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SCREENING MAMMOGRAPHY

Low-Cost Services Do Not Compromise Quality

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The Honorable Lloyd Bentsen
Chairman, Committee on Finance
United States Senate

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
House of Representatives

The Honorable Dan Rostenkowski
Chairman, Committee on Ways and Means
House of Representatives

The Honorable Barbara B. Kennelly
House of Representatives

This report responds to a provision of the Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) that required the Comptroller General to review the quality of screening mammography provided in a variety of settings. The report also responds to a request from Representative Barbara Kennelly to provide additional information on screening mammography, including the services constituting a complete mammography examination and the procedural differences between screening and diagnostic mammography.

We are sending copies of this report to certain other House and Senate committees and subcommittees, the Secretary of Health and Human Services, the Director of the Office of Management and Budget, state health departments, and other interested parties. We also will make copies available to others on request.

Please call me on (202) 275-6195 if you or your staff have any questions about this report. Other major contributors are listed in appendix VI.

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Executive Summary

Purpose

The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) introduced screening mammography for symptom-free women as a new benefit for Medicare-eligible women, to become effective in 1990. The act limited the charge for Medicare-funded screening to approximately $50. Some members of Congress were concerned that this limit could compromise women's ability to obtain quality services. To help assure that quality services would be provided, the act required (1) the Secretary of Health and Human Services (HHS) to establish standards to assure the safety and accuracy of this test and (2) the Comptroller General to report on the quality of screening mammography performed in a variety of settings. Representative Barbara Kennelly also asked GAO to provide additional information on screening mammography, including what constitutes a complete screening examination.

In November 1989, the Congress repealed most provisions of the Medicare Catastrophic Coverage Act of 1988, including the mammography benefit. However, legislation to restore the mammography benefit has been introduced.

Background

Breast cancer causes over 40,000 deaths per year in the United States. The best method for improving a woman's chance of survival is early detection, and the most effective tool for early detection is mammography, an X-ray that can find cancers too small for the woman or her physician to feel. Leading medical organizations recommend that women begin periodic mammographic screening at the age of 40; regular screening can reduce mortality rates by 30 percent. Screening mammography, which is performed on women without symptoms to detect unsuspected abnormalities, can be provided more economically than diagnostic mammography. The latter is used to provide more detailed information about abnormalities that have been discovered. (See pp. 10-12.)

Despite the recommendations for regular screening mammography, studies indicate that over half of women over 40 have never had the test. A new Medicare benefit could greatly increase the number of women receiving such screening. (See pp. 12-13.)

GAO interviewed mammography experts to identify quality standards that contribute to optimal screening mammography and sent a questionnaire to 1,485 facilities providing mammography in four states—California, Florida, Idaho, and Michigan. The facilities were asked to

categorize their type of setting and supply information on services provided, equipment, personnel performing and interpreting mammograms, quality assurance activities, reporting and record-keeping, volume, and charges for screening mammography services. In addition to obtaining information on federal oversight of mammography and laws and regulatory programs in the four states reviewed, GAO visited 15 screening mammography providers to supplement the survey data. (See pp. 14-16.)

Results in Brief

Many providers lack adequate quality assurance programs. This may contribute to the wide range of image quality and patient radiation dose that occurs in current mammography practice. GAO found no relationship between the price charged for screening mammography and adherence to quality standards. Providers with higher mammography volume were more likely to comply with many quality standards than were those with lower volume. There is evidence that high volume permits economies of scale and does not compromise quality.

Federal and state oversight programs have been limited by the absence of legally binding quality standards. In September 1989, however, HHS published proposed regulations for Medicare-funded screening mammography that parallel professional quality standards. Such regulations would help federal and state regulators in assuring that mammography providers deliver quality services. Because the Medicare Catastrophic Coverage Act of 1988 was repealed, HHS will withdraw its proposed regulations.

GAO's Analysis

Quality Standards Exist, but Image Quality and Patient Dose Vary

The quality of screening mammography depends on providers complying with a wide range of quality standards. The primary goal is a mammographic image of good quality, obtained with low radiation dose to the patient and followed by accurate interpretation of the image. Although professional groups have established quality standards to guide facilities, these standards are not uniformly followed, and image quality and dose vary widely in current mammography practice. (See pp. 23-25.)

Quality Assurance Standards Met Less Often Than Other Standards

To maintain a consistent level of quality, providers should perform quality assurance activities, such as periodic inspections of equipment performance. Many providers that GAO surveyed, however, were not complying with standards for quality assurance programs. Inadequate quality assurance programs may be a cause of the variation in image quality and dose. Primary care physicians and multispecialty clinics were the providers reporting the lowest rates of compliance with standards for quality assurance activities. (See pp. 26-32.)

