follow-up study. Proven benefit from screening requires measurement of breast cancer mortality rates in a randomized controlled trial.

7.1.5 *Randomized Controlled Trials*

7.1.5.1 *Advantages and Limitations*. A randomized controlled trial (RCT) is a prospective comparison of breast cancer deaths among study group women offered screening and control group women not offered screening. These two groups should have no other significant differences. There have been seven population-based RCTs of breast cancer screening by mammography alone or in combination with physical examination: the Health Insurance Plan (HIP) of Greater New York Trial (Shapiro *et al*., 1988), the Swedish Two-County Trial (Tabar *et al*., 2000) consisting of Kopparberg and Ostergotland Counties, the Malmo (Sweden) Trial (Andersson and Janzon, 1997), the Stockholm (Sweden) Trial (Frisell *et al*., 1991), the Gothenburg (Sweden) Trial (Bjurstam *et al*., 1997), and the Edinburgh (Scotland) Trial (Alexander *et al*., 1999). There has been one nonpopulation-based RCT, the National Breast Screening Study (NBSS) of Canada (Miller *et al*., 1992a; 1992b; 2000; 2002). In a population-based RCT, a population is defined, and study and control groups are randomly selected from that population. In a nonpopulation-based RCT, study and control groups are randomly selected from women who volunteer to participate in the study. The issue of population base does not affect the internal validity of a trial, but can affect generalizability to other populations. Properly planned and conducted population-based RCTs cannot be influenced by lead-time bias, length bias sampling, selection bias, and deaths from interval cancers. RCTs are generally acknowledged as the gold standard for documentation of benefit from screening.

However, RCTs may be difficult to conduct properly. Their ability to establish the presence and quantify the amount of screening benefit is subject to limitations.

Adequate sample size and length of follow-up are among the most basic requirements of RCTs. A sufficiently large study population is necessary because breast cancer, although a relatively common malignancy, has a low annual incidence: 1.6, 2.8, 3.8, and 4.7 cases per 1,000 women for ages 40 to 49, 50 to 59, 60 to 69, and 70 to 79, respectively (Ries *et al*., 2000). Long-term follow-up is necessary because breast cancer is a chronic disease; many women who eventually succumb to breast cancer are still alive 10 to 20 y after diagnosis. Due to these considerations, the number of women in the study and control groups, their age-related breast cancer incidence and mortality, and the years of follow-up will determine the statistical power of any trial.

Proper compliance of study group women with their screening invitation is also important. By definition, a randomized trial must measure mortality among women offered screening, rather than among those actually screened. Yet, some women in the study group may choose not to attend any or all of the screening rounds. Only those who attend all screening rounds receive the full possibility of benefit. Therefore, incomplete participation of the study population will dilute the effect of screening and underestimate mortality reduction.

Another potential problem, contamination, occurs when women in the control group obtain screening outside the trial. Contamination can reduce the number of breast cancer deaths among control group women, diminishing any mortality difference between the control group and the study group. This effect has become an especially difficult problem today because mammography screening is widely available and increasingly accepted, diminishing any potential mortality difference between the control and study groups if a study were done today.

Randomization problems will also affect the validity of any conclusions from trial results. A well-designed RCT should insure that any difference (or lack of difference) in mortality between study and control groups reflects only the screening process and not an unequal distribution of confounding factors that may affect mortality. One example of a confounding factor would be preferential channeling of symptomatic women with late-stage cancers into the study group. Many other known and unknown confounding factors are possible. A larger study will reduce the chance of unequal representation of confounding factors and reduce the effect of random variation.

Another pitfall is that a subgroup analysis not planned in the original study design may yield statistically meaningless conclusions. For example, even a substantial mortality reduction among women ages 40 to 49 in a trial designed to test screening of an entire population ages 40 to 65 may not be statistically significant. Any conclusions could be further weakened if screening parameters, such as screening frequency and mammographic technique, were not optimized for younger women.

Screening sensitivity will be affected by a number of factors. Excessively long screening intervals will limit mortality reduction if faster growing cancers are not intercepted at an early stage by sufficiently frequent screening. Perhaps the most important factors influencing screening efficacy are the quality of mammographic technique and interpretation.

With these considerations in mind, it should be apparent that results from any randomized trial depend on the quality of its design and implementation. Although a RCT embodies the scientific method more than does any other type of screening study, a screening mammogram is not a standardized product that is identical, regardless of how it is performed.

7.1.5.2 *Results for Women of All Ages*. Protocols and results for women of all ages at entry into RCTs are shown in Table 7.2. Mortality reduction is equal to one minus the relative risk (RR) of dying from breast cancer in study group women versus control group women. The HIP Trial was the first RCT ever conducted and found a 23 percent reduction in breast cancer deaths (RR = 0.77) among women ages 40 to 64 y who were offered screening mammography and physical examination (Shapiro *et al*., 1988).

The Two-County Sweden Trial was the first to demonstrate a statistically significant benefit from screening by mammography alone. The most recent 20 y follow-up reports a 32 percent reduction in breast cancer deaths among women ages 40 to 74 y at entry (Tabar *et al*., 2000). Screening by annual physical examination and biennial mammography in the Edinburgh RCT resulted in a statistically significant 29 percent decrease in breast cancer deaths among women ages 45 to 64 y at entry (Alexander *et al*., 1999).

Three Swedish screening mammography trials reported benefits that were not statistically significant. The Malmo Trial found a 18 percent reduction in breast cancer deaths among women who began screening between the ages 45 and 69 (Nystrom *et al*., 2002). The Stockholm Trial described a nine percent reduction in breast cancer deaths among women screened between 40 and 64 y of age

TABLE 7.2—*RCTs: Results for all ages combined.*

Trial (dates)	Age at Entry (y)	Number of Mammograph Views	Mammograph Frequency (months)	Rounds (number)	CBE[a]	Follow-Up (y)	RR[b] (95% CI)[c]	Reference
HIP (1963 – 1969)	40 – 64	2	12	4	Annual	18	0.77 (0.61 – 0.97)	Shapiro *et al.* (1988)
Malmo (1976 – 1986)	45 – 69	1 – 2	18 – 24	5	None	17.1	0.82 (0.67 – 1.00)	Nystrom *et al.* (2002)
Two-County: Kopparberg, Ostergotland (1979 – 1988)	40 – 74	1	23 – 33	4	None	20	0.68 (0.59 – 0.80)	Tabar *et al.* (2000)
Edinburgh (1979 – 1988)	45 – 64	1-2	24	4	Annual	14	0.71 (0.53 – 0.95)	Alexander *et al.* (1999)
NBSS-2 (1980 – 1987)	50 – 59	2 + CBE versus CBE	12	5	Annual	13	1.02 (0.78 – 1.33)	Miller *et al.* (2000)
Stockholm (1981 – 1985)	40 – 64	1	28	2	None	13.8	0.91 (0.65 – 1.27)	Nystrom *et al.* (2002)
Gothenburg (1982 – 1988)	40 – 59	2	18	4	None	12.8	0.76 (0.56 – 1.04)	Nystrom *et al.* (2002)

[a]CBE = clinical breast examination.
[b]RR = relative risk of death from breast cancer in study group/control group.
[c]CI = confidence interval.

(Nystrom *et al*., 2002). The Gothenburg Trial had a 24 percent reduction in deaths from breast cancer among women ages 40 to 59 at entry into screening (Nystrom *et al*., 2002).

Combined results from a 15.8 y follow-up of women ages 38 to 75 at entry into four Swedish trials (Malmo 1 and 2, Ostergotland, Stockholm, and Gothenburg) showed a statistically significant 21 percent reduction in breast cancer mortality (Nystrom *et al*., 2002).

The second National Breast Screening Study of Canada (NBSS-2) failed to show any benefit for mammography screening of women ages 50 to 59. In that trial women receiving annual mammography and physical examination were compared with those being screened by physical examination alone (Miller *et al*., 2000). Possible explanations for the variance between NBSS-2 results and those of the seven other randomized trials include technical quality of mammography (Baines *et al*., 1990; Kopans, 1990), study design (Boyd, 1997; Boyd *et al*., 1993; 1998; Tarone, 1995), and control group contamination (Sun *et al*., 2002).

Two recent evaluations of all randomized trials claimed that none of them provided convincing evidence that screening prevents breast cancer deaths (Gotzsche and Olsen, 2000; Olsen and Gotzsche, 2001). This conclusion was based primarily on their critique of the methodology and the conduct of the trials. Although their assertions received considerable print and electronic media attention, they were disputed in the medical literature (Duffy *et al*., 2002a; Feig, 2003; Kopans, 2003). The Gotzsche and Olsen studies, along with trial data were later reviewed by expert panels of numerous scientific organizations which concluded that the trials, though not perfect, had no major flaws that would invalidate the considerable evidence that screening reduces breast cancer mortality rates. Several organizations reaffirmed their support for screening following the evidence-based reviews including the American Cancer Society (Smith *et al*., 2003), the European Institute of Oncology (Veronesi *et al*., 2002), the Health Council of the Netherlands (HCN, 2002), the International Agency for Research on Cancer of the World Health Organization (IARC, 2002), the Swedish Board of Health and Welfare (SBHW, 2002), and the U.S. Preventive Services Task Force (PSTF, 2002).

7.1.5.3 *Results for Women Ages 50 and Older at Entry.* Early follow-up results from two RCTs showed statistically significant reductions in breast cancer deaths among women ages 50 and older at entry. Annual screening by mammography and physical examination in the HIP Trial resulted in a 23 percent reduction in breast

cancer deaths among women ages 50 to 74 at entry that persists on the latest 18 y follow-up. Among women ages 50 to 74 at entry who were screened every 33 months in the Two-County Sweden Trial, there was a 34 percent reduction in breast cancer deaths that persists on the latest 20 y follow-up (Tabar *et al*., 1995; 2000).

7.1.5.4 *Results for Women Ages 40 to 49 y at Entry.* Deaths from breast cancers diagnosed within 5 y from entry into the HIP Trial were measured by Shapiro *et al*. (1988). A difference in breast cancer death rates between study and control groups for women age 50 and over at entry was apparent by year four, but did not emerge for women ages 40 to 49 until 7 to 8 y of follow-up. By 18 y of follow-up, the reduction in breast cancer deaths among study women ages 40 to 49 at entry was 23 percent (Table 7.3), the same as the reduction in breast cancer deaths found among study group women ages 50 to 59 at entry (Table 7.2). However, due to the relatively smaller number of younger women enrolled and their lower breast cancer incidence, Shapiro *et al*. (1988), found that the benefit for younger women was not statistically significant. This observation along with the negative results from the NBSS-1 study (Miller *et al*., 1992a) served as a major cause of the controversy regarding screening women in their forties.

However, the HIP study was not designed to determine the efficacy of screening separate age groups, but rather a single age group of all women ages 40 to 65. Attempts to subdivide the study group reduce statistical power. The observation that the mortality reduction for younger women lacked statistical significance was often cited in the screening debate (Fletcher *et al*., 1993). It was hardly appreciated that statistical significance was also absent for women ages 50 to 59 and for those age 60 and older at entry, when these groups were analyzed separately (Hurley and Kaldor, 1992).

Using a different method of analysis of HIP results, Chu *et al*. (1988), calculated breast cancer deaths among cancers diagnosed within 6 y of entry, the earliest point for which the number of breast cancer cases in study and control groups were then equal. Using this method, these investigators found statistically significant mortality reductions of 24 percent for women ages 40 to 49 and 21 percent for those ages 50 to 64 at entry.

Despite the analysis of Chu *et al*. (1988), some observers were still not convinced that screening women in their forties would reduce breast cancer deaths. There are a couple of reasons for this opinion: (1) benefit for women ages 40 to 49 did not appear in any RCTs until 7 to 8 y after entry versus 4 to 5 y for older women;

TABLE 7.3—*RCTs: Most recent results for women ages 49 and younger.*

Trial (dates)	Age at Entry (y)	Number of Mammograph Views	Mammograph Frequency (months)	Rounds (number)	CBE[a]	Follow-Up (y)	RR[b] (95% CI)[c]	Reference
HIP (1963 – 1969)	40 – 49	2	12	4	Annual	18	0.77 (0.53 – 1.11)	Shapiro *et al*. (1988)
Malmo (1976 – 1986)	45 – 49	1 – 2	18–24	5	None	12.7	0.64 (0.45 – 0.89)	Andersson and Janzon (1997)
Kopparberg (1977 – 1985)	40 – 49	1	24	4	None	15.2	0.67 (0.37 – 1.22)	Nystrom *et al*. (1997)
Ostergotland (1977 – 1985)	40 – 49	1	24	4	None	14.2	1.02 (0.59 – 1.77)	Nystrom *et al*. (1997)
Edinburgh (1979 – 1988)	45 – 49	1 – 2	24	4	Annual	14	0.75 (0.48 – 1.18)	Alexander *et al*. (1999)
NBSS-1 (1980 – 1987)	40 – 49	2	12	4 – 5	Annual	13	0.97 (0.74 – 1.27)	Miller *et al*. (2002)
Stockholm (1981 – 1985)	40 – 49	1	28	2	None	11.4	1.08 (0.54 – 2.17)	Frisell and Lidbrink (1997)
Gothenburg (1982 – 188)	39 – 49	2	18	5	None	12	0.55 (0.31 – 0.96)	Bjurstam *et al*. (1997)

[a]CBE = clinical breast examination.
[b]RR = relative risk of death from breast cancer in study group/control group.
[c]CI = confidence interval

(2) at that time (prior to 1997), no individual trial had yet found statistically significant benefit for screening women below age 50 (Nystrom *et al*., 1993; SCS/SNBHW, 1996; Tabar *et al*., 1995).

Several successive meta-analyses of combined data for multiple RCTs were analyzed beginning in 1993. By accruing a greater number of women-years of follow-up than possible from any one RCT, these studies attempted to demonstrate statistically significant benefit for screening women in their forties. The earliest published meta-analyses by Elwood *et al*. (1993), Glasziou *et al*. (1995), and Kerlikowske *et al*. (1995) suggested little, if any, benefit from screening women under 50 y of age (Tables 7.4 and 7.5).

Subsequent meta-analyses by Smart *et al*. (1995) and SCS/SNBHW (1996) included more recent follow-up and showed statistically significant 24 percent mortality reductions for women ages 40 to 49 at entry into seven population-based RCTs (Table 7.5) and a 15 to 16 percent mortality reduction that barely missed statistical significance when a nonpopulation-based RCT, the NBSS, was also included (Table 7.4). A more recent meta-analysis by Hendrick *et al*. (1997) found statistically significant mortality reduction of 18 percent for all eight RCTs (Table 7.4), and 29 percent for the five Swedish RCTs (Table 7.6) for women invited to screening at ages 40 to 49. Thus, with increasing length of follow-up, successive meta-analyses have shown progressively greater mortality reduction, as well as narrowing of the confidence limits for women ages 40 to 49 at entry.

Another origin of the controversy regarding women ages 40 to 49 was the 7 y follow-up report from the NBSS Trial that found no reduction in breast cancer deaths among these women who were offered five annual screenings by mammography and physical examination (Miller *et al*., 1992a). Critics of the NBSS maintain that problems such as poor mammographic technique and an allegedly flawed randomization process have cast doubts on the validity of these findings. For the majority of the trial, >50 percent of the mammograms were poor or completely unacceptable, even as assessed by the standards of the day (Baines *et al*., 1990; Kopans, 1990; Kopans and Feig, 1993). It has been suggested that the excess of late-stage cancers found throughout the trial in the study group compared with the control group resulted from a preferential allocation of women with breast masses to the study group because women were given a physical examination prior to their randomization (Boyd, 1997; Boyd *et al*., 1993; 1998; Day and Duffy, 1991; Tarone, 1995). Regardless of whether NBSS results are included or excluded in meta-analyses of screening women ages 40 to 49, the

TABLE 7.4—*All RCTs: Results of successive meta-analyses of women ages 40 to 49 y at entry.*

Trials	Follow-Up (y)	RR[a] (95% CI)[b]	Reference
Six population-based[c] + NBSS[d]	5 – 7	1.08 (0.85 – 1.39)	Elwood *et al*. (1993)
All eight trials[e]	7 – 8	0.95 (0.77 – 1.18)	Glasziou *et al*. (1995)
All eight trials[e]	7 – 18	0.92 (0.75 – 1.13)	Kerlikowske *et al*. (1995)
All eight trials[e]	7 – 18	0.84 (0.69 – 1.02)	Smart *et al*. (1995)
All eight trials[e]	10.5 – 18	0.82 (0.71 – 0.95)	Hendrick *et al*. (1997)
Seven trials[f]	14	0.85 (0.73 – 0.99)	Humphrey *et al*. (2002)

[a]RR = relative risk.
[b]CI = confidence interval.
[c]Six population-based trials (HIP, Kopparberg, Ostergotland, Malmo, Stockholm, and Edinburgh).
[d]NBSS = National Breast Screening Study of Canada.
[e]All eight trials [seven population-based trials (HIP, Kopparberg, Ostergotland, Malmo, Stockholm, Edinburgh, and Gothenburg) plus NBSS].
[f]Seven trials (HIP, Kopparberg, Ostergotland, Malmo, Stockholm, Gothenburg, and NBSS).

TABLE 7.5—*All population-based RCTs. Results of successive meta-analyses of women ages 40 to 49 y at entry.*

Trials	Follow-Up (y)	RR[a] (95% CI)[b]	Reference
Six trials[c]	5 – 7	0.99 (0.74 – 1.32)	Elwood *et al*. (1993)
Seven trials[d]	7 – 18	0.76 (0.62 – 0.95)	Smart *et al*. (1995)
Seven trials[d]	7 – 18	0.76 (0.62 – 0.93)	SCS/SNBHW (1996)

[a]RR = relative risk.
[b]CI = confidence interval.
[c]Six population-based trials (HIP, Kopparberg, Ostergotland, Malmo, Stockholm, and Edinburgh).
[d]Seven population-based trials also includes Gothenburg (plus the other six population-based trials).

TABLE 7.6—*All five Swedish RCTs:*[a] *Results of successive meta-analyses of women ages 40 to 49 y at entry.*

Follow-Up (y)	RR[b] (95% CI)[c]	Reference
7 – 12	0.87 (0.63 – 1.20)	Nystrom *et al*. (1993)
10 – 15	0.77 (0.54 – 1.01)	SCS/SNBHW (1996)
11.4 – 15.2	0.71 (0.57 – 0.89)	Hendrick *et al*. (1997)

[a]Kopparberg, Ostergotland, Malmo, Stockholm and Gothenburg
[b]RR = relative risk.
[c]CI = confidence interval.

results do show statistically significant benefit. Inclusion of NBSS results merely lowers the point estimate of benefit.

Two other individual RCTs have now shown statistically significant benefit for women ages 40 to 49 (Table 7.3). Bjurstam *et al*. (1997) reported a statistically significant 45 percent mortality reduction for women ages 39 to 49 at randomization in the Gothenburg Sweden Trial. Andersson and Janzon (1997) reported a statistically significant 36 percent breast cancer mortality reduction for women ages 45 to 49 at randomization in the Malmo Trial. The results from Gothenburg are more persuasive, however, because a smaller proportion of women in the Gothenburg Trial who began screening in their forties had their cancers detected at age 50 or over.

7.1.5.5 *Results for Screening Women Ages 75 and Older.* The question of mammographic screening for elderly women is clinically relevant because there are approximately 9.6 million women aged 75 y and older in the United States today (USCB, 2000). The average life expectancy for a woman at age 75 is 12 y (USCB, 2000). It is reasonable to expect that elderly women of good health will benefit from screening. For most older women with screen-detected breast cancer, death from another illness will not occur before they experience the benefit from screening. Reduction in breast cancer mortality among women aged 50 y and older becomes apparent within 4 y from entry into randomized trials.

Strictly speaking, benefit from screening women age 75 y and older has not been proven because this age group was not included in any RCT (Table 7.2). Nevertheless, there is no biologic reason why early detection should not be effective for these women. Survival rates according to stage of disease are almost as high in older, as in younger women (Yancik *et al*., 1989). The detection sensitivity of mammography is higher in the elderly due to their generally

more fatty breast composition (Faulk *et al*., 1995). Therefore, screening mammography should be performed on women aged 75 y and older if their general health and life expectancy are good (Feig, 1996b).

7.1.5.6 *Estimation of Currently Attainable Benefit from Mammographic Screening*. Benefits from screening mammography should be greatest when all screening parameters are optimized. However, no RCT has had all of the following characteristics: annual screening intervals, high-quality mammography including two views per breast, physical examination, nearly complete participation of the screening group, and minimal contamination of the control group. The deficiencies found in every trial have limited, and in some cases precluded, demonstration of any benefit.

Among the RCTs, noncompliance (incomplete participation of study group women) ranged from 10 to 39 percent (Smart *et al*., 1995). Studies performed on data from the individual trials have estimated that, if all women in the study group had attended each screening round, there would have been at least an additional 10 percent reduction in breast cancer deaths (Day, 1991; Feig, 1995; 1997).

Performance of a CC view, in addition to a MLO view, will detect 3 to 11 percent (mean, seven percent) more cancers than are detected by a MLO view alone (Andersson *et al*., 1978; Anttinen *et al*., 1989; Bassett *et al*., 1987a; Muir *et al*., 1984; Sickles *et al*., 1986b; Thurfjell *et al*., 1994). Among the seven population-based trials, only the HIP Trial and the Gothenburg Trial used two views on all examinations (Bjurstam *et al*., 1997; Shapiro *et al*., 1988). The Malmo Trial used two views in the first two screenings and a MLO view alone on all subsequent screenings, unless the patient had dense breasts (Andersson *et al*., 1988; Nystrom *et al*., 2002). Edinburgh used two views on the initial screening and one view on all subsequent screenings (Roberts *et al*., 1990). The Stockholm, Kopparberg and Ostergotland Trials used a single-MLO view in all screenings (Frisell *et al*., 1991; Tabar *et al*., 1995).

Aside from the HIP Trial, which screened annually, screening intervals at the other population-based RCTs ranged from 18 to 33 months. Numerous studies indicate that greater benefit should result from annual screening, especially for women ages 40 to 49 where breast cancer growth rates appear to be faster (Feig, 1994; Moskowitz, 1986; Pelikan and Moskowitz, 1993; Tabar *et al*., 1987). Based on a tumor growth-rate model, Michaelson *et al*. (1999) calculated that annual screening would result in a 51 percent reduction in the rate of distant metastic disease compared with a 22 percent reduction at a screening interval of 2 y.

It has been estimated that the use of annual screening in the Swedish Two-County Trial could have resulted in an additional 18 percent mortality reduction for women ages 40 to 49 at entry who were screened every 2 y, and an additional 12 percent mortality reduction for women ages 50 to 59 at entry who were screened every 33 months (SCS/SNBHW, 1996). For women ages 39 to 49 at entry into the Gothenburg Trial, who were screened every 18 months, it has been estimated that annual screening could have resulted in an additional 20 percent mortality reduction (Feig, 1997).

The fact that no randomized trial had more than four to five screening rounds places a limit on the magnitude of relative mortality reduction that could be measured using standard methods. Screening needs to be performed for a much longer duration in order to reach a "steady state" when the greatest mortality reduction will be apparent. Miettinen *et al*. (2002), showed that for women ages 55 to 69 y at entry into the Malmo Sweden Trial, mortality reduction was highest between 8 to 11 y of follow-up. For that period, they calculated a 55 percent reduction in breast cancer deaths. This value was much higher than the 26 percent mortality reduction reported by Andersson and Nystrom (1995) who had included data from before year eight when benefit had not yet peaked, and from after year 11 when benefit was being diluted.

7.1.6 *Recent Service Screening Results*

After the success of the Swedish randomized trials, organized service screening mammography became routine in nearly all Swedish counties (Duffy *et al*., 2002b). A recent study by Tabar employed a new, non-RCT method to measure the effect of mammography in a population where service screening is offered to all women age 40 and over (Tabar *et al*., 2001). This method is not affected by study group noncompliance nor control group contamination. The authors compared breast cancer death rates in two Swedish counties over three periods of time: 1968 to 1977 when virtually no women were screened, 1978 to 1987 when half the population was offered screening in the RCT, and 1988 to 1996 after completion of the trial when screening was offered to all women and 85 percent of the population was being screened.

When compared with breast cancer death rates among women ages 40 to 69 in the prescreening era, breast cancer death rates in 1988 to 1996 were reduced 63 percent (RR = 0.37, 95 percent CI = 0.30 to 0.46) for screened women and 50 percent (RR = 0.50, 95 percent CI = 0.41 to 0.60) for the entire population (85 percent

screened plus 15 percent nonscreened). During this time, reduction in death rates from breast cancer for screened women were similar to those for women screened during the trial (*i.e.*, 63 versus 57 percent). However, during the RCT trial period (1978 to 1987) only half of the population was offered screening. For that era, breast cancer death rate reduction in the entire population was only 21 percent.

It seems probable that screening rather than advances in treatment was responsible for nearly all the benefit. The RR of breast cancer death among nonscreened women age 40 to 69 was similar (1, 1.17, and 1.19) during the three consecutive periods. Moreover, the breast cancer death rate for women ages 20 to 39, virtually none of whom were screened, showed no significant difference (*e.g.*, 1, 1.10, and 0.81, respectively) during these three consecutive periods.

Possibly women who agree to be screened have selection bias factors, that, apart from the screening process, improved their survival rates. Even assuming the maximum effect of selection bias, screening was shown to reduce breast cancer deaths by approximately 50 percent (Feig, 2002).

A study by Duffy *et al*. (2002b), assessed the effect of service screening in seven Swedish counties. Among women ages 40 to 69 y, breast cancer mortality was reduced 44 percent for screened women and 30 percent for women offered screening compared to the prescreening era. Based on breast cancer mortality trends, it was estimated that only 12 percent of the mortality reduction was due to improved therapy and patient management apart from the screening process.

Similar results were found by Garne *et al*. (1997) for women in Malmo, Sweden. Between 1977 and 1992 breast cancer mortality decreased in Malmo by 43 percent (95 percent CI = 26 to 56 percent) among women ages 45 y and older as compared with 12 percent (95 percent CI = 8 to 16 percent) in the rest of Sweden. There was no change in mortality among women younger than age 45 y. The decrease in mortality occurred in temporal relationship to the introduction of screening mammography and adjuvant therapy consistent with a causal relationship. The Malmo Trial (1976 to 1986) offered screening mammography to women age 45 to 69. Screening compliance was estimated at 79 percent and approximately 24 percent of control group women obtained screening outside the trial (Andersson *et al*., 1988; Nystrom *et al*., 2002).

In another service screening study, Lenner and Jonsson (1997), found a 28 percent decrease in breast cancer mortality among women ages 40 to 74 y in two northern Swedish counties. Two

adjacent counties, where screening was not yet offered and that until that time had an identical breast cancer mortality served as controls.

In Finland, nationwide population-based breast carcinoma screening for women ages 50 to 59 y was introduced gradually between 1987 and 1991. Women born in even years began screening in 1987 or 1988. Women born in odd years began screening between 1989 and 1991 and served as controls. An effect from screening emerged after 3 to 4 y of follow-up and rapidly diluted as controls were screened. For this narrow window of time, Hakama *et al*. (1997), found that mortality from breast carcinoma was 24 percent lower among those women offered screening and 33 percent lower among those who were actually screened.

Results from these many service screening studies indicate that the reduction in breast cancer mortality found in the randomized trials can be obtained and exceeded in nonresearch organized screening settings. These studies indicate that there is benefit from screening mammography.

7.1.7 *Screening Guidelines*

Many major medical organizations, including the American Cancer Society (Leitch *et al*., 1997), the ACR (Feig *et al*., 1998), and the American Medical Association (AMA, 1999), now advise annual screening mammography beginning at age 40. Other organizations, such as NCI and the American College of Obstetrics and Gynecology, advise screening mammography at 1 to 2 y intervals for women ages 40 to 49 y and annual mammography thereafter. The U.S. Preventive Services Task Force recommends screening every 1 to 2 y for women age 40 and older (PSTF, 2002). In contrast to these recommendations, a National Institutes of Health Consensus Panel was unable to find sufficient evidence for screening women in their forties (NIH, 1997). It must be recognized that screening *per se*, even when performed every year, does not guarantee benefit. For a given screening interval, the amount of benefit, whether greater or less than that observed at the RCTs, depends on the quality of mammographic technique and interpretation.

7.2 Radiation Risks of Mammography

The risks associated with routine mammographic screening which have received the most attention are those concerned with the possible induction of breast cancer by the low-energy radiation

associated with mammography, and these are the risks discussed in detail in this Section. However, it must be remembered that there are other and likely more important costs of mammography including the psychological and physical (due to surgical intervention) effects on women with FP diagnoses (Feig, 2004), and the very substantial resource implications for the health care system of a mammography program (Lindfors and Rosenquist, 1995; 2001; Rosenquist and Lindfors, 1998). These latter costs are very difficult to quantify in a cost-benefit analysis, and are not considered further in this Section.

A number of epidemiologic studies of adult women have contributed knowledge of the long-term risks of ionizing radiation to the female breast (Boice, 2001; Preston *et al*., 2002a; UNSCEAR, 2000). Among these studies are those of Japanese atomic-bomb survivors (Shimizu *et al*., 1990; Thompson *et al*., 1994); female tuberculosis patients in Massachusetts who received multiple chest fluoroscopies in conjunction with artificial pneumothorax (Boice *et al*., 1991); a similar series of female tuberculosis patients in Canada (Howe and McLaughlin, 1996); women in New York State receiving radiotherapy for postpartum mastitis (Shore *et al*., 1986); and Swedish women receiving x-ray treatment for fibroadenomatosis and other benign breast conditions (Baral *et al*., 1977; Mattsson *et al*., 1993).

7.2.1 *Factors Defining Breast Cancer Risk*

The key findings from the above studies can be summarized as follows:

- The great majority of studies demonstrated increased incidence or mortality from breast cancer following irradiation.
- A linear dose-response function generally provides a reasonable fit to the data, though for some studies it is not possible to exclude the possibility of a linear-quadratic relationship. Using a linear model to fit the data from high dose studies to predict risk from the low doses employed in mammography is a conservative approach (if the quadratic term is positive) in that it predicts greater breast cancer risk than with the use of the linear-quadratic model.
- Age at exposure has a substantial moderating effect on risk per unit of dose. Generally, the older a woman is at the time of exposure, the lower the risk per unit of dose.

- There appears to be a minimum latent period between exposure and the time at which risk increases, a period that appears to be at least 5 y. In addition, there appears to be no measurable increase in risk until the age at which natural breast cancer risk increases in the population around the age of 30.
- Fractionation of dose or reduced dose rate does not appear to have a major impact on subsequent risk. Thus, risk estimates based on studies, such as the atomic-bomb survivors in which doses were received in a single exposure, are generally similar to those based on studies such as the fluoroscopy studies in which doses were highly fractionated. Therefore, a conservative assumption would be that fractionation does not reduce risk per unit of dose, and this assumption is used in the following risk analyses.
- There is no evidence to date that risk of breast cancer returns to the normal background rate for any of the cohorts under observation, some of which have been followed for 40 or more years.
- The nature of the interaction between radiation and other risk factors in inducing breast cancer has been most studied with respect to the interaction between radiation and age at risk. Two simple probabilistic models have often been used, particularly for risk projections, namely the simple multiplicative and simple additive models. In the former, it is assumed that the RR for breast cancer following an exposure to a certain amount of radiation subsequently remains constant and multiplies the natural background age-specific risk of breast cancer. In the latter model, it is assumed that following irradiation, a constant amount of risk is added to the natural background age-specific breast cancer risk. The simple RR model predicts much larger excesses of breast cancer due to radiation than does the simple additive risk model. Recent analyses (Howe and McLaughlin, 1996; NAS/NRC, 1990, Preston *et al*., 2002a), have used modified versions of these two models as discussed below. Neither the simple additive nor the simple RR model provide adequate descriptions of either breast cancer incidence or mortality.

  Several studies (Boice and Stone, 1978; Goodman *et al*., 1997; Holmberg *et al*., 2001; Howe, 1989; Land *et al*., 1994; Shore *et al*., 1980), have examined the interaction between radiation and other risk factors for breast cancer, in addition to age. In general, these studies are reasonably consistent

with a multiplicative (*i.e.* constant RR) model, though, because of small sample sizes, it generally is not possible to exclude the possibility of other types of interaction models.

- There is no evidence that the case fatality rate from radiation-induced breast cancer is any different than that for other breast cancers.
- Although a number of women in the various cohort studies had breast tissue doses in excess of 1 Gy, both the atomic-bomb survivors study, and some other cohorts, had a substantial number of women with breast tissue doses below 1 Gy. Therefore, although the models used for risk estimation for women exposed to the very low doses involved in mammography (typically, a mean glandular dose of 4 mGy) inevitably involve extrapolation from higher doses, there is a substantial contribution to these risk estimates from women exposed at doses of <1 Gy.

7.2.2 *Quantitative Risk Estimates*

The BEIR V Committee (NAS/NRC, 1990), conducted a combined analysis of breast cancer incidence from the atomic-bomb survivors study, the Massachusetts fluoroscopy study, and the New York postpartum mastitis study, and a combined analysis of the breast cancer mortality from the atomic-bomb survivors and the Canadian fluoroscopy series.

The BEIR V Committee's preferred risk model for breast cancer incidence (I) for women age 40 y or more is given by:

$$RR_{\mathrm{I}} = 1 + 0.48\ D\ \mathrm{e}^{-0.90 + 6.67\ LT_{15} - 1.28\ LT_{30}} \tag{7.1}$$

where RR_{I} is the relative risk for breast cancer incidence, D is the breast tissue dose in gray, LT_{15} is log of years since exposure divided by 15 (if time since exposure is <15 y and is zero otherwise), and LT_{30} is log of years since exposure divided by 30 (if time since exposure is ≥15 y and is zero otherwise). Thus, the excess relative risk (ERR) for incidence does not continue to decrease with age at exposure once a woman is past 40 y of age. Calculated RRs for breast cancer incidence predicted by this model for a mean glandular dose of 4 mGy, a typical dose from a mammographic screen (Section 5), demonstrates the lack of dependence on age at exposure once the age has reached 40 y.