More High-Volume Providers Comply With Quality Standards

High-volume providers were more likely to comply with many quality standards than were low-volume providers. However, providers charging higher fees were no more likely to adhere to quality standards than were those charging lower fees. Several providers that GAO visited reported that they met many quality standards while charging $50 or less for screening mammograms; all were high-volume facilities. (See pp. 32-34).

Economies Possible With Screening Mammography Not Always Realized

Compared with diagnostic mammography, screening mammography is a less complex process, which permits certain economies of scale that make it less costly to provide. The radiologist need not be present during the examination to read the films, but can read a large batch of films at once, resulting in a more efficient use of the radiologist's time. In addition, increasing patient volume results in more efficient use of expensive equipment. (See pp. 12 and 20-21.)

Most providers operate at relatively low volume—fewer than 50 mammograms per week. Survey respondents reported charging a wide range of fees for screening mammography, with the average about $100. One reason most charges are higher than $50 may be that providers base these charges on the more complex and expensive diagnostic procedure. (See pp. 21-22.)

Limits of Current Regulation Make HHS Standards Important

State oversight of mammography is limited. Three of the four states GAO reviewed have no legally binding standards for image quality or radiation dose; nor do they require the use of equipment specifically designed for mammography. The federal government currently does not regulate the quality of mammography. The Food and Drug Administration (FDA) is responsible for ensuring the correct manufacture and installation of X-ray equipment, but not for overseeing its subsequent use. FDA inspects a relatively small number of mammography machines. (See pp. 35-40.)

The limitations of existing oversight and evidence of problems with image quality and radiation dose underscore the importance of quality standards the Medicare Catastrophic Coverage Act of 1988 required the Secretary of HHS to issue for Medicare-funded screening mammography. Proposed standards published by HHS before repeal of the screening mammography benefit paralleled professional quality standards. Such standards would have filled existing regulatory gaps. (See pp. 41 and 43.)

Recommendations

GAO makes no recommendations in this report.

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Figures

Abbreviations

ACR	American College of Radiology
ACS	American Cancer Society
ARCRT	American Registry of Clinical Radiographic Technologists
ARRT	American Registry of Radiologic Technologists
BCDDP	Breast Cancer Detection Demonstration Project
BSE	breast self-examination
CC	craniocaudal
CDRH	Center for Devices and Radiological Health
CRCPD	Conference of Radiation Control Program Directors
DHS	Department of Health Services
DRH	Division of Radiological Health
FDA	Food and Drug Administration
HCFA	Health Care Financing Administration
HHS	Department of Health and Human Services
HIP	Health Insurance Plan
HMO	health maintenance organization
HVL	half value layer
ICS	Investigation and Compliance Section
MAP	Mammography Accreditation Program
NCI	National Cancer Institute
NCRP	National Council on Radiation Protection and Measurements
OTA	Office of Technology Assessment
PPRC	Physician Payment Review Commission
XMRC	X-ray Machine Registration and Control

Introduction

Breast cancer is a leading cause of death and illness in the United States; over 40,000 breast cancer deaths are expected to occur in 1989. No preventive strategies are known, but early detection through periodic screening mammography can lower a woman's risk of dying from breast cancer by 30 percent. The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) created a new benefit for periodic screening mammography for Medicare-eligible women that was to go into effect in January 1990. However, on November 22, 1989, the Congress repealed most provisions of the act, including the mammography benefit. Legislation that would restore a Medicare screening mammography benefit has been introduced in the House of Representatives. If such a benefit is enacted, millions of women would become eligible for low-cost screening, which could have a significant impact on breast cancer morbidity and mortality in the United States.

To help contain costs, the act generally limited the fee providers could charge for a screening mammogram to $50. Some members of Congress expressed concern that the charge limit could compromise the quality of Medicare-funded screening mammography. To help assure that quality services would be provided, the Congress required the Secretary of Health and Human Services (HHS) to establish quality standards for facilities providing screening mammography to Medicare beneficiaries. To provide the Congress with information on the quality of current screening mammography services, the act also required GAO to assess quality of care in a variety of settings. In response to this requirement and a request from Representative Barbara Kennelly, we developed information on which settings currently provide screening mammography, what they charge, whether quality of care varies by setting or charge, and government regulation of screening mammography.