The preferred mortality risk model selected by the BEIR V Committee (NAS/NRC, 1990) was a RR model which was linear in dose,

TABLE 7.7—*RR of breast cancer incidence following a mean glandular dose of 4 mGy predicted by the BEIR V model (NAS/NRC, 1990).*

Age at Exposure	Time Since Exposure (y)			
	10	20	30	40
40	1.00005	1.00133	1.00079	1.00055
45	1.00005	1.00133	1.00079	1.00055
50	1.00005	1.00133	1.00079	1.00055
55	1.00005	1.00133	1.00079	1.00055
60	1.00005	1.00133	1.00079	1.00055
65	1.00005	1.00133	1.00079	1.00055

but with the slope of the line modified both by age at exposure and time since exposure. For women exposed at age 15 y or greater (which includes the age group relevant to the issue of mammography), the mortality risk model selected by the committee was:

$$RR_{\mathrm{M}} = 1 + 1.22\ D\ \mathrm{e}^{-0.104\ LT\ -2.212\ LT_{20}\ -0.0628\ A} \qquad (7.2)$$

where RR_{M} is the relative risk of breast cancer mortality, D is the breast tissue dose in gray, LT is log of years since exposure divided by 20, LT_{20} in the log squared of years since exposure divided by 20, and A is age at exposure minus 15 y. Thus, this model predicts that the ERR per unit of dose decreases with increasing age at exposure, and peaks approximately 20 y after exposure. Table 7.8 shows the estimated RR for a mean glandular dose of 4 mGy for breast cancer mortality based on the BEIR V model (NAS/NRC, 1990) as a function of age at exposure and years since exposure.

A number of other models for both breast cancer incidence and mortality have been presented either by the authors of individual studies, or from the combined analysis of several studies. UNSCEAR (2000) presents an excellent summary of many of these models, and a thorough discussion of the ERR and excess absolute rate models is presented by Preston *et al*. (2002a; 2002b). In general, predictions of incidence and mortality from these various models differ, to some extent, from the predictions based on the BEIR V models (NAS/NRC, 1990), but, in general, these differences do not materially change the benefit/risk calculations presented later in this Section. The studies chosen by the BEIR V committee

TABLE 7.8—*RR of breast cancer mortality following a mean glandular dose of 4 mGy predicted by the BEIR V model (NAS/NRC, 1990).*

Age at Exposure	Time Since Exposure (y)			
	10	20	30	40
40	1.00037	1.00101	1.00068	1.00033
45	1.00028	1.00075	1.00049	1.00024
50	1.00020	1.00055	1.00036	1.00017
55	1.00015	1.00040	1.00027	1.00013
60	1.00011	1.00029	1.00020	1.00009
65	1.00008	1.00021	1.00015	1.00007

(NAS/NRC, 1990) all had a reasonable number of women in the age group of 40 plus (the age at which screening mammography generally starts) and all had a reasonable number of years of follow-up. The risk models proposed by NAS/NRC (1990) are used in this Report for estimating the risk of incidence and mortality from mammographic radiation exposures.

It must be emphasized that there is substantive uncertainty in risk estimates of both the breast cancer incidence and mortality. This uncertainty is primarily from four sources. First, there is the usual sampling variability in the observed number of cases or deaths in the epidemiologic studies on which the risk estimates are based; this uncertainty is reflected in the width of the corresponding confidence interval (CI). Second, there is uncertainty in the most appropriate choice of statistical model used to fit the data observed in the epidemiologic studies. This applies both to the shape of the dose-response curve and, in particular, the modifying effects of factors such as age at exposure and time since exposure. The distinction between ERR (multiplicative) and excess risk (additive) statistical models is less critical if both models include time dependent terms (Miller *et al.*, 1989). In particular, there are very different background breast cancer rates in different countries (*e.g.*, Japan), as compared to North American and Western European populations. For mortality, it has been reported that ERR models which allow for modification by age at exposure give similar parameter estimates for both the atomic-bomb survivors study, and the large Canadian fluoroscopy cohort (Howe and McLaughlin, 1996). In contrast, for breast cancer incidence it appears as though

the excess risk model rather than an ERR model when fitted to the data from a number of cohorts, including the atomic-bomb survivors study, but not including the Canadian fluoroscopy study, gives more similar parameter estimates across studies (Preston *et al*., 2002a). However, the two models (*i.e*., the ERR mortality model and the excess risk incidence model) both give similar predictions as these models include modifying effects. It appears as though the ERRs estimated from the Japanese atomic-bomb study, and cohorts of western women, are in general, fairly similar, which provides justification for use of the multiplicative model. Third, there is the problem of measurement error in the doses estimated for the epidemiologic studies and such measurement error also introduces bias in the risk estimates. A fourth uncertainty factor is the relative biological effectiveness of the low-energy photons used for mammography compared to the high-energy photons involved in virtually all the epidemiologic studies of breast cancer and radiation. It has been suggested, based on *in vitro* and *in vivo* studies, that the relative biological effectiveness (RBE) for such low-energy photons could be of the order of two (Brenner, 1999; Brenner and Amols, 1989). However, as yet, there appears to be no definitive epidemiologic evidence to support this magnitude of difference in RBE. In addition, there does exist a dose or dose rate effectiveness factor for low-LET radiation that could diminish the risk for the highly-fractionated, very low doses involved in mammography, and which might compensate, to some extent, for differential RBEs. This, clearly, is still a matter of uncertainty, but, even if the RBE was of the order of twofold, the interpretation of the subsequent benefit/risk calculations would not be materially altered. No comprehensive assessment of the overall magnitude of the error arising from these four sources is available, but it is likely that all four will contribute to the uncertainty in estimates based on current risk models.

7.3 Radiation Risk Versus Benefit of Mammographic Screening

In this Section, a comparison is presented between the risks of breast cancer induced by radiation exposure of the breast during mammography and the possible reduction in breast cancer mortality arising from mammographic screening. Risks are estimated in terms of the BEIR V models (NAS/NRC, 1990), presented above, and benefits are considered in terms of various assumed reductions in breast cancer mortality rates as a consequence of mammographic screening. The benefit/risk model uses standard life table

techniques to estimate the numbers of breast cancer cases and breast cancer deaths that will occur in a population of 100,000 women under various mammographic screening scenarios. The numbers of cases or deaths are those which will occur from the age at which a woman is first screened, under a particular scenario, to the end of life.

A population of 100,000 women was assumed to have the ethnic or racial composition of the current United States population. The assumptions of, and data used in, the model are as follows:

- Single-year age-specific breast cancer incidence, breast cancer mortality and all other cause mortality rates were estimated by linear interpolation from the corresponding 5 y age specific United States rates for 1998 (incidence) and 1995 to 1999 (mortality). For women aged 90 y or more, it was assumed that the age-specific rate for age 89 applied, in view of the substantial uncertainty in estimates, based on direct observation of women at these ages.
- "Lifetime" refers to experience to the end of age 99 y.
- A value of 4 mGy was used for the mean glandular dose from one mammographic screening.
- Breast cancer incidence and mortality ERRs were computed using the NAS/NRC (1990) models described above for each year, starting 5 y after the particular mammography and continuing to the end of life, with modification by time since exposure, as in the models. ERRs were added for each year in which a mammographic procedure was received.
- The baseline breast cancer incidence and breast cancer mortality rates were then multiplied by the corresponding RRs arising from the radiation dose due to mammography.
- The benefit of mammographic screening was modeled as a percentage reduction in breast cancer mortality rates starting 2 y after the first screen in a particular series and ending 15 y after the end of screening. It was assumed that the percentage reduction remained constant for this period, but clearly this must be an approximation since presumably any benefit will be expected to increase during the first few years of screening, and decrease following the cessation of screening. Various arbitrary values of the percent reduction were used since the primary objective was to assess the degree of benefit that would be required to offset the increased risk. No attempt was made to use more biologically mechanistic models of the effectiveness of screening

utilizing factors such as growth rates, transition probabilities and lead-time distributions, since this was beyond the scope of this Report.

- Benefit was measured, both, in terms of the decrease in the estimated number of lifetime breast cancer deaths, and, also in terms of the number of women-years of life saved.
- Assuming the linear extrapolation inherent in the NAS/NRC (1990) models applies at the very low doses and dose rates used, any mammographic screening program may increase breast cancer incidence. This arises because of radiation-induced breast cancer, and also because any reduction in breast cancer mortality due to screening leads to more women-years at risk and, hence, greater opportunity for developing breast cancer. The first effect is clearly a detrimental effect of mammographic screening, and must be weighted against benefits in terms of reduced breast cancer mortality due to screening. However, it seems inappropriate to consider the second effect (*i.e.*, increased incidence due to longer life expectancy) as a "cost." Therefore, the impact of mammographic screening on breast cancer incidence is presented only for the scenario in which it is assumed that there is no benefit from screening, since under this scenario excess breast cancer incidence is attributable directly to the radiation effect of mammography.

The results of applying the above-model to scenarios involving only a single mammogram are shown in Tables 7.9 and 7.10. Table 7.9 shows the number of extra breast cancer cases expected to be induced by mammography (under the scenario of no assumed benefit), together with the reduction in numbers of breast cancer deaths for various assumed percentage benefits from screening at various ages. Table 7.10 shows the corresponding data with the benefit expressed in terms of years of life saved.

Tables 7.11 and 7.12 show the data for scenarios in which mammographic screening starts at various ages and is carried out yearly, up to and including age 69. It should be noted that the model, *per se*, does not take into account the extra benefits which might be expected to accrue from repeated, as opposed to, single mammographic screening other than the fact that the benefit of screening under multiple screens will operate for more years than with a single screen. If screening is beneficial, then presumably, this will result in a greater percentage reduction in breast cancer mortality risk from repeated, as opposed to, single screenings.

TABLE 7.9—*Effect of mammographic screening on the number of breast cancer cases and breast cancer deaths in a population of 100,000 women subsequent to a single screening examination at various ages.*[a]

Age	Total Cases[b]	Excess Cases[c]	Total Deaths[b]	Change in Number of Deaths with Benefit of:						
				0%	1%	5%	10%	20%	30%	40%
40	16,131	2	3,273	0	–4	–24	–49	–98	–148	–197
45	15,591	1	3,207	0	–6	–33	–67	–134	–201	–269
50	14,569	0	3,087	0	–8	–41	–83	–167	–251	–335
55	13,211	0	2,910	0	–9	–49	–99	–199	–298	–398
60	11,610	0	2,694	0	–11	–57	–115	–231	–347	–463
65	9,935	0	2,457	0	–12	–64	–129	–259	–388	–518

[a]Assuming each screening examination leads to a total mean glandular dose of 4 mGy.
[b]Total breast cancer cases or breast cancer deaths subsequent to a given age in the absence of screening.
[c]Excess breast cancer cases assuming no reduction in mortality due to mammographic screening.

TABLE 7.10—*Effect of mammographic screening on years of life in a population of 100,000 women subsequent to a single screening examination at various ages.*[a]

Age	Increase in Years of Life with Benefit of:						
	0%	1%	5%	10%	20%	30%	40%
40	–7	150	780	1,563	3,137	4,712	6,292
45	–3	181	928	1,859	3,721	5,586	7,452
50	0	194	982	1,971	3,943	5,919	7,897
55	0	191	969	1,941	3,887	5,835	7,783
60	0	179	907	1,819	3,642	5,468	7,294
65	0	157	799	1,600	3,207	4,814	6,423

[a]Assuming each screening examination leads to a total mean glandular dose of 4 mGy.

TABLE 7.11—*Effect of mammographic screening on the number of breast cancer cases and breast cancer deaths in a population of 100,000 women subsequent to annual screening examinations starting at indicated ages up to age 69.*[a]

Age	Total Cases[b]	Excess Cases[c]	Total Deaths[b]	Change in Number of Deaths with Benefit of:						
				0%	1%	5%	10%	20%	30%	40%
40	16,131	18	3,273	4	–22	–128	–260	–525	–792	–1,059
45	15,591	9	3,207	2	–23	–125	–252	–508	–764	–1,021
50	14,569	4	3,087	1	–22	–118	–238	–478	–719	–960
55	13,211	2	2,910	0	–21	–108	–217	–436	–656	–876
60	11,610	0	2,694	0	–19	–96	–192	–386	–580	–774
65	9,935	0	2,457	0	–16	–82	–164	–328	–493	–658

[a]Assuming each screening examination leads to a total mean glandular dose of 4 mGy.
[b]Total breast cancer cases or breast cancer deaths subsequent to given age in absence of screening.
[c]Excess breast cancer cases assuming no reduction in mortality due to mammographic screening.

TABLE 7.12—*Effect of mammographic screening on years of life in a population of 100,000 women subsequent to annual screening examinations starting at indicated age up to age 69.*[a]

Age	Increase in Years of Life with Benefit of:						
	0%	1%	5%	10%	20%	30%	40%
40	–55	415	2,306	4,669	9,406	14,152	18,910
45	–26	407	2,135	4,299	8,631	12,975	17,328
50	–12	364	1,874	3,759	7,540	11,328	15,122
55	–6	304	1,558	3,124	6,260	9,406	12,554
60	–2	243	1,231	2,470	4,947	7,427	9,915
65	0	181	920	1,842	3,691	5,541	7,392

[a]Assuming each screening examination leads to a total mean glandular dose of 4 mGy.

From Table 7.9, it will be seen that a single mammographic screening, even for women aged 40, results in an excess of only two per 100,000 women screened during the remainder of life, as compared to the naturally occurring number of cases of >16,000. Even if screening confers no benefit (*i.e.*, reduction of zero percent in breast cancer mortality rate), the excess number of breast cancer deaths is again extremely small, particularly when compared to the background number of >3,000. Even a reduction in breast cancer mortality rate of one percent confers more benefit than risk, in terms of reduced number of breast cancer deaths, and a reduction of 20 to 40 percent leads to a substantial decrease in the number of deaths. The increase in reduction of breast cancer deaths with increasing age reflects the fact that the model assumes that screening is effective for a fixed period following a single screen (*i.e.*, 2 to 15 y subsequently), and hence, as breast cancer mortality rates increase with age, the benefit is correspondingly greater amongst older women.

Table 7.10, which presents the benefits in terms of women-years of life saved, again demonstrates that a reduction in breast cancer mortality rates of even one percent is more than sufficient to offset any increased mortality due to radiation-induced breast cancer. However, the pattern of benefit with respect to age at which screening is conducted is different. Reduction of breast cancer mortality in younger women obviously leads to a larger number of years saved per breast cancer cases. Hence, maximal benefit in terms of this measure is accrued to earlier ages than that shown in Table 7.9.

With multiple screens (Tables 7.11 and 7.12), the excess number of breast cancer cases is substantially more than for a single screen with a maximum percentage increase in subsequent lifetime breast cancer cases of 0.1 percent for women first screened at age 40. However, again, even a one percent reduction in breast cancer mortality rates more than offsets the increased risk of breast cancer mortality from screening and the benefit substantially increases for higher reductions in the mortality rate. The pattern of maximal benefit with respect to age at which screening starts is somewhat different for multiple screening than that for a single screen in terms of reduced breast cancer deaths. Under the present model, the benefits shown in Table 7.11 will extend to age 84 for all women, and hence, the benefit for younger women as compared to older women is relatively greater under the multiple, as opposed to single-screen scenario. This is emphasized even more when the benefit is presented in terms of women-years of life saved (Table 7.12).

In summary, it is clear that in terms of breast cancer mortality, the risk of radiation-induced mortality, even given a series of 30 annual screenings, is offset by even a minimal benefit in reduced breast cancer mortality from screening as low as one percent. While there is an increased risk of breast cancer incidence from screening, this cannot be equated directly with reduction in breast cancer mortality. However, it seems reasonable to conclude qualitatively that the slight increase in the risk of breast cancer incidence is more than offset by reduction in breast cancer mortality, given even a minimal benefit of mammographic screening.

8. Other Breast Imaging Modalities

Among the various imaging methods designed to evaluate the breast for cancer, conventional mammography is the most accurate and most widely used. It has gained clinical acceptance for screening because it may depict a cancer often before the tumor mass becomes large enough to be palpable. Conventional mammography is valuable in helping to distinguish benign from malignant lesions, facilitating prompt biopsy of cancers, while encouraging clinical management of many benign breast lesions.

Digital mammography has undergone clinical testing and several manufacturers' digital units have been approved for clinical use in both screening and diagnostic mammography. The clinical studies performed by manufacturers to gain FDA approval were conducted primarily among women being examined by diagnostic mammography for workup of mammographic or palpable findings. Lewin *et al*. (2001; 2002) conducted a screening study comparing digital to screen-film mammography. It was done on a single manufacturer's prototype digital mammography system (Senographe 2000D digital mammography prototype, General Electric Medical Systems, Waukesha, Wisconsin) at two academic screening centers. The study recruited asymptomatic women attending for routine screening exams and obtained informed consent to add a digital screening exam to their routine screen-film exam. Sixty-seven hundred and thirty-six (6,736) women were recruited between August 1997 and June 2000. Results based on biopsy or 1 y follow-up indicated that digital mammography had a significantly lower recall rate (11.8 versus 14.9 percent, $p > 0.001$) and significantly lower biopsy rate (14 versus 21 per 1,000 exams, $p < 0.001$) than screen-film mammography. Digital had an insignificantly lower sensitivity of 54 percent, compared to 66 percent for screen-film mammography, based on a total of 50 cancers ($p > 0.1$). The receiver operating curve (ROC) areas were also insignificantly lower for digital (0.74) than for screen-film mammography (0.80): $p = 0.18$ (Lewin *et al*., 2002).