Screening Mammography Can Reduce Breast Cancer Mortality

Breast cancer is the most common cancer and second leading cause of cancer deaths in women in the United States, and its incidence is increasing. One in 10 women will develop breast cancer during her lifetime; only 4 years ago, the rate was 1 in 13. The American Cancer Society (ACS) estimates that during 1989, nearly 143,000 women in the United States will develop breast cancer and 43,000 will die from it. Increasing age is the most important risk factor for developing breast cancer. There is a dramatic increase in risk after age 40, and over one-third of the cases diagnosed occur in women over 65.

At present, the best method known to reduce breast cancer mortality is early detection, which permits treatment that greatly increases the

chance for survival. Detection of breast cancer is accomplished through mammography, clinical breast examination, and monthly breast self-examination. Of these methods, mammography, an X-ray of the breast, is the most effective for detection of early stage breast cancer.

The value of mammography for breast cancer screening is that it can detect cancers that are too small to be felt through physical examination (palpation), and these early stage cancers can be 90 to almost 100 percent curable. When detected at a later stage, they are much more likely to have spread to the axillary lymph nodes or distant sites, and the 5-year survival rate can drop as low as 18 percent.[1] Not only is treatment then more debilitating, it also is much less effective.

The National Cancer Institute (NCI) and ACS believe that a breast physical examination is also an essential element of breast cancer screening, as a small percentage of cancers is identified by palpation but cannot be seen on a mammogram. However, this examination need not necessarily occur at the same time as the mammogram.

Through technological refinement of mammography equipment, the effectiveness of mammography has increased, while the amount of radiation exposure has dropped dramatically. Current levels are one-tenth of those produced during the 1960s. They are considered safe enough so that the value of the mammographic examination for women eligible for screening far outweighs any risk from the exposure.

Studies indicate a significant decrease in breast cancer mortality for women who have screening mammograms at recommended intervals. Among the studies are those of the Health Insurance Plan (HIP) of Greater New York Screening Project and the Breast Cancer Detection Demonstration Project (BCDDP), a collaborative effort of NCI and ACS. Leading medical organizations, including NCI, ACS, and the American College of Radiology (ACR),[2] have endorsed the following breast cancer screening guidelines:

- An annual or biennial mammogram for women 40-49 and
- An annual mammogram for women age 50 and older.

[1]Survival rate in white women.

[2]ACR is a professional and educational association of 20,000 board-certified radiologists and radiological physicists.

Purposes of Screening and Diagnostic Mammography Differ

Mammography is performed for two different purposes, screening and diagnosis:

- Screening mammography is an examination of a woman without breast symptoms to detect breast cancer before a lesion can be felt by her or her physician. It is done simply to detect unknown abnormalities in women who appear to be disease-free.
- Diagnostic mammography is an examination of a woman who exhibits a symptom, such as a lump, that indicates the possible presence of breast cancer. It is performed to fully characterize lesions, providing as much information as possible.

The process of performing the mammograms is the same for both. A diagnostic procedure, however, may require additional breast views and other tests, such as ultrasound, to provide more information about a suspicious lesion. Because of its more limited purpose, screening mammography can take advantage of certain economies not possible during diagnostic mammography. For example, a radiologist need not be on the premises for immediate interpretation of screening mammograms. Instead, the day's films can be read all at one time, allowing greater efficiency in the costly use of a radiologist's time.

Efforts Made to Increase Use of Screening Mammography

Despite the recommendations for regular screening mammography, studies indicate that around 60 percent of women age 40 and over have never had a screening mammogram. The most common reasons women give for not being screened are that they do not think they need screening mammograms and that their physicians did not recommend them. Other reasons include fear of excess radiation and high fees. Fear of detecting breast cancer also may act as a deterrent, because until recently, such a diagnosis meant the likelihood of death or at least loss of a breast.

In an effort to increase the number of women who are screened, ACS has been supporting numerous local campaigns since 1987 to establish programs that promote and provide low-cost screening mammography. Common features of these programs include low charges for screening ranging from $35 to $50 and criteria for participating facilities to assure provision of high-quality services. Some states also sponsor programs to increase the use and awareness of mammography, and some mandate health insurance coverage of screening mammography.

Medicare Benefit for Screening Mammography Proposed

Currently, Medicare covers diagnostic mammography only, as it generally pays only for treatment, not preventive services. The only exceptions have been immunizations for pneumococcal pneumonia and hepatitis B. During 1987, Medicare spent approximately $75 million on diagnostic mammograms.

The Medicare Catastrophic Coverage Act of 1988 (P.L. 100-360) introduced a new Medicare benefit for screening mammography, effective in 1990. This would have represented the first mass screening procedure supported by Medicare. The population eligible for this benefit includes nearly 18 million women age 65 and over and a portion of the more than 1 million disabled women under age 65. The Health Care Financing Administration (HCFA) estimated that the cost of providing this benefit would be $150 million in fiscal year 1990 and $275 million in fiscal year 1991.