In a similarly designed trial performed on 3,683 women in Norway, Skaane *et al*. (2003) found that screen-film mammography depicted 28 malignancies and that digital mammography performed using a General Electric unit depicted 23 malignancies. The

differences between cancer detection rates was not significant ($P = 0.23$). The recall rate for digital mammography was slightly higher than that for conventional mammography (4.6 versus 3.5 percent). The investigators attributed this difference to a learning curve effect.

A larger study of similar design comparing digital to screen-film mammography is now being conducted by the ACR Imaging Network. The digital mammographic screening trial is comparing digital mammography from four different manufacturers to screen-film mammography. Enrollment of 49,500 asymptomatic women, who will receive both digital and screen-film mammography, was completed at the end of 2003. This study is powered to detect a 0.06 difference in ROC areas with statistical significance, if such a difference exists in favor of either modality.

Other breast imaging methods currently have less widespread application; these include ultrasonography, magnetic resonance imaging (MRI), thermography, transillumination, CT, and nuclear imaging. Except for ultrasonography, all involve electromagnetic wave radiation. CT exposes breast tissue to higher levels of ionizing radiation than screen-film or digital mammography, making it unsuitable for annual screening and it does not have the spatial resolution of conventional mammography. Thermography, and nuclear imaging have not been shown to contribute significantly to either lesion detection or characterization. Ultrasound has specific applications for evaluating breast masses and guiding interventional procedures. MRI is currently being studied for its potential roles in screening for and staging breast cancer, as well as other indications.

8.1 Ultrasound

Ultrasonography employs mechanical energy (sound) rather than electromagnetic radiation to produce a pictorial representation of the internal structure of the breast. The image is produced by transmission of sound pulses into the breast and measurement of the returning echoes at later times, depending upon the depth of interfaces between different tissue types. The transducer functions as both transmitter and receiver. An attractive feature of sonographic imaging is that there are no known carcinogenic effects of ultrasound at the power levels employed for diagnostic purposes.

In addition to cyst-solid differentiation, other indications as listed in the ACR's *Standard for the Performance of Breast Ultrasound Examination* (ACR, 2000b) are: (1) identification and characterization of palpable and nonpalpable abnormalities

and further evaluation of clinical and mammographic findings, (2) guidance of interventional procedures, and (3) evaluation of problems associated with breast implants.

8.1.1 *Ultrasound for Cyst-Solid Differentiation*

One of the major applications of breast ultrasonography is in distinguishing cysts from solid masses. Ultrasound is the least costly, most rapidly performed, and most readily available additional imaging method for evaluating mammographic masses that may represent cysts. Ultrasound is more accurate than either mammography or physical examination for identifying cysts. If a mass demonstrates the four sonographic criteria of round or oval shape, circumscribed margins, posterior acoustic enhancement, and anechogenicity, a benign cyst can be diagnosed with nearly 100 percent accuracy (Bassett *et al*., 1987b; Feig, 1992; Hilton *et al*., 1986; Kopans *et al*., 1984; Rubin *et al*., 1985; Sickles *et al*., 1984). It is unnecessary to aspirate simple cysts unless they cause symptoms, such as pain (Hilton *et al*., 1986; Mendelson, 1998). In addition, with high resolution ultrasound, cysts that contain homogeneous low-level internal echoes can be commonly encountered. These complicated cysts, which mimic solid lesions, require aspiration if they are symptomatic or if the diagnosis is uncertain, but they may otherwise be placed in a follow-up category (Kolb *et al*., 1998; Venta *et al*., 1999). Furthermore, ultrasound can be used to characterize complex cysts containing solid components that require biopsy.

In the past and currently in some situations, needle aspiration guided by palpation was employed as a rapid and possibly less expensive method to achieve cyst-solid differentiation, while simultaneously providing therapy (Bassett *et al*., 1987b; Kopans, 1986). As utilization of ultrasound in breast imaging practices has become more frequent, it has been observed that when the palpable mass is a cyst, other simple cysts may also be present, none of them requiring intervention (Kolb *et al*., 1998; Mendelson, 1998). If ultrasound imaging is planned, it should be performed prior to any intervention. The introduction of blood into a cyst during an incomplete or unsuccessful aspiration may change the ultrasound appearance from that of a simple cyst to a complicated or complex cyst, or to an indeterminate solid-appearing lesion.

8.1.2 *Ultrasound for Benign-Malignant Differentiation*

Although ultrasound has been established as reliable in cyst-solid differentiation, the characterization of solid masses as benign

or malignant has been more difficult. Previously, technical inadequacies, interobserver variability in performance, and interpretation, and inexperience resulted in a mistrust of diagnoses and subsequent management of solid breast masses based on their ultrasound appearances (Jackson, 1990; 1995). Also noted were difficulties encountered in locating hypoechoic masses, particularly if small or in fatty breasts, where the tissue surrounding the lesion might be isoechoic with the mass (Bassett and Kimme-Smith, 1991; Sickles *et al*., 1983). The lack of contrast between lesion and surrounding breast tissue is similar to that in mammography of a dense mass hidden in dense breast tissue (*i.e*., the sensitivity of the imaging technique diminishes). For these reasons, it has been believed that solid masses were not well enough characterized sonographically to forego tissue sampling on the basis of the ultrasound appearance alone.

Although there is overlap of features of benign and malignant masses, and operator dependence remains a problem (Mendelson *et al*., 2001; Merritt, 1999; Stavros *et al*., 1995), progress has been made in the characterization of solid breast masses. A combination of sonographic features such as shape, orientation, margin, echo pattern, and posterior acoustic characteristics has greater predictive value for malignancy than any single, stand-alone sonographic feature (ATL, 1997; Cole-Beuglet *et al*., 1980; Stavros *et al*., 1995). In 1995, Stavros and colleagues published the constellation of features that enabled him to characterize a solid lesion as probably benign, with less than a two percent likelihood of malignancy [*e.g*., uniform hyperechogenicity relative to fat; oval or gently lobular shape; and thin, circumscribed margin (Sickles, 1991; Stavros *et al*., 1995)]. However, the Stavros *et al*. findings have not been validated in a multicenter study or other peer-reviewed single-institution publication. Therefore, the use of ultrasound to characterize solid breast lesion as probably benign remains controversial and it is generally accepted that ultrasound cannot reliably avert tissue sampling and histologic diagnosis unless characteristically benign sonographic features (*e.g*., inflammatory lymph nodes) are demonstrated.

As with other imaging techniques, irregularity of margin and shape are the dominant features that predict malignancy at ultrasound with PPVs of 80 to 93 percent (ATL, 1997; Mendelson, 1999; Mendelson *et al*., 2001; Stavros *et al*., 1995). Other features, including orientation and acoustic attenuation characteristics, are less specific.

Considerable research continues in the management of masses seen with ultrasound. For consistency in interpretation, which has

long required a solution, a lexicon of descriptors similar to that used in the Breast Imaging Reporting and Data System (BI-RADS®) for mammography is being developed by ACR (1998). The ultrasound findings, together with the mammographic interpretation, clinical examination, and patient's history should result in more specific assessments and management plans. Indeed, the use of ultrasound adjunctively with mammography has significantly reduced the numbers of benign biopsies (ATL, 1997; Zonderland *et al*., 1999).

Although Doppler has been studied for its contribution to the characterization of masses, the initial enthusiastic endorsement of Schoenberger and colleagues, who found 100 percent sensitivity and specificity in distinguishing benign from malignant masses, has never been corroborated (Schoenberger *et al*., 1988). Subsequently, several researchers reported their disappointing results (Adler *et al*., 1990; Dock *et al*., 1991; Jackson *et al*., 1993). Unless refinements of Doppler technique, such as the use of intravenous contrast agents, are shown to be of value, blood-flow characteristics of masses may be regarded as an additional and optional feature to apply in the categorization of masses as benign or malignant, largely accomplished through the application of morphologic criteria.

8.1.3 *Ultrasound for Breast Cancer Screening*

Breast ultrasound is regarded as a targeted examination at the current time, although the use of ultrasound for breast cancer screening has been proposed for at least 20 y. In the early 1980s, automated water-path scanners were available. These scanners had transducer frequencies as high as 7.5 and 10 MHz (Jackson *et al*., 1986), but the equipment was costly, cumbersome and time consuming in clinical application. In preliminary clinical studies, automated water-path scanners failed to detect many small non-palpable cancers that were detected by mammography (Kopans, 1984; Sickles *et al*., 1983).

A further negative note was sounded by the European Group for Breast Cancer Screening as a result of a literature review and consensus conference held in 1996. This group acknowledged the benefits of ultrasound as an adjunct to mammography, but cited the published low sensitivities and specificities for ultrasound in the screening setting with attendant risk of high FP and FN rates (Teh and Wilson, 1998). In North America, the results of several studies have supported the institution of a screening trial. Gordon

and Goldenberg (1995) reported on 1,575 solid masses, 44 (0.3 percent) of which were cancers seen only with survey ultrasound in the 12,706 women being evaluated for palpable or mammographic masses. Kolb *et al*. (1998) studied 3,626 women with normal mammographic and clinical examinations. Women with fatty breasts were excluded. Ultrasound depicted 215 solid masses not seen mammographically, of which 11 (five percent) were malignant. Nine hundred seventy-four (974) women (27 percent) had cysts, and 132 (3.6 percent) had complicated cysts with no malignancy found in follow-up of that group. Six thousand, one hundred thirteen (6,113) asymptomatic women were screened with ultrasound by Buchberger *et al*. (1999). Twenty-three (23) cancers were identified in 21 women, and 353 masses found incidentally were biopsied or aspirated. The average size of the cancers seen with ultrasound was 0.9 cm, no larger than that found by screening mammography. Studies by Crystal *et al*. (2003), Kaplan (2001), and Leconte *et al*. (2003) have also reported that ultrasound can often find small breast cancers that were not detectable in dense breasts by screening mammography.

Kolb *et al*. (2002) has recently extended his 1998 study to include evaluation of 11,130 asymptomatic women in 27,825 screening sessions. This study found that mammography alone had a sensitivity of 98 percent in women with fatty breasts, with sensitivity decreasing as breast density increased, to a sensitivity of 48 percent in women classified in the highest ACR BI-RADS® density category. Excluding fatty breasts, Kolb *et al*. (2002) found that breast ultrasound had a sensitivity of 75 percent while physical examination alone had a sensitivity of 32 percent. Adding screening breast ultrasound for women with nonfatty breasts to screening mammography for all women in the study yielded an overall 97 percent sensitivity, compared with a sensitivity of 74 percent when physical examination was added to screening mammography. The difference between these two combined screening strategies was highly significant ($p < 0.001$).

These studies suggest that certain groups ultimately may benefit from ultrasonographic screening. These include those with mammographically dense breasts; women with known carcinomas for multifocal or multicentric disease (Berg and Gilbreath, 2000), and other high-risk women, by virtue of family history or biopsy histologies of lobular neoplasia or atypical ductal hyperplasia. However, because efficacy has not yet been demonstrated, the use of ultrasound for breast cancer screening is currently considered experimental.

Possible impediments to screening breast ultrasound are cost, additional physician time, and likelihood of increased numbers of benign biopsies. Importantly, although screening breast ultrasound will undoubtedly uncover occult carcinomas presenting as masses, it is unlikely to be effective in screening breast tissue for microcalcifications, the major form of presentation for DCIS, unless the microcalcifications are embedded in a mass or contained within a dilated duct. Axial and lateral resolutions of the transducers used for breast ultrasound are approximately the size of larger microcalcifications (0.2 to 0.5 mm), but specular reflectors representing acoustic noise or transverse views of connective tissue elements may simulate microcalcifications, making them difficult to see and characterize.

A multicenter trial of breast ultrasound is in development, based on protocols written with support from the Office on Women's Health, DHHS (ACR, 2000b). Such a trial will be performed with high resolution, linear array transducers with compound scanning capability and a foot print of 50 mm or greater to scan larger areas of breast tissue expeditiously. This type of trial is needed to determine if the effectiveness of screening ultrasound found by Kolb *et al*. (2002) can be reproduced by a cross-section of experienced breast ultrasound users.

8.1.4 *Ultrasound to Evaluate Complications of Breast Implants*

Ultrasound has been used for evaluation of complications of silicone implants, such as rupture or leakage. Extracapsular rupture, extrusion of silicone into the breast parenchyma and surrounding tissues, has a distinctive sonographic appearance: "echogenic noise" or a "snowstorm pattern," obliterating sonographic information located posterior to the silicone (Caskey *et al*., 1999; DeBruhl *et al*., 1993; Harris *et al*., 1993; Mendelson, 1992). Other findings in extracapsular rupture, usually of long duration, are silicone granulomas, angular, hypoechoic masses that can be palpable. One of the major roles for ultrasound in patients who have had breast augmentation is distinguishing between a parenchymal lesion and an implant-related finding, such as a wrinkle or fold. Extravasated silicone may also be seen on mammograms, depending on its location. Intracapsular rupture, signifying the degradation of the silicone polymeric shell of the implant, has some sonographic signs including the 'stepladder' effect of the shreds of implant envelope suspended in the silicone gel. Intracapsular rupture is also suggested by low level internal echoes with or without cystic areas within the implant.

Ultrasound is more accurate than mammography in identifying implant rupture, but MRI and CT are more sensitive and specific (Berg *et al*., 1995; Gorczyca *et al*., 1994; Ikeda *et al*., 1999).

If a lesion can be visualized sonographically, no matter what its size, any of the percutaneous procedures can be performed with ultrasound guidance. These procedures include presurgical needle-hookwire localization, spring-activated or vacuum-assisted core needle biopsy, fine-needle aspiration, abscess drainage, and retrograde ductography. Sonographically-guided procedures can be performed rapidly in real time, providing an opportunity for instant adjustment of the path of the needle towards its target. Core biopsies performed with ultrasound guidance are less costly than stereotactically-guided procedures (Liberman *et al*., 1998; Parker and Klaus, 1997; Parker *et al*., 1993). Ultrasound guidance, for most radiologists, is the preferred method (Jackson, 1995; Parker and Klaus, 1997), particularly for masses. For microcalcifications not present within a mass, stereotactic guidance is used most often.

The most common method of performance of these procedures is that of freehand placement of the biopsy or localization needle under direct sonographic visualization. For optimal viewing of the entire needle shaft, the needle entry should be nearly horizontal, perpendicular to the acoustic beam, and entirely within the plane of the beam (ACR, 2000b).

8.2 Thermography

Thermography is a direct method to measure temperature, either as discrete values or in the form of a visual image (thermal "map") suitable for diagnostic interpretation. Thermography has been extensively investigated for breast cancer detection. Many adaptations of breast thermographic technique have been developed. Telethermography utilizes a photovoltaic detector to measure infrared rays emitting from the skin, converting this thermal signal into a skin temperature map, which is displayed on a video screen either in black and white or in color (Isard and Ostrum, 1974; Nyirjesy *et al*., 1977).

Liquid crystal thermography is a less expensive technique by which "liquid crystals" (esters of cholesterol that change color in response to subtle temperature changes) confined between mylar sheaths are placed directly in contact with the skin of the breast to produce thermographic images (Gautherie *et al*., 1975; Tricoire *et al*., 1975). Variations of this technique include the cholesteric analysis profile test (Hobbins, 1981) and the use of brassieres that contain thermal receptors.

Microwave thermography measures microwave radiation naturally emitted from the breasts. Since microwaves have considerably longer wavelengths than infrared emissions, they penetrate body tissues to a much larger extent and, therefore, provide thermal information from subcutaneous and parenchymal tissues, as well as from the skin surface, albeit with less spatial resolution (Barrett *et al*., 1980; Myers *et al*., 1980). Computer-assisted thermography is a technique that uses discrete temperature measurements taken at standardized locations on each breast. These thermal data then are entered into a computer programmed with one or several diagnostic pattern-recognition algorithms designed to calculate a "likelihood of malignancy" index. This produces objective and repeatable results that are independent of observer performance (Milbrath and Schlager, 1980; Ziskin *et al*., 1975).

Graphic stress telethermometry utilizes computer-assisted diagnostic interpretation of two sets of temperature readings taken before and immediately after the patient's hands are immersed in ice water for 15 s. The rationale behind this technique is based on the observation that breast cancer detection by thermography is facilitated following cold stress, presumably, since local thermoregulatory mechanisms (*e.g*., vasoconstriction) do not operate normally in areas of malignancy.

A vast body of literature has been accumulated which describes the thermographic characteristics of breast cancer and the sensitivity and specificity of thermography in the detection and diagnosis of breast cancer. This material represents experience primarily with telethermography, but studies using the other techniques show similar results. To summarize the results to date, thermography operates at a high level of diagnostic accuracy for advanced breast cancer, but is ineffective in indicating the presence of nonpalpable cancer, detecting no more than half of the preclinical malignancies that can be discovered with the use of mammography (Dodd, 1983; Feig *et al*., 1977; Lapayowker and Revesz, 1980). This fact severely limits the potential usefulness of thermography in mass screening for early breast cancer (ACR, 1985; 1990b; Gold *et al*., 1984; 1986). Indeed, thermography essentially has been abandoned as a breast cancer screening test.

Some reports have indicated a possible prognostic role for thermography. Breast cancers that produce grossly abnormal thermograms may have a significantly lower survival probability than those with normal thermograms, or only minimal thermal abnormalities (Amalric *et al*., 1976; Tricoire *et al*., 1975). It also has been suggested that abnormal breast thermograms may be a strong predictor of breast cancer risk (Gautherie and Gros, 1980),

although other reports dispute these conclusions (Moskowitz *et al*., 1981; Sickles, 1984a; Sterns and Zee, 1991; Threatt *et al*., 1980). Currently, there is insufficient evidence to justify the use of breast thermography for cancer risk prediction, nor is it used clinically as an indicator of breast cancer prognosis.

8.3 Transillumination

Transillumination of the breast began in 1929 with the real-time viewing (diaphanoscopy) of the breast by a dark-adapted examiner (Cutler, 1929). The technique was found somewhat helpful in distinguishing cystic from solid lesions and, specifically, in suggesting the diagnosis of hematoma and retroareolar intraductal papilloma. After a period of initial interest, the technique lapsed into relative obscurity, only to be revived in France in the 1950s with the recording of hard-copy images (diaphanography) on photographic film. Subsequent modifications in technique resulted in improved diagnostic performance, but transillumination still was considered useful only as an adjunct to other breast diagnostic procedures, especially, for identifying hematomas and some benign breast cysts (Gros *et al*., 1972). Specifically, the technique was not able to distinguish reliably between benign and malignant breast masses. For this reason, and particularly because dramatic advances in mammography were permitting accurate and early detection of breast cancer, transillumination was not used widely.

In the 1980s, changes in diaphanoscopy and diaphanography derived from the observation that tumor visibility was improved when transillumination imaging emphasized the near infrared wavelengths (Carlsen, 1982; Isard, 1981; Ohlsson *et al*., 1980). Two theories have been advanced to explain these findings. One is based on the concept of preferential near infrared absorption of nitrogen-rich components [*i.e*., that material high in nitrogen content will absorb more (therefore appear to transilluminate less) near infrared radiation than will nitrogen-poor materials]. It, therefore, has been proposed that the breast is suitable for study with transillumination because fibroglandular tissue is thought to contain considerably less nitrogen than does cancerous tissue (Caspersson and Santesson, 1942). The second theory suggests that transillumination with near infrared radiation does not depict tumor masses *per se*, but rather images the increased amount of blood, specifically hemoglobin molecules that they contain. It is well-known that both reduced and oxygenated hemoglobin have strong absorption bands in the near infrared spectrum and one can speculate that breast cancers harbor relatively large quantities of hemoglobin,

either because of tumor neovascularity or because of increased transcapillary leakage of red blood cells within areas of malignancy. To take advantage of the enhanced tumor detection that comes with use of the near infrared spectrum, some transillumination techniques record images with special infrared sensitive photographic film (Isard, 1981; Ohlsson *et al*., 1980). A more technically advanced application of breast transillumination involves the recording of images by a television camera sensitive to near infrared radiation coupled to a standard television monitor (Bartrum and Crow, 1984; Carlsen, 1982; Watmough, 1982). This provides both real-time viewing of near infrared-rich images and hard-copy recording of images with videotape or with a multiformat film camera. A sophisticated modification of television-based transillumination involves post acquisition image processing with false color rendition of transmitted near infrared wavelength light to maximize visibility of those findings most likely to represent malignancy (Bartrum and Crow, 1984). Pilot studies using television-enhanced transillumination systems indeed have detected some nonpalpable breast cancers (Carlsen, 1982; Marshall *et al*., 1984; Merritt *et al*., 1984). However, several more fully-documented clinical studies, in which state-of-the-art mammography was done on all patients, indicated that these transillumination techniques are far inferior to mammography in detecting nonpalpable cancer (Alveryd *et al*., 1990; Bosanko *et al*., 1990; Geslien *et al*., 1985; Gisvold *et al*., 1986; Jarlman *et al*., 1992a; 1992b; Monsees *et al*., 1987a; 1987b; 1988; Sickles, 1984b).

Currently, all transillumination techniques remain experimental procedures. The major weakness of transillumination appears to be a relative inability to image both deep lesions and most of the very small cancers now routinely detected by mammography (Bartrum and Crow, 1984; Bosanko *et al*., 1990; Geslien *et al*., 1985; Gisvold *et al*., 1986; Jarlman *et al*., 1992a; 1992b; Monsees *et al*., 1987a; 1987b; 1988; Sickles, 1984b).

8.4 Computed Tomography

Computed tomography (CT) scanning has become a major tool in diagnostic radiology, principally, by virtue of its ability to resolve density differences much smaller than those demonstrable by conventional x-ray techniques. Experience with a prototype CT unit dedicated to breast scanning showed the capability to detect some preclinical cancers including tumors not detectable by mammography. However, this high level of diagnostic accuracy was possible only when the breasts were scanned twice, both, before and after intravenous iodide administration. It was observed that most

breast cancers demonstrate at least a five percent increase in density following iodide administration, whereas most benign lesions do not (Chang *et al*., 1977). Thus, criteria for diagnosis of malignancy or benignity relate to change in CT density (contrast enhancement) of corresponding areas of the breast in the pre- and post-iodide scans. Absolute density values, as well as shape and size of high-density areas, were found to be of lesser diagnostic importance. Cancers presenting mammographically as clustered microcalcifications without an associated mass were not identified on preiodide scans because CT resolution is too poor to image such minute structures; however, many of these cancers could be imaged on post-iodide scans as tiny area(s) of significant contrast enhancement.

Clinical trials with the prototype breast CT units produced seemingly contradictory results. One trial showed increased cancer detection for CT scanning over mammography (Chang *et al*., 1979; 1980), but the other found no difference (Gisvold *et al*., 1979). In any case, both research groups concluded that breast CT scanning was inappropriate as a primary screening test because of the need for intravenous iodide administration, the relatively high radiation dose involved and the high cost of the examination. As a result, the prototype CT units were withdrawn. Boone *et al*. (2001) has renewed investigations into the feasibility of a dedicated CT breast scanner using newer detector technology, but clinical evaluation has not yet been performed.

Shortly thereafter, there was brief interest in using general purpose CT units for breast cancer detection and diagnosis (Chang *et al*., 1982). However, clinical results were no more encouraging than those that prompted withdrawal of the prototype dedicated CT units. Furthermore, two new problems appeared: (1) the examination became exceedingly tedious to interpret because point-for-point comparisons of CT density to determine contrast enhancement had to be made without the computer assistance built into the dedicated breast scanner; and (2) the radiation dose increased considerably because the x-ray beam of a whole-body scanner must penetrate the entire chest, rather than the breast alone. As a result, currently, CT scanning is not used either for breast cancer screening or for additional imaging of mammographically detected lesions.

Other roles suggested for breast CT scanning include the preoperative localization of nonpalpable lesions that are too close to the chest wall to be included on orthogonal (right-angle) mammographic projections (Kopans and Meyer, 1982; Zegel *et al*., 1991), the preoperative assessment for axillary or internal mammary

lymphadenopathy (Muller *et al*., 1983) and the assessment of silicone-gel implant integrity when there is clinical suggestion of disruption, but mammography and ultrasonography do not provide clear supporting evidence (Gorczyca *et al*., 1994). Breast CT scanning is used only rarely for these purposes.

8.5 Magnetic Resonance Imaging

Magnetic resonance (MR) imaging (MRI) is a noninvasive technique that uses the interaction between the magnetic properties of nuclei and radio waves to portray the structure of biological tissues (Damadian, 1971; Lauterbur, 1973). When placed in an external magnetic field and exposed to radio waves of proper frequency, the hydrogen nuclei within body tissues resonate [*i.e*., can absorb energy from a tuned radio wave and then, after a delay (relaxation time) emit the energy back at the same frequency]. The energy radiated back by the resonating nuclei, typically hydrogen nuclei (protons) for imaging, is the signal that is used for generating the MR image. The intrinsic differences in hydrogen density between the various components of body tissues (*e.g*., fat, blood, glandular tissue, muscle, etc.), as well as differences in magnetic relaxation times from voxel to voxel, determine the contrast of the MR image. Since these differences in MR characteristics are greater than differences in electron density and atomic number, the two factors that determine x-ray contrast, there is potentially more contrast in an MR image than in its x-ray equivalent image. Moreover, MR creates planar images, like CT, rather than summation or projection images, like mammography, which further improves the visability of low-contrast lesions.

The spin-lattice (T1) and spin-spin (T2) relaxation times substantially influence the MR signal. They are dependent on such factors as temperature, viscosity, crystalline-lattice structure or other microstructure which affect subtle magnetic interactions within tissues. Relaxation times provide imaging parameters other than simple hydrogen density mapping; indeed they are capable of yielding physiologic as well as anatomic data. For example, conditions such as local hyperemia and necrosis will alter both the temperature and solid-liquid characteristics of tissue, thereby, changing the T1 and T2 values from those of surrounding normal tissues.

In vivo MRI of the breast has been possible since the advent of whole-body MR scanners in the early 1980s, but initial investigations with whole-body imaging coils achieved very limited success (El Yousef *et al*., 1983; Ross *et al*., 1982). Subsequently, the development of high-resolution surface imaging coils designed

specifically for the breast, along with MR magnet, gradient, computer, and pulse sequence improvements, have resulted in superior breast images capable of demonstrating smaller lesions and finer structural detail (Alcorn *et al*., 1985; Bydder *et al*., 1985; Dash *et al*., 1986; El Yousef and Duchesneau, 1984; El Yousef *et al*., 1984; 1985; Hornak *et al*., 1986; Sinha *et al*., 1993; Stelling *et al*., 1985; Turner *et al*., 1988; Wiener *et al*., 1986; Wolfman *et al*., 1985). Up until 1986, MRI examinations were done using T1 and T2 weighted-spin echo pulse sequences. Subsequently, there was additional progress with the use of gradient echo sequences, such as fast low-angle shot and fast imaging with steady progression (Kaiser and Oppelt, 1987; Kaiser and Zeitler, 1989). More recently, pulse sequences that obtain three-dimensional blocks of data with fat suppression have been used, producing still further improvement in resolution, contrast, and overall lesion visualization (Harms *et al*., 1993a; 1993b; Pierce *et al*., 1991; Rubens *et al*., 1991).

Current clinical experience with breast MRI indicates its several strengths and weaknesses. Fatty and fibroglandular regions of the breast are clearly distinguished and areas of dense fibroglandular tissue are imaged with a greater range of contrast than with either mammography or CT scanning. Large and some small breast masses also are readily portrayed, especially, if surrounded by substantial amounts of fatty tissue with most cancers showing relatively irregular and ill-defined borders and benign lesions demonstrating more smooth and sharply-defined margins (El Yousef *et al*., 1984). However, even when using the best currently available surface coils, the spatial resolution of nonenhanced MRI is far inferior to that of mammography, so that the tiny clustered calcifications of DCIS and the fine spiculations characteristic of many invasive carcinomas are not imaged with MRI. The lack of inherent contrast difference between breast lesions and normal glandular tissue also makes it difficult for MRI to portray some of the smaller mammographically detected masses, particularly, those invasive cancers that present with vague, ill-defined margins, without the use of contrast agents. Unless new techniques can be developed, it is unlikely that nonenhanced MRI will achieve widespread use for either screening or diagnosis of breast cancer (Dash *et al*., 1986; Kopans, 1984; Pierce *et al*., 1991; Turner *et al*., 1988).

Rather, most investigators have utilized nonenhanced MRI to evaluate breast disease that already has been detected by mammography or physical examination. For this use, MRI does appear to be both sensitive and specific in the diagnosis of simple benign cysts, but no more so than the already established and far less expensive methods of aspiration and ultrasonography (Alcorn

et al., 1985; Dash *et al*., 1986; El Yousef *et al*., 1985; Kaiser, 1990; Rubens *et al*., 1991; Stelling *et al*., 1985; Turner *et al*., 1988). For solid breast masses, nonenhanced MRI cannot reliably distinguish fibroadenomas and post-biopsy scars from malignancies on the basis of either morphological features or T1 and T2 values (Alcorn *et al*., 1985; Heywang *et al*., 1986a; Stelling *et al*., 1987; Turner *et al*., 1988).

These disappointing results have led to additional avenues of investigation, especially to the use of the paramagnetic metal ion chelate, gadolinium diethylene triamine penta-acetic acid (Gd-DTPA). This MRI-specific contrast agent serves as an indirect indicator of tissue perfusion, since it accumulates at a faster rate in more highly vascularized lesions than in normal tissues. Therefore, similar to results observed with CT scanning following iodide administration, many breast cancers also demonstrate differential enhancement after intravenous infusion of Gd-DTPA (Adler and Wahl, 1995; Dao *et al*., 1993; Harms *et al*., 1993a; 1993b; Heywang *et al*., 1986a; 1986b; 1989; Kaiser and Zeitler, 1989; Pierce *et al*., 1991; Revel *et al*., 1986; Rubens *et al*., 1991; Stack *et al*., 1990). Enhancement is found not only for invasive carcinomas, but also for some cases of DCIS that present mammographically only by virtue of clustered microcalcifications (Davis and McCarty, 1997; Gilles *et al*., 1993; 1995; Nunes *et al*., 1997a; 1997b; Orel *et al*., 1997). A particularly helpful aspect of contrast-enhanced MRI is that breast cancer displays much higher levels of enhancement than benign post-biopsy scar tissue, permitting differentiation often not possible by either mammography or physical examination (Dao *et al*., 1993; Gilles *et al*., 1993; Harms *et al*., 1993a; 1993b; Heywang *et al*., 1989; 1990).

Another potentially useful application of contrast enhanced MRI is in determining the extent of tumor for breast cancer patients who desire breast conservation therapy. MRI indeed is more sensitive than mammography in this regard, often identifying nonpalpable multifocal and multicentric tumor deposits not depicted at mammography (Harms *et al*., 1993a; 1993b; Orel and Schnall, 2001; Orel *et al*., 1994; 1995; Weinreb and Newstead, 1995). However, the utility of MRI in treatment planning is limited by its relatively low specificity and the lack of general availability of MR-guided localization devices to permit tissue diagnosis for lesions detected only at MRI (Adler and Wahl, 1995; Frankel and Sickles, 1997; Weinreb and Newstead, 1995).

Although most cancers exhibit considerable contrast enhancement, many fibroadenomas also demonstrate similar substantial amounts of enhancement. An interesting variation in contrast-

enhancement technique involves dynamic fast-sequence imaging. Some investigators suggest that this approach may permit differentiation between carcinoma and fibroadenoma, whereas cancers typically show rapid enhancement within the first 2 min after contrast injection, the enhancement seen in fibroadenomas progresses more slowly (Boetes *et al*., 1994; Hulka *et al*., 1995; Kaiser, 1990; Kaiser and Zeitler, 1989; Stack *et al*., 1990). Unfortunately, there are reports also indicating the unreliability of dynamic fast sequence contrast enhancement; some fibroadenomas and other benign conditions have been shown to enhance just as rapidly as do most cancers (Frankel and Sickles, 1997; Gilles *et al*., 1994; Harms *et al*., 1993a; 1993b; Orel *et al*., 1994).

As with the use of ultrasonography (Section 8.1.3), there also has been recent interest in using MRI to identify complications of breast implants, especially, leakage and rupture of gel-filled silicone implants (Brem *et al*., 1992; Gorczyca *et al*., 1992a; Harms *et al*., 1992; Schneider and Chan, 1993). The combination of a T2 weighted fast spin-echo technique, T2 weighted fast spin-echo technique with water suppression, and T1 weighted spin-echo technique with fat suppression or, alternatively, a modified three-point Dixon (1984) technique may reliably differentiate silicone from native breast tissues, thereby, permitting identification of both extracapsular and many intracapsular ruptures and leaks (Gorczyca *et al*., 1992a; 1992b; Schneider and Chan, 1993). The relative efficacy of MRI versus ultrasonography has not been determined. However, ultrasonography is more readily available and considerably less expensive, while MRI is less operator dependent and has the imaging advantage of being able to portray deep structures through the full-thickness of an implant. Indeed, MRI is more accurate than either mammography or ultrasonography in identifying implant disruption and is widely used as the ultimate imaging procedure to assess implant integrity when there is clinical suggestion of disruption, particularly when other imaging modalities do not provide clear supporting evidence (Berg *et al*., 1995; Gorczyca *et al*., 1994).