Because of the potential cost of the benefit, the law established an indexed limit on the amount providers could have charged. Participating physicians (those who agree to accept Medicare-approved charges as payment in full for services) could have charged a maximum of $50 for screening mammography performed in 1990, including both examination and interpretation, of which Medicare would have reimbursed 80 percent. In years subsequent to 1990, the charge limit would have been the preceding year's limit increased by the percentage increase in the Medicare Economic Index.[3] Nonparticipating physicians could have charged 125 percent of the $50 limit ($62.50) in 1990, and their maximum charge would have decreased to 115 percent of the indexed limit by 1992.

The Congress specified that the Secretary of HHS was to establish standards to assure the safety and accuracy of Medicare-funded screening mammography. The law also set limits on the individual's use of the screening mammography benefit. These frequency limitations generally coincided with NCI's guidelines for screening mammography, with the following exception. For women over age 64, Medicare would have provided reimbursement for a screening mammogram every 2 years instead of every year.

[3]After 1991, the Secretary of HHS could have reduced the limit to the amount required to assure the availability of convenient screening mammography of good quality.

Objectives, Scope, and Methodology

The Medicare Catastrophic Coverage Act of 1988 required the Comptroller General to report to the House Committees on Ways and Means and Energy and Commerce and the Senate Committee on Finance on the quality of care of screening mammography provided in a variety of settings. Congressional conferees indicated that these settings include hospital outpatient departments, clinics, radiology practices, physicians' offices, and other facilities where Medicare beneficiaries could obtain screening mammography.[4] In addition, Representative Barbara Kennelly, in a letter of June 28, 1988, asked GAO to provide additional information on mammography.

In response to the statutory requirement and the request from Representative Kennelly, and as agreed with congressional staff, our objectives were to collect and analyze data across settings on the provision of screening mammography, charges for services, and quality assurance mechanisms. We developed information to answer the following questions:

- What provider settings currently offer screening mammography programs, and where do Medicare patients currently obtain mammography?
- What do different settings that provide screening mammography charge for their services?
- What are the factors necessary for screening mammography of acceptable quality, and do quality factors vary by setting or by charge?
- What governmental and professional regulations and oversight programs are in place to assure the quality of screening mammography?

We conducted our work in four states: California, Florida, Idaho, and Michigan. The criteria used to select these states were availability of information on facilities with mammography equipment, geographic diversity, size of the Medicare population, population density, and inclusion of a variety of mammography settings.

Our principal source of information on the first three questions was a mail survey we conducted of 1,485 facilities (757 in California, 313 in Florida, 35 in Idaho, and 380 in Michigan) providing mammography in the four states. These were all the facilities identified by the state radiological health departments as having mammography equipment. Our

[4]The law also required the Physician Payment Review Commission to report on the cost of providing screening mammography in a variety of settings and at different volume levels.

questionnaire requested information on providers' screening mammography practices, focusing on equipment, personnel, services provided, quality assurance mechanisms, reporting and record-keeping, volume, and charges. (Our survey methodology is described in more detail in app. I, and a copy of the questionnaire is presented in app. II.) The response rate was 82 percent overall, and, for each state, at least 80 percent.

Questionnaire items were based on the standards and recommendations developed by the ACR for use in granting accreditation to screening mammography programs (see p. 24 for more detailed information on ACR accreditation), the requirements of Public Law 100-360, and factors identified by other experts as associated with quality in screening mammography. The questionnaire was reviewed by officials from ACR and NCI.

When analyzing the questionnaire responses, we used the following setting categories:

- Primary care physician: Office of a primary care physician such as a gynecologist, internist, or surgeon;
- Radiology private practice: Individual or group radiology practice;
- Hospital: Hospital radiology department, outpatient clinic, or ambulatory care center;
- Hospital breast clinic: Breast screening clinic located in a hospital;
- Breast clinic: Freestanding facility for screening and/or treatment of breast disease;
- HMO: Health maintenance organization;
- Multispecialty clinic: Multispecialty group practice or outpatient clinic;
- Mobile van: Mobile van fitted with mammography equipment that may or may not be affiliated with a hospital, clinic, or physician's practice; and
- Other: Includes freestanding imaging centers not owned by radiologists, military primary care clinics, and other outpatient facilities.

Our survey results are based completely on self-reporting in the questionnaire, pertain only to the four states, and cannot be projected nationwide. The data from the questionnaire are reported in the aggregate, but any marked differences between the states are pointed out.