Ultimately, the major promise of MRI in the diagnosis of breast disease is its potential to image the radiographically dense breast with uniquely high contrast, perhaps also permitting the differentiation of benign from malignant tissue on the basis of the physiological information transmitted *via* contrast enhancement techniques combined with new pulse sequences. Another advantage of MRI is that it does not involve ionizing radiation. Indeed, in its current clinical form, it causes no known genetic damage (Wolff *et al*., 1980) and there is no indication of other

significant hazards (Budinger, 1979). Breast MRI is now an accepted diagnostic adjunct to mammography and breast ultrasound, especially in cancer staging to aid in determining extent of disease, and in evaluating cancer recurrence (Heywang-Kobrunner *et al*., 2001; Morris, 2002; Orel and Schnall, 2001). There is also mounting evidence that breast MRI is useful beyond mammography for evaluation of the contralateral breast in women with a known breast cancer (Fischer *et al*., 1999; Lee *et al*., 2003; Liberman *et al*., 2003). Recent studies have found that breast MRI detects cancer in the contralateral breast in four to five percent of women with a known breast cancer, even after negative mammography and physical examination.

Several recent studies have found that MRI appears to be more sensitive than mammography among women with an inherited susceptibility to breast cancer (Kriege *et al*., 2004; Kuhl *et al*., 2000; Stoutjesdijk *et al*., 2001; Tilanus-Linthorst *et al*., 2000; Warner *et al*., 2001). Unlike screening mammography trials, none of these studies measured breast cancer mortality as an endpoint. In addition the design of these studies might have artificially increased the sensitivity of MRI with respect to mammography. Nevertheless, these studies do suggest that MRI screening may benefit women at extremely high risk for development of breast cancer. There are several reasons why MRI is not advised for screening all other women. These include need for intravenous contrast injection, an extremely high cost of equipment and examination, limited availability of equipment, and a high FP biopsy rate.

8.6 Magnetic Resonance Spectroscopy

Magnetic resonance spectroscopy (MRS) provides an indication of biochemical differences between tissues by its ability to measure specific metabolic products. Current experience with MRS of breast tissues principally involves pilot studies that characterize cancer-associated metabolites using ^{31}P and ^{1}H MR spectral profiles. While phosphate metabolites are virtually undetectable in breast fat and are identified in relatively low concentration in normal breast parenchyma, they appear to be considerably more abundant in many abnormal breast tissues, especially, in most breast cancers (Degani *et al*., 1986; Merchant *et al*., 1988; 1991a; 1991b; Sijens *et al*., 1988; Twelves *et al*., 1994). The principal ^{31}P MRS signals come from inorganic phosphate, phosphomonoesters, phosphocreatine, nucleoside triphosphates (including ATP), phosphorylated glycans, and phosphodiesters. The biochemical data derived from

analysis of these spectral components may permit reliable differentiation of malignant from benign breast tissues.

Recent work with ^{1}H MR spectral profiles at 1.5 T (tesla) suggest that the ^{1}H spectroscopy is even more sensitive to some of the same molecules observed in ^{31}P spectroscopy, due to their high ^{1}H content. In particular, the ^{1}H choline peak appears to provide a sensitive marker for malignancy in breast lesions. A recent pooled analysis of five smaller studies of ^{1}H in spectroscopy in 153 breast lesions (100 of which were malignant) showed that using the presence of a detectable choline signal as the sole criterion for malignancy yielded 83 percent sensitivity and 85 percent specificity (Katz-Brull *et al*., 2002). Among younger women, the sensitivity and specificity of ^{1}H spectroscopy was even higher, but only 20 subjects were included in this group.

In the earlier ^{31}P spectroscopy studies, relatively large voxel sizes (6 to 8 cm^3) were needed for MRS to obtain adequate spectral signal. As a result, the primary application of breast MRS was limited to monitoring the response of large tumors to radiation therapy and chemotherapy (Merchant *et al*., 1991a; Ng *et al*., 1989; Sijens *et al*., 1988). The use of higher field strength for *in vivo* imaging or spectroscopy (up to 4 T) has made it possible to decrease voxel size in ^{31}P spectroscopy. The much higher molar concentration of water in fibroglandular tissue permits typical voxel sizes of 1 to 2 cm^3 for ^{1}H spectroscopy, making it easier to perform at 1.5 T in a region isolated to a specific breast lesion. The use of ^{1}H spectra means that the same coils used for imaging can be used for spectroscopy, without addition of broadband coils and amplifiers. This, along with improved clinical spectroscopic techniques, may make it feasible to add a targeted MRS study to hydrogen imaging in cases where a suspicious enhancing lesion is found. If the ^{1}H choline marker provides improved separation of benign from malignant lesions, MRS of the breast may become a useful diagnostic tool to increase specificity for breast cancer.

8.7 Nuclear Imaging

There are two forms of nuclear imaging that have been applied to the breast: scintimammography and positron emission tomography (PET). Scintimammography involves injection of a gamma-ray emitting compound (^{99m}Tc Sestamibi), which selectively accumulates in breast cancer cells, and a gamma camera, which detects gamma rays emitted when the radionuclide ^{99m}Tc spontaneously decays. PET imaging makes use of short-lived positron emitting compounds, in particular the glucose analog 2-(^{18}F)-flouro-2-deoxy-

D-glucose (called FDG). When FDG spontaneously emits a positron, the positron combines with an electron and annihilates, producing two 511 keV photons, at 180 degrees from each other. The PET scanner consists of a 360 degree ring of detectors that can measure the occurrence of nearly coincident absorption of the 511 keV photons, determining the line along which the photons originated. The subtle timing differences in detection can determine the point along that line where positron emission occurred. This locates the source of the positron emission, and therefore the distribution of FDG, in three dimensions in the patient. Both scintimammography and PET imaging have been evaluated in a number of small studies, usually in women with known breast cancers.

8.7.1 *Sestamibi Scintimammography*

Sestamibi scintimammography was approved by FDA in 1998 for use in breast imaging. Sestamibi is marketed under the name Miraluma® (Bristol-Myers Squibb Medical Imaging, Inc., New York). Sestamibi accumulates in myocardial cells and in several types of cancer cells, including breast cancer. Sestamibi scintimammography requires an intravenous bolus injection of 740 to 1,110 MBq of the ^{99m}Tc-labelled drug. A few minutes after injection, lateral views of each breast are acquired using a gamma camera. The woman is placed in the prone position on an imaging table with the imaged breast pendent. The gamma camera head is placed in contact with the lateral portion of the breast. In some cases, a supine or prone anterior view is obtained to help evaluate the axilla. In the anterior view, however, evaluation of the breast is compromised by the radionuclide accumulating in the liver and heart.

Focal areas of increased uptake are considered suspicious for breast cancer. Proliferative fibrocystic changes and breast inflammation can cause FPs with Sestamibi. Clinical testing of Sestamibi has typically been performed on patients with palpable or mammographically-detected breast abnormalities. Taillefer (1999) summarized data from 20 studies published between 1994 and 1998, concluding that Sestamibi nuclear medicine procedures were 85 percent sensitive and 89 percent specific to breast cancer. Additional individual studies published since that time have found sensitivities ranging from 71 to 89 percent and specificities ranging from 52 to 89 percent (Buscombe *et al*., 2001; Cwikla *et al*., 1998; Flanagan *et al*., 1998; Khalkhali *et al*., 2002; Prats *et al*., 1999). In all but the last cited study, nearly 70 percent of study subjects had palpable masses. In Khalkhali *et al*. (2002), 45 percent of subjects

had palpable masses, but sensitivity was lower (71 percent) as a result. The possibility of developing high-resolution gamma cameras specifically for breast imaging holds promise of detecting smaller lesions, but this has yet to be tested clinically.

8.7.2 *Positron Emission Tomography*

Positron emission tomography (PET) scanning in breast cancer is most often used to evaluate local lymph nodes and distant metastases. There are also studies demonstrating FDG uptake in primary breast cancer. The first published study of PET for primary breast cancer detection by Wahl *et al*. (1991), reported 100 percent sensitivity in a group of 10 patients with breast cancer. Average tumor size in these women, however, was >5 cm. Other relatively small series studying PET in breast cancer detection reported sensitivities of 80 to 96 percent and specificities of 83 to 100 percent (Adler *et al*., 1993; Avril *et al*., 1996; 2001; Hoh *et al*., 1993; Nieweg *et al*., 1993; Palmedo *et al*., 1997; Tse *et al*., 1992; Yasuda *et al*., 2000). Mean tumor sizes were smaller (*e.g*., 2.9 cm in Palmedo *et al*.), but not approaching the mean tumor sizes detected by mammography or breast ultrasound. The resolution of current PET systems makes it unlikely that PET will reliably detect lesions of 1 cm diameter or less. Moreover, the lack of availability of PET scanners and the cyclotrons needed to produce ^{18}F (half-life 110 min) for FDG production and the cost of the procedure inhibit the widespread use and acceptance of this procedure as a diagnostic adjunct to mammography and ultrasound.

9. Summary and Conclusions

9.1 Summary

Mammographic studies are performed for both diagnosis of breast disease and screening for cancer. Diagnostic mammography can demonstrate the presence of breast cancer in a symptomatic patient and more specifically, the size, location and extent of tumor. Mammographic screening involves examination of asymptomatic women in an attempt to detect breast cancer before it grows large enough to be palpable. The use of diagnostic mammography is well accepted due to the compelling clinical need for the information provided. The implementation of a mammographic screening program depends upon: (1) indication of a favorable benefit/risk ratio for the population being screened; (2) availability of suitably trained radiologists, medical physicists, and technologists and appropriate mammographic equipment subject to a vigorous QA program; and (3) acceptably low cost.

Breast anatomy and function must be understood (Section 2) in order to design and utilize the mammographic techniques which will effectively detect and demonstrate breast cancer. The technique which is employed for the preponderance of mammography examinations is screen-film mammography with a grid.

Good screen-film mammography requires dedicated equipment which can provide an appropriate soft x-ray beam (proper choice of operating potential, target, filter, window, HVL) (Section 3), proper compression, a target-film distance of suitable length for the given focal-spot size, and provision for vertical adjustment and mechanical rotation of the tube and image-receptor assembly for proper positioning (Section 2). The two views, which are recommended, are the CC and the MLO view (Section 2) which allow more visualization of the posterior glandular tissues, particularly in the auxiliary tail than a lateral view. The lateral view should also be employed whenever a nonpalpable lesion is discovered, in order to provide accurate three-dimensional localization. Screen-film mammography should be performed by a technologist who has had special training in compression and positioning techniques for the

standard and special views used for mammography (ACR, 1999). Only an intensifying screen designed specifically for mammography should be used in combination with a suitable single-emulsion film (Section 3). The combination should be placed in low-absorption cassettes designed for mammography.

There are many factors which affect image quality (Section 4). The three major components of image quality are contrast, sharpness and noise. Image quality can be optimized by suitable adjustment of the x-ray spectrum (operating potential, filtration, target material), breast compression, grids, imaging geometry (small focal spot, long target-film distance), choice of screens and films, and optimization of film-processing techniques. Image quality may be checked with suitable phantoms.

Section 4 provides information to allow facilities to determine whether the particular combination of x-ray machine, compression devices, technique factors and image receptors in current use, or under consideration for use, for mammography will provide optimum image quality.

A major objective of mammography dosimetry is to provide relevant information so that potential radiation risks from alternative techniques may be compared. For this purpose a single-valued "dose" per view for each technique, which corresponds reasonably well to the resulting carcinogenic potential, should be determined. This task involves consideration of tissue vulnerability to radiation effects, anatomy, technique and dosimetry. In addition, a unique dose value for each technique requires that the dose be determined for a fixed-reference breast composition with breast thickness stated.

Simple computational models of the breast have been developed for estimation of mammographic dose. Several assumptions are implicit in these models relating to radiation risk, breast anatomy, and technique (Section 5). Three specific points are relevant to radiation risk: (1) breast glandular tissue is most vulnerable as compared with adipose, skin and areolar tissues; (2) an average breast dose (namely, the mean glandular dose), rather than a maximum dose, is most useful in characterizing risk of carcinogenesis consistent with a linear dose-response relationship; and (3) the population of primary interest is women 40 y and older since younger women are likely to receive only diagnostic and baseline studies. This assumption that the population of primary interest is women 40 y and older limits application of the computational models to the older on average, more adipose breast, which helps justify certain simplifying assumptions. A major technique variable is the

degree of compression employed. Firm compression, which is assumed in dose computations, greatly distorts the breast anatomy, making more rectangular the sagittal and transverse cross-sections of the volume that includes the glandular tissue. This greatly simplifies the breast geometry and makes the computational models more appropriate than otherwise would be the case (Section 5).

The mean glandular dose ($\overline{D}_g$) meets the stated requirements outlined above. The computational model used in this Report for $\overline{D}_g$ assumes that 0.5 cm thick adipose layers enclose a central "glandular tissue" containing a uniform mix of glandular and adipose tissues in roughly equal amounts. The procedure for estimating mean glandular dose for a specific population of patients is described in Table 4.3 (Approach II).

A basic requirement for maintaining optimum image quality in mammography is implementation of a suitable QA program (Section 6). Each of the items contributing to image quality must be evaluated on a regular basis. The quality administration program (medical audit) evaluates the appropriateness and accuracy of image interpretation (Section 6.3).

The benefit from screening by mammography and physical examination in the form of decreased breast cancer mortality has long been accepted for women above age 50 on the basis of a randomized trial (the HIP study, see Section 7), which indicated that the contribution of mammography to decreased breast cancer mortality was significant in older women.

The randomized clinical trials of mammographic screening have not demonstrated a benefit for women age 40 to 49, within the first 7 y of starting screening. Those trials for which 10 or more years of follow-up is available, show evidence of a 23 percent benefit in reducing mortality. Although this reduction is smaller than that observed for older women, it is statistically significant and therefore, one can reject the possibility that this may have happened by chance.

Compared with mammography practiced in the previous randomized trials, high-quality modern mammography could result in increased benefit. Even a very small benefit (*e.g.*, one percent) more than offsets any risk of radiation-induced breast cancer. The benefit versus risk will be substantial, if analysis of ongoing screening experience demonstrates a reduction in breast cancer mortality rate of 30 percent or more.

Among the various imaging methods designed to evaluate the breast for cancer, mammography is the most accurate and most widely used. It has gained clinical acceptance primarily because of

its ability to detect a cancer before the tumor mass becomes large enough to be palpable, thereby permitting "early" diagnosis. It has also been proven an invaluable tool to distinguish benign from malignant lesions and can facilitate prompt biopsy of cancers, while encouraging clinical observation (rather than biopsy) of many benign masses. Other breast imaging methods have, thus far, been considered less successful; these include thermography, transillumination, ultrasonography, and MRI and MRS all of which do not utilize ionizing radiation. Computed tomography (Section 8.4) and digital mammography (Section 3.3) which use x rays, and therefore involve the potential risk of mammary carcinogenesis are being subjected to clinical investigation to determine their role in breast cancer diagnosis. Explanations of the principles of operation, a chronology of developments, and an extensive discussion of the limitations of each of these methods is contained in Sections 3.3 and 8.4.

9.2 Conclusions

- Mammography, in conjunction with physical examination, is the method of choice for early detection of breast cancer. Other methods should not be substituted for mammography in diagnosis or screening, but may be useful adjuncts in specific diagnostic situations.
- Diagnostic mammography of symptomatic women should always be performed when indicated, utilizing recommended equipment and techniques and well-trained, knowledgeable personnel.
- Screen-film mammography requires dedicated x-ray units, firm compression, and an x-ray spectrum produced by an appropriate combination of x-ray tube target, tube window, filtration, operating potential, screen-film combination, film processors, technique, and viewing conditions. The CC and MLO views are recommended as the standard views for all types of mammography.
- Mammographic equipment should be chosen to provide acceptable image quality at a typical mean glandular dose (for a two-view examination) of 6 mGy, or less for screen-film image receptor with grid for a patient having 4.5 cm thick-compressed breasts of 50 percent adipose and 50 percent glandular tissue composition.
- Image quality and appropriate dose level should be maintained by a QA program conducted by a QA technologist and

medical physicist, involving specified periodic measurements and readjustment of all aspects of the imaging and viewing system.

- Mean glandular dose should be determined at least annually at each installation for the techniques used at representative breast thicknesses. This dose can be calculated from data supplied in this Report by measuring beam quality and in-air exposure at the entrance surface of the breast.
- A quality administration program (medical audit) should be used to compare the facility's clinical outcomes with established guidelines.
- Annual mammographic screening examinations appear to provide favorable benefit/risk ratios in terms of breast cancer mortality in women age 50 or above, if acceptable image quality and dose are maintained.
- Results of randomized clinical trials of screening mammography for women age 40 to 49, for which 10 or more years of follow-up is available, have shown evidence of a substantial benefit in reducing mortality which exceeds any risk of radiation-induced breast cancer.

Glossary

This glossary is adapted from ACR (1999) with permission, AHCPR (1994), and other sources.

abnormal screening examination: Mammography examination resulting in the recommendation of further imaging evaluation, short-interval follow-up or biopsy.

absorbed dose (*D*): The energy imparted to matter by ionizing radiation per unit mass of irradiated material at the point of interest. The special name for the unit of absorbed dose is the gray (Gy), where 1 Gy = 1 J kg^{-1}.

aliasing: The false frequency information (or alias) detected when the signal being detected is grater than the Nyquist frequency.

areola: The pigmented ring of tissue that surrounds the nipple.

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.

axilla: The underarm area containing lymph nodes and channels, blood vessels, nerves, muscle, and fat; anterior border is the pectoralis major muscle and posterior border is the latissimus dorsi muscle.

axillary tail: Anatomical projection of breast tissue that extends into axilla (axillary tail of Spence).

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.

benign: A noncancerous condition that does not spread to other parts of the body.

biopsy: Removal of an entire abnormality (excisional biopsy) or a sampling or portion of an abnormality (core biopsy and incisional biopsy) for microscopic examination in order to diagnose a problem.

breast carcinoma *in situ*: Breast change in which malignant cells are localized and confined to breast ducts or lobules and may press against adjoining breast tissue but have not penetrated or spread beyond the breast (also called noninvasive breast cancer or noninfiltrating breast cancer).

breast conservation: A surgical procedure for removing a cancerous tumor, lesion, or lump along with a rim of normal tissue around it (also called a lumpectomy).

breast self-examination: Inspection and palpation of her breasts by the woman herself.

bucky: A component of the mammography x-ray unit that contains a moving grid, holds the x-ray film cassette, and supports the breast during imaging.

calcifications: (see **microcalcifications**).

cancer: A general term for more than 100 diseases characterized by abnormal and uncontrolled growth of cells.

cancer detection rate: The overall number of cancers detected per 1,000 patients examined by mammography.

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.

clinical breast examination (CBE): A complete examination of the breasts and axilla with palpation by a health care professional, including examination of the breasts with the woman upright and supine.

compression: Involves pressing the breast between the compression device and the platform holding the film during mammography.

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.

confidence interval: A measure of the extent to which an estimate of risk, dose or other parameter is expected to lie within a specified interval (*e.g.*, a 90 percent confidence interval of a risk estimate means that, based on available information, the probability is 0.9 that the true but unknown risk lies within the specified interval).

contact mammography: Usual mammography, with the breast in direct contact with the Bucky (unlike magnification technique).

contralateral: Originating in or affecting the opposite side of the body.

correlative physical examination: Directed palpation of the breast performed by either the radiologic technologist or the interpreting physician to improve interpretation and ensure that a palpable abnormality is included on the film.

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.

cyst: A fluid-filled sac that may be felt on physical examination or depicted by mammography or ultrasonography.

darkroom fog: Added optical density on a film due to light leaks or safe lights in a darkroom. It degrades image contrast and must be tested and eliminated to ensure image quality.

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.

deterministic effects: Biological effects for which the severity of the effect in affected individuals varies with the dose, and for which a threshold usually exists.

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: A radiologic examination used to evaluate a patient with a breast mass or masses, other breast signs or symptoms (spontaneous nipple discharge, skin changes, etc.), an abnormal or questionable screening mammogram, or special cases such as a history of breast cancer with breast conservation or augmented breasts.

diaphanography: A noninvasive breast imaging technique that uses visible or near-visible light in an attempt to visualize breast masses.

digital mammography: Mammography performed with an image detector that converts the x-ray signal into electronic form. The acquisition and display operations are separated.

dose: Often used generically when not referring to a specific quantity such as **mean glandular dose**.

dose equivalent (*H*): A quantity used in measurement of radiation at a point that expresses the biological effect of all kinds of radiation

on a common scale. Dose equivalent is defined as the product of the absorbed dose (D) and the quality factor (Q) for the particular radiation (*i.e.*, $H = D \times Q$). The special name for the unit of dose equivalent is the sievert (Sv) where 1 Sv = 1 J kg^{-1}.

duct: A channel for transporting fluid from the lobules (breast glands that produce milk) to the nipple.

ductal carcinoma *in situ* (DCIS): A form of breast carcinoma *in situ* confined to the breast ducts; often reveals itself with microcalcification on mammography (also called noninvasive breast carcinoma or intraductal breast carcinoma).

effective dose (E): The sum of the equivalent doses (H_T) to individual organs or tissues multiplied by their respective tissue weighting factors (w_T). The special name for the unit of effective dose is the sievert (Sv) where 1 Sv = 1 J kg^{-1}.

equivalent dose (H_T): A quantity used for radiation protection purposes that is the product of the mean absorbed dose ($\overline{D}_T$) in a tissue or organ and the radiation weighting factor (w_R). The equivalent dose allows for differences in the detriment to tissue from identical absorbed doses of various forms of ionizing radiation. The special name for the unit of equivalent dose is the sievert (Sv) where 1 Sv = 1 J kg^{-1}.

exposure: The amount of x-ray irradiation, quantitated by measuring the amount of ionization in air caused by the radiation.

fibroadenoma: A benign breast condition common in young adult women in which the breast develops a solid lump, usually firm but movable in the breast.

filtration: A metal absorber placed in the path of the x-ray beam just after the x-ray tube to absorb very low-energy x rays to produce an x-ray beam with a narrow energy range. Molybdenum is the most common metal for use as filtration in mammography.

fine-needle aspiration biopsy: A diagnostic technique used to sample cells from breast lumps. Cells from lumps are aspirated with a thin needle, smeared on a glass slide, stained, and evaluated by a pathologist.

first-degree relative: Mother, daughter or sister.

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.

gray (Gy): The special name for the SI unit of absorbed dose, 1 Gy = 1 J kg^{-1}.

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.

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.

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: How well the margins of linear structures, masses and calcifications are depicted in the radiograph.

***in situ*:** Confined to site of origin, not having invaded adjoining tissues or metastasized to other parts of the body (*e.g.*, intraductal).

invasive breast cancer: Disease in which breast cancer cells have penetrated surrounding breast tissue and can spread into distant organs.

ipsilateral: Originating in or affecting the same side of the body.

kilovolt (kV): A unit of electrical potential difference equal to 1,000 volts.

kilovolt peak (kVp): (also see **operating potential**). The crest value in kilovolts of the potential difference of a pulsating potential generator. When only one-half of the voltage wave cycle is used, the value refers to the useful half of the cycle.

latent period: The period of time between exposure to ionizing radiation and the appearance of the radiation effect.

lateral view: A 90 degree view performed medial to lateral or lateral to medial; used for triangulation with the craniocaudal and to demonstrate gravity-dependent calcifications.

lateromedial: A 90 degree view performed with the x-ray beam directed from the outer aspect of the breast to the inner aspect of the breast.

lateromedial oblique: Performed with the x-ray beam directed from the lower-outer to the upper-inner aspect of the breast; the exact reverse of the mediolateral-oblique view; improves visualization of medial breast tissue (also called true reverse oblique).

lobe: A portion of the breast that contains a complete unit for producing, transporting and delivering milk.

lobular carcinoma *in situ* (LCIS): A high-risk condition in which multiple atypical cells fill and distend the lobules. Because it is a risk factor and not a direct precursor of invasive cancer, LCIS is considered a marker for increased risk of development of breast cancer in any location in either breast (also called lobular neoplasia).

localization: Prebiopsy localization provides a method for biopsy of nonpalpable mammographic abnormalities; can be performed by needle placement alone, spot dye injection, or needle-hookwire methods.

lux: A unit of illumination equal to the direct illumination on a surface that is everywhere 1 m from a uniform point source of one candle intensity or equal to one lumen per square meter.

lymph nodes: Kidney bean-shaped structures scattered along vessels of the lymphatic system seen in the axilla or sometimes in the breast itself; act as filters, collecting bacteria or cancer cells that may travel through the lymph system (also called lymph glands).

magnetic resonance imaging (MRI): An imaging modality using a strong magnetic field and radiofrequency signals to produce multiplanar images of the body. Image contrast is based on the hydrogen concentration, molecular response to radiofrequency signals, and flow of structures within the part of the body being imaged.

magnification view: A technique for producing an enlarged image with greater detail of a small area of suspicious breast tissue.

malignant: Cancerous; a growth of cancer cells.

mammogram: An x-ray image of the breast recorded on film, paper or digital receptor.

mammography: An x-ray examination of the breast (see **screening mammography** and **diagnostic mammography**).

Mammography Quality Standards Act (MQSA): MQSA 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.

mean glandular dose: Calculated from values of entrance exposure (free-in-air), the x-ray beam quality (half-value layer), and compressed breast thickness, mean 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 (*i.e.*, the mean absorbed dose to glandular tissue). The mean glandular dose should be <3 mGy for a single screen-film craniocaudal view of a standard (4.2 cm thick, 50 percent glandular, 50 percent adipose) breast. The mean glandular dose is the value used to estimate the radiation risk of the exposure.

medical audit: Systematic collection and analysis of mammography results, comparing those results with outcomes data.

mediolateral-oblique (MLO) view: Now one of the standard two views of the breast. The image receptor is angled 30 to 60 degrees 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.

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.

metastasis: The spread of cancer from the place where it arises to another part of the body.

microcalcifications: Tiny white specks of calcium salts that can sometimes be seen on a mammogram. In clusters, they can be the only sign of ductal carcinoma *in situ* or early invasive cancer, or they can be associated with benign breast changes (also called calcifications).

milliampere seconds (mAs): The product of electron current (milliampere) and the exposure time (in seconds). For a fixed operating potential, total x-ray output is linearly proportional to milliampere seconds.

milliampere (mA) setting: The electron current (milliampere) passing from the cathode to the anode in an x-ray tube. For a fixed operating potential, the output of x rays per unit time from the tube is linearly proportional to the milliampere setting.

nipple discharge: Secretion of fluid from the nipple, either spontaneously or elicited from the nipple area. Nipple discharge (other than milk in a lactating woman) often results from benign breast changes or minor hormonal irregularities but, if spontaneous, needs to be checked by a health professional.

nodularity: General lumpiness of normal textured tissue consistency, often bilateral.

nodule: A discrete small lump as opposed to normal nodularity.

Nyquist frequency: Equal to one-half the sampling frequency (Nyguist theorem). Frequencies higher than the Nyquist frequency cannot be accurately reproduced.

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.

operating potential: (see also **kilovolt peak**). The potential difference between the anode and cathode of an x-ray tube.

palpation: Generally, examination by touch; the part of breast examination during which the breast tissue and structures are felt with the finger pads.

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.

positioning: The maneuvers the radiologic technologist uses to place the breast in the desired position on the film for a specific mammographic view.

positron emission tomography (PET): A nuclear medicine procedure that utilizes a positron emitting radionuclide to visualize various tissue and/or organ abnormalities.

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.

projection: The direction of the central ray (*e.g.*, mediolateral, craniocaudal) in an x-ray exam.

provider: Referring physician or other health care professional who refers women for mammography (*e.g.*, family practice physician, nurse practitioner, physician's assistant).

quality assurance (QA): 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.

radiation weighting factor: A factor used for radiation-protection purposes that accounts for differences in biological effectiveness between different radiations. The radiation weighting factor (w_R) is independent of the tissue weighting factor (w_T).

radiographic noise: Unwanted fluctuations in optical density on the mammographic image.

radiographic sharpness: The distinctness or perceptibility of the edge or boundary of the structure in a radiograph.

radiopaque: Not penetrable by x rays or other forms of radiant energy; radiopaque areas appear light or white on the exposed film.

relative risk (RR): The mortality rate in women who have a risk factor divided by the mortality rate due to breast cancer in women who do not have the risk factor.

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.

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 light when exposed to radiation. 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.

sensitivity: The probability of detecting a cancer when a cancer exists, otherwise defined as the fraction of all patients found to have breast cancer within 1 y of screening who were correctly diagnosed as being suspicious for breast cancer at the screening session.

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.

Sestamibi scintimammography: Sestamibi (cardiolite) labeled with ^{99m}Tc. Scintimammography is used to visualize some types of breast cancer utilizing a gamma camera.

sievert (Sv): The special name for the SI units of dose equivalent (H) and equivalent dose (H_T).

spatial resolution: The ability to image two separate objects and visually detect one from the other.

specificity: The probability of a normal mammogram report when no cancer exists, otherwise defined as the fraction of all patients found not to have breast cancer within 1 y of screening who were correctly identified as normal at the time of screening.

specimen radiography: The technique for examining a biopsy specimen by x-ray imaging.

spot compression: Allows for greater reduction in thickness of the localized area of interest and improved separation of breast tissues by the use of a small compression device; requires collimation to the area of interest (also called coned compression).

sterotactic breast biopsy: Breast biopsy performed with location of the area to be biopsied determined by utilizing two x-ray images in parallax.

stochastic effects: Effects, the probability of which, rather than their severity is a function of dose without threshold.

thermography: A breast imaging technique that measures body heat at the skin surface to identify hot spots caused by inflammation or cancer.

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.

tissue weighting factor (w_T): A factor for a particular tissue representing the fraction of the detriment (cancer) plus hereditary effects attributed to that tissue when the whole body is irradiated uniformly.

transillumination: A noninvasive breast imaging technique that uses visible or near-visible light in an attempt to visualize breast masses.

ultrasonography: The use of sonic energy (sound) to produce a pictorial representation of the internal structure of the breast. The image is produced by pulse-echo techniques, with detection and display of tissue interfaces rather than densities.

unsharpness: The inability of an x-ray imaging system to clearly define an edge on the final image (also called blur).

view: The image of the breast on the film resulting from projection of the x-ray beam and the breast-positioning maneuvers performed by the radiologic technologist; usually named according to the direction of the x-ray beam relative to the breast (*e.g.*, mediolateral, craniocaudal).

viewbox: A device providing a relatively uniform surface luminance for viewing mammographic films. Mammographic viewboxes should have a luminance level of at least 3,000 candela per square meter (cd m^{-2} or nit).

x rays: The electromagnetic radiations emitted in the de-excitation of bound atomic electrons referred to as characteristic x rays, or the electromagnetic radiation produced in the deceleration of energetic charged particles in passing through matter such as continuous x rays from the deceleration of electrons in a cathode-ray tube (x-ray tube) or bremsstrahlung from the deceleration of high-energy beta particles.

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The NCRP

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1. Collect, analyze, develop and disseminate in the public interest information and recommendations about (a) protection against radiation and (b) radiation measurements, quantities and units, particularly those concerned with radiation protection.
2. Provide a means by which organizations concerned with the scientific and related aspects of radiation protection and of radiation quantities, units and measurements may cooperate for effective utilization of their combined resources, and to stimulate the work of such organizations.
3. Develop basic concepts about radiation quantities, units and measurements, about the application of these concepts, and about radiation protection.
4. Cooperate with the International Commission on Radiological Protection, the International Commission on Radiation Units and Measurements, and other national and international organizations, governmental and private, concerned with radiation quantities, units and measurements and with radiation protection.

The Council is the successor to the unincorporated association of scientists known as the National Committee on Radiation Protection and Measurements and was formed to carry on the work begun by the Committee in 1929.

The participants in the Council's work are the Council members and members of scientific and administrative committees. Council members are selected solely on the basis of their scientific expertise and serve as individuals, not as representatives of any particular organization. The scientific committees, composed of experts having detailed knowledge and competence in the particular area of the committee's interest, draft proposed recommendations. These are then submitted to the full membership of the Council for careful review and approval before being published.

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- SC 1-13 Effects of Therapeutic Medical Treatment and Genetic Background
- SC 1-15 Radiation Safety in NASA Lunar Missions
- SC 85 Risk of Lung Cancer from Radon

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- SC 46-13 Design of Facilities for Medical Radiation Therapy
- SC 46-17 Radiation Protection in Educational Institutions

Program Area Committee 3: Nonionizing Radiation
- SC 89-5 Study and Critical Evaluation of Radiofrequency Exposure Guidelines

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- SC 91-1 Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides

Program Area Committee 5: Environmental Radiation and Radioactive Waste Issues
- SC 64-22 Design of Effective Effluent and Environmental Monitoring Programs
- SC 64-23 Cesium in the Environment
- SC 87-3 Performance Assessment of Near Surface Radioactive Waste Facilities

Program Area Committee 6: Radiation Measurements and Dosimetry
- SC 6-1 Uncertainties in the Measurement and Dosimetry of External Radiation Sources
- SC 57-17 Radionuclide Dosimetry Models for Wounds

Advisory Committee 1: Public Policy and Risk Communication

In recognition of its responsibility to facilitate and stimulate cooperation among organizations concerned with the scientific and related aspects of radiation protection and measurement, the Council has created a category of NCRP Collaborating Organizations. Organizations or groups of organizations that are national or international in scope and are concerned with scientific problems involving radiation quantities, units, measurements and effects, or radiation protection may be admitted to collaborating status by the Council. Collaborating Organizations provide a means by

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American Industrial Hygiene Association
American Institute of Ultrasound in Medicine
American Medical Association
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American Pharmaceutical Association
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The NCRP has found its relationships with these organizations to be extremely valuable to continued progress in its program.

Another aspect of the cooperative efforts of the NCRP relates to the Special Liaison relationships established with various governmental organizations that have an interest in radiation protection and measurements. This liaison relationship provides: (1) an opportunity for participating organizations to designate an individual to provide liaison between the organization and the NCRP; (2) that the individual designated will receive copies of draft NCRP reports (at the time that these are submitted to the members of the Council) with an invitation to comment, but not vote; and (3) that new NCRP efforts might be discussed with liaison individuals as appropriate, so that they might have an opportunity to make suggestions on new studies and related matters. The following organizations participate in the Special Liaison Program:

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China Institute for Radiation Protection
Commonwealth Scientific Instrumentation Research Organization (Australia)
European Commission
Health Council of the Netherlands
Institut de Radioprotection et de Surete Nucleaire
International Commission on Non-ionizing Radiation Protection
International Commission on Radiation Units and Measurements
Japan Radiation Council
Korea Institute of Nuclear Safety
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Initial funds for publication of NCRP reports were provided by a grant from the James Picker Foundation.

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NCRP Reports

No.	Title
8	*Control and Removal of Radioactive Contamination in Laboratories* (1951)
22	*Maximum Permissible Body Burdens and Maximum Permissible Concentrations of Radionuclides in Air and in Water for Occupational Exposure* (1959) [includes Addendum 1 issued in August 1963]
25	*Measurement of Absorbed Dose of Neutrons, and of Mixtures of Neutrons and Gamma Rays* (1961)
27	*Stopping Powers for Use with Cavity Chambers* (1961)
30	*Safe Handling of Radioactive Materials* (1964)
32	*Radiation Protection in Educational Institutions* (1966)
35	*Dental X-Ray Protection* (1970)
36	*Radiation Protection in Veterinary Medicine* (1970)
37	*Precautions in the Management of Patients Who Have Received Therapeutic Amounts of Radionuclides* (1970)
38	*Protection Against Neutron Radiation* (1971)
40	*Protection Against Radiation from Brachytherapy Sources* (1972)
41	*Specification of Gamma-Ray Brachytherapy Sources* (1974)
42	*Radiological Factors Affecting Decision-Making in a Nuclear Attack* (1974)

44 *Krypton-85 in the Atmosphere—Accumulation, Biological Significance, and Control Technology* (1975)
46 *Alpha-Emitting Particles in Lungs* (1975)
47 *Tritium Measurement Techniques* (1976)
49 *Structural Shielding Design and Evaluation for Medical Use of X Rays and Gamma Rays of Energies Up to 10 MeV* (1976)
50 *Environmental Radiation Measurements* (1976)
52 *Cesium-137 from the Environment to Man: Metabolism and Dose* (1977)
54 *Medical Radiation Exposure of Pregnant and Potentially Pregnant Women* (1977)
55 *Protection of the Thyroid Gland in the Event of Releases of Radioiodine* (1977)
57 *Instrumentation and Monitoring Methods for Radiation Protection* (1978)
58 *A Handbook of Radioactivity Measurements Procedures*, 2nd ed. (1985)
60 *Physical, Chemical, and Biological Properties of Radiocerium Relevant to Radiation Protection Guidelines* (1978)
61 *Radiation Safety Training Criteria for Industrial Radiography* (1978)
62 *Tritium in the Environment* (1979)
63 *Tritium and Other Radionuclide Labeled Organic Compounds Incorporated in Genetic Material* (1979)
64 *Influence of Dose and Its Distribution in Time on Dose-Response Relationships for Low-LET Radiations* (1980)
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67 *Radiofrequency Electromagnetic Fields—Properties, Quantities and Units, Biophysical Interaction, and Measurements* (1981)
68 *Radiation Protection in Pediatric Radiology* (1981)
69 *Dosimetry of X-Ray and Gamma-Ray Beams for Radiation Therapy in the Energy Range 10 keV to 50 MeV* (1981)
70 *Nuclear Medicine—Factors Influencing the Choice and Use of Radionuclides in Diagnosis and Therapy* (1982)
72 *Radiation Protection and Measurement for Low-Voltage Neutron Generators* (1983)
73 *Protection in Nuclear Medicine and Ultrasound Diagnostic Procedures in Children* (1983)
74 *Biological Effects of Ultrasound: Mechanisms and Clinical Implications* (1983)
75 *Iodine-129: Evaluation of Releases from Nuclear Power Generation* (1983)
76 *Radiological Assessment: Predicting the Transport, Bioaccumulation, and Uptake by Man of Radionuclides Released to the Environment* (1984)

77 *Exposures from the Uranium Series with Emphasis on Radon and Its Daughters* (1984)
78 *Evaluation of Occupational and Environmental Exposures to Radon and Radon Daughters in the United States* (1984)
79 *Neutron Contamination from Medical Electron Accelerators* (1984)
80 *Induction of Thyroid Cancer by Ionizing Radiation* (1985)
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132 *Radiation Protection Guidance for Activities in Low-Earth Orbit* (2000)
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136 *Evaluation of the Linear-Nonthreshold Dose-Response Model for Ionizing Radiation* (2001)
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NCRP Commentaries

No.	Title
1	*Krypton-85 in the Atmosphere—With Specific Reference to the Public Health Significance of the Proposed Controlled Release at Three Mile Island* (1980)
4	*Guidelines for the Release of Waste Water from Nuclear Facilities with Special Reference to the Public Health Significance of the Proposed Release of Treated Waste Waters at Three Mile Island* (1987)
5	*Review of the Publication, Living Without Landfills* (1989)
6	*Radon Exposure of the U.S. Population—Status of the Problem* (1991)
7	*Misadministration of Radioactive Material in Medicine—Scientific Background* (1991)
8	*Uncertainty in NCRP Screening Models Relating to Atmospheric Transport, Deposition and Uptake by Humans* (1993)
9	*Considerations Regarding the Unintended Radiation Exposure of the Embryo, Fetus or Nursing Child* (1994)
10	*Advising the Public about Radiation Emergencies: A Document for Public Comment* (1994)
11	*Dose Limits for Individuals Who Receive Exposure from Radionuclide Therapy Patients* (1995)
12	*Radiation Exposure and High-Altitude Flight* (1995)

13 *An Introduction to Efficacy in Diagnostic Radiology and Nuclear Medicine (Justification of Medical Radiation Exposure)* (1995)
14 *A Guide for Uncertainty Analysis in Dose and Risk Assessments Related to Environmental Contamination* (1996)
15 *Evaluating the Reliability of Biokinetic and Dosimetric Models and Parameters Used to Assess Individual Doses for Risk Assessment Purposes* (1998)
16 *Screening of Humans for Security Purposes Using Ionizing Radiation Scanning Systems* (2003)
17 *Pulsed Fast Neutron Analysis System Used in Security Surveillance* (2003)
18 *Biological Effects of Modulated Radiofrequency Fields* (2003)

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3 *Critical Issues in Setting Radiation Dose Limits*, Proceedings of the Seventeenth Annual Meeting held on April 8-9, 1981 (including Taylor Lecture No. 5) (1982)
4 *Radiation Protection and New Medical Diagnostic Approaches,* Proceedings of the Eighteenth Annual Meeting held on April 6-7, 1982 (including Taylor Lecture No. 6) (1983)
5 *Environmental Radioactivity,* Proceedings of the Nineteenth Annual Meeting held on April 6-7, 1983 (including Taylor Lecture No. 7) (1983)
6 *Some Issues Important in Developing Basic Radiation Protection Recommendations*, Proceedings of the Twentieth Annual Meeting held on April 4-5, 1984 (including Taylor Lecture No. 8) (1985)
7 *Radioactive Waste*, Proceedings of the Twenty-first Annual Meeting held on April 3-4, 1985 (including Taylor Lecture No. 9)(1986)
8 *Nonionizing Electromagnetic Radiations and Ultrasound,* Proceedings of the Twenty-second Annual Meeting held on April 2-3, 1986 (including Taylor Lecture No. 10) (1988)
9 *New Dosimetry at Hiroshima and Nagasaki and Its Implications for Risk Estimates*, Proceedings of the Twenty-third Annual Meeting held on April 8-9, 1987 (including Taylor Lecture No. 11) (1988)
10 *Radon*, Proceedings of the Twenty-fourth Annual Meeting held on March 30-31, 1988 (including Taylor Lecture No. 12) (1989)
11 *Radiation Protection Today—The NCRP at Sixty Years*, Proceedings of the Twenty-fifth Annual Meeting held on April 5-6, 1989 (including Taylor Lecture No. 13) (1990)

12 *Health and Ecological Implications of Radioactively Contaminated Environments*, Proceedings of the Twenty-sixth Annual Meeting held on April 4-5, 1990 (including Taylor Lecture No. 14) (1991)

13 *Genes, Cancer and Radiation Protection,* Proceedings of the Twenty-seventh Annual Meeting held on April 3-4, 1991 (including Taylor Lecture No. 15) (1992)

14 *Radiation Protection in Medicine,* Proceedings of the Twenty-eighth Annual Meeting held on April 1-2, 1992 (including Taylor Lecture No. 16) (1993)

15 *Radiation Science and Societal Decision Making,* Proceedings of the Twenty-ninth Annual Meeting held on April 7-8, 1993 (including Taylor Lecture No. 17) (1994)

16 *Extremely-Low-Frequency Electromagnetic Fields: Issues in Biological Effects and Public Health*, Proceedings of the Thirtieth Annual Meeting held on April 6-7, 1994 (not published).

17 *Environmental Dose Reconstruction and Risk Implications,* Proceedings of the Thirty-first Annual Meeting held on April 12-13, 1995 (including Taylor Lecture No. 19) (1996)

18 *Implications of New Data on Radiation Cancer Risk*, Proceedings of the Thirty-second Annual Meeting held on April 3-4, 1996 (including Taylor Lecture No. 20) (1997)

19 *The Effects of Pre- and Postconception Exposure to Radiation*, Proceedings of the Thirty-third Annual Meeting held on April 2-3, 1997, Teratology **59**, 181–317 (1999)

20 *Cosmic Radiation Exposure of Airline Crews, Passengers and Astronauts*, Proceedings of the Thirty-fourth Annual Meeting held on April 1-2, 1998, Health Phys. **79**, 466–613 (2000)

21 *Radiation Protection in Medicine: Contemporary Issues*, Proceedings of the Thirty-fifth Annual Meeting held on April 7-8, 1999 (including Taylor Lecture No. 23) (1999)

22 *Ionizing Radiation Science and Protection in the 21st Century*, Proceedings of the Thirty-sixth Annual Meeting held on April 5-6, 2000, Health Phys. **80**, 317–402 (2001)

23 *Fallout from Atmospheric Nuclear Tests—Impact on Science and Society*, Proceedings of the Thirty-seventh Annual Meeting held on April 4-5, 2001, Health Phys. **82**, 573–748 (2002)

24 *Where the New Biology Meets Epidemiology: Impact on Radiation Risk Estimates*, Proceedings of the Thirty-eighth Annual Meeting held on April 10-11, 2002, Health Phys. **85**, 1–108 (2003)

25 *Radiation Protection at the Beginning of the 21st Century–A Look Forward*, Proceedings of the Thirty-ninth Annual Meeting held on April 9–10, 2003, Health Phys. **87**, 237–319 (2004)

Lauriston S. Taylor Lectures

No.	Title
1	*The Squares of the Natural Numbers in Radiation Protection by* Herbert M. Parker (1977)
2	*Why be Quantitative about Radiation Risk Estimates?* by Sir Edward Pochin (1978)
3	*Radiation Protection—Concepts and Trade Offs* by Hymer L. Friedell (1979) [available also in *Perceptions of Risk*, see above]
4	*From "Quantity of Radiation" and "Dose" to "Exposure" and "Absorbed Dose"—An Historical Review* by Harold O. Wyckoff (1980)
5	*How Well Can We Assess Genetic Risk? Not Very* by James F. Crow (1981) [available also in *Critical Issues in Setting Radiation Dose Limits*, see above]
6	*Ethics, Trade-offs and Medical Radiation* by Eugene L. Saenger (1982) [available also in *Radiation Protection and New Medical Diagnostic Approaches*, see above]
7	*The Human Environment—Past, Present and Future* by Merril Eisenbud (1983) [available also in *Environmental Radioactivity*, see above]
8	*Limitation and Assessment in Radiation Protection* by Harald H. Rossi (1984) [available also in *Some Issues Important in Developing Basic Radiation Protection Recommendations*, see above]
9	*Truth (and Beauty) in Radiation Measurement* by John H. Harley (1985) [available also in *Radioactive Waste*, see above]
10	*Biological Effects of Non-ionizing Radiations: Cellular Properties and Interactions* by Herman P. Schwan (1987) [available also in *Nonionizing Electromagnetic Radiations and Ultrasound*, see above]
11	*How to be Quantitative about Radiation Risk Estimates* by Seymour Jablon (1988) [available also in *New Dosimetry at Hiroshima and Nagasaki and its Implications for Risk Estimates*, see above]
12	*How Safe is Safe Enough?* by Bo Lindell (1988) [available also in *Radon*, see above]
13	*Radiobiology and Radiation Protection: The Past Century and Prospects for the Future* by Arthur C. Upton (1989) [available also in *Radiation Protection Today*, see above]
14	*Radiation Protection and the Internal Emitter Saga* by J. Newell Stannard (1990) [available also in *Health and Ecological Implications of Radioactively Contaminated Environments*, see above]
15	*When is a Dose Not a Dose?* by Victor P. Bond (1992) [available also in *Genes, Cancer and Radiation Protection*, see above]

16 *Dose and Risk in Diagnostic Radiology: How Big? How Little?* by Edward W. Webster (1992) [available also in *Radiation Protection in Medicine*, see above]
17 *Science, Radiation Protection and the NCRP* by Warren K. Sinclair (1993) [available also in *Radiation Science and Societal Decision Making,* see above]
18 *Mice, Myths and Men* by R.J. Michael Fry (1995)
19 *Certainty and Uncertainty in Radiation Research* by Albrecht M. Kellerer. Health Phys. **69**, 446–453 (1995)
20 *70 Years of Radiation Genetics: Fruit Flies, Mice and Humans* by Seymour Abrahamson. Health Phys. **71**, 624–633 (1996)
21 *Radionuclides in the Body: Meeting the Challenge* by William J. Bair. Health Phys. **73**, 423–432 (1997)
22 *From Chimney Sweeps to Astronauts: Cancer Risks in the Work Place* by Eric J. Hall. Health Phys. **75**, 357–366 (1998)
23 *Back to Background: Natural Radiation and Radioactivity Exposed* by Naomi H. Harley. Health Phys. **79**, 121–128 (2000)
24 *Administered Radioactivity: Unde Venimus Quoque Imus* by S. James Adelstein. Health Phys. **80**, 317–324 (2001)
25 *Assuring the Safety of Medical Diagnostic Ultrasound* by Wesley L. Nyborg. Health Phys. **82**, 578–587 (2002)
26 *Developing Mechanistic Data for Incorporation into Cancer and Genetic Risk Assessments: Old Problems and New Approaches* by R. Julian Preston. Health Phys. **85**, 4–12 (2003)
27 *The Evolution of Radiation Protection–From Erythema to Genetic Risks to Risks of Cancer to ?* by Charles B. Meinhold, Health Phys. **87**, 240–248 (2004)

Symposium Proceedings

No. Title

1 *The Control of Exposure of the Public to Ionizing Radiation in the Event of Accident or Attack*, Proceedings of a Symposium held April 27-29, 1981 (1982)
2 *Radioactive and Mixed Waste—Risk as a Basis for Waste Classification,* Proceedings of a Symposium held November 9, 1994 (1995)
3 *Acceptability of Risk from Radiation—Application to Human Space Flight,* Proceedings of a Symposium held May 29, 1996 (1997)
4 *21st Century Biodosimetry: Quantifying the Past and Predicting the Future*, Proceedings of a Symposium held February 22, 2001, Radiat. Prot. Dosim. **97**(1), (2001)
5 *National Conference on Dose Reduction in CT, with an Emphasis on Pediatric Patients*, Summary of a Symposium held November 6-7, 2002, Am. J. Roentgenol. **181**(2), 321–339 (2003)

NCRP Statements

No.	Title
1	"Blood Counts, Statement of the National Committee on Radiation Protection," Radiology **63**, 428 (1954)
2	"Statements on Maximum Permissible Dose from Television Receivers and Maximum Permissible Dose to the Skin of the Whole Body," Am. J. Roentgenol., Radium Ther. and Nucl. Med. **84**, 152 (1960) and Radiology **75**, 122 (1960)
3	*X-Ray Protection Standards for Home Television Receivers, Interim Statement of the National Council on Radiation Protection and Measurements* (1968)
4	*Specification of Units of Natural Uranium and Natural Thorium, Statement of the National Council on Radiation Protection and Measurements* (1973)
5	*NCRP Statement on Dose Limit for Neutrons* (1980)
6	*Control of Air Emissions of Radionuclides* (1984)
7	*The Probability That a Particular Malignancy May Have Been Caused by a Specified Irradiation* (1992)
8	*The Application of ALARA for Occupational Exposures* (1999)
9	*Extension of the Skin Dose Limit for Hot Particles to Other External Sources of Skin Irradiation* (2001)
10	*Recent Applications of the NCRP Public Dose Limit Recommendation for Ionizing Radiation* (2004)

Other Documents

The following documents of the NCRP were published outside of the NCRP report, commentary and statement series:

Somatic Radiation Dose for the General Population, Report of the Ad Hoc Committee of the National Council on Radiation Protection and Measurements, 6 May 1959, Science **131** (3399), February 19, 482–486 (1960)

Dose Effect Modifying Factors in Radiation Protection, Report of Subcommittee M-4 (Relative Biological Effectiveness) of the National Council on Radiation Protection and Measurements, Report BNL 50073 (T-471) (1967) Brookhaven National Laboratory (National Technical Information Service, Springfield, Virginia)

Residential Radon Exposure and Lung Cancer Risk: Commentary on Cohen's County-Based Study, Health Phys. **87**(6), 656–658 (2004)

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