To gather information about topics not addressed in the questionnaire, we conducted site visits in each state at some facilities participating in the survey. We visited 15 facilities—5 in California, 4 each in Florida

and Michigan, and 2 in Idaho. The types of setting visited included primary care physician, radiology practice, hospital, breast clinic, multispecialty clinic, mobile van, and "other." (The latter was a practice in which portable mammography equipment was transported among several rural hospitals and physicians' offices.)

In the four states studied, we identified state laws and regulations pertaining to mammography, interviewed officials responsible for oversight of mammography facilities, and analyzed data on state inspections. To analyze the federal role in oversight of screening mammography and promoting quality assurance, we interviewed Food and Drug Administration (FDA) and HCFA officials and obtained data on FDA inspections. For information on quality standards and on the role of screening mammography in early detection of breast cancer, we reviewed the literature and interviewed many health care practitioners and experts from a wide range of organizations.

Our work was performed from September 1988 to July 1989 in accordance with generally accepted government auditing standards.

Variation in Screening Mammography Charges May Be Linked to Volume

The majority of screening and diagnostic mammograms currently are done in hospitals and radiology offices, where most Medicare-funded diagnostic mammography also occurs. The fees charged for screening mammography vary widely, from $50 or less to over $150, our survey showed. More than two-thirds of our respondents reported charges in the $51-125 range, with an average charge of $104.

One reason for the wide range of charges for screening mammography is providers' lack of distinction between screening and diagnostic services. Most of our respondents began providing screening within the past 5 years, and many did not distinguish between screening and diagnostic purposes. Screening programs can operate at a higher patient volume and take advantage of certain economies of scale that allow them to provide services at a lower fee. Mobile vans typically concentrate on screening mammography. Of the mobile vans in our survey, 60 percent charged $50 or less, and none charged more than $125. The Physician Payment Review Commission found that, at facilities that did not differentiate between screening and diagnostic mammography, the average charge was $103. However, at providers that did make a distinction, the average charges for screening and diagnostic mammography were $53 and $113 respectively.

Most survey respondents perform fewer than 50 mammograms per week, a relatively low volume. Practitioners and studies have indicated a relationship between high volume and the ability to lower the price of screening, and our survey data showed a similar trend.

Hospitals and Radiology Offices Predominate Among Mammography Settings

The majority of our respondents (65 percent) were hospitals and radiology private practices, and the majority of screening and diagnostic mammograms (57 percent) were performed in those settings, as table 2.1 shows.[1] (For information on setting distribution by state, see table V.1.)

Table 2.1: Distribution of Survey Respondents and Mammography Volume, by Setting

	Distribution (percent)	
Setting	**Respondents[a]**	**Volume[b]**
Hospital	40	33
Radiology private practice	25	25
Multispecialty clinic	10	8
Primary care physician	9	4
Breast clinic	8	13
HMO	4	10
Hospital breast clinic	2	4
Mobile van	1	2
Other	1	1
Totals	**100**	**100**

[a]A total of 1,026 respondents reported doing screening mammography and reported where it was done.

[b]Based on reported weekly volume of screening and diagnostic mammography.

The distribution of settings our respondents reported is similar to the distribution of settings where Medicare beneficiaries currently receive diagnostic mammography services. Most mammograms reimbursed by Medicare in 1987 took place in an outpatient hospital setting or a radiologist's office, according to data provided by HCFA.

About 83 percent of respondents that did screening mammography reported an urban or suburban location and 17 percent a rural location. Of the four states we focused on, only Idaho reported that a majority of its facilities were in rural areas (66 percent).

[1]Respondents were asked to name the principal setting from the list we provided (see ch. 1 and app. II).

Lack of Distinction Between Screening and Diagnostic Mammography Contributes to Fee Variations

Our survey respondents reported charging a wide range of fees for screening mammography. Since many providers do not differentiate between screening and diagnostic mammography, they may not take advantage of the economies of scale possible with screening mammography. This may explain why most respondents currently charge more than the $50 Medicare generally would have allowed under the screening benefit.

Screening Charges Vary Widely

Questionnaire recipients' reported charges for a screening mammogram, including both performance and interpretation of the mammogram, ranged from $50 or less[2] to $275, with an average of $104. The median charge was $100.

About 7 percent of the charges were in the lowest ($1-50) of five charge ranges that we established (see table 2.2). This range coincides with the reimbursement limit set for screening mammograms that would have been funded by Medicare. Overall, about 48 percent of respondents reported charging less than $100, and 52 percent charged $100 or more.

Table 2.2: Survey Respondents' Charges for Screening Mammography

Charge range	No. of respondents	Percent of respondents[a]
$1 - 50	71	7
$51 - 99	395	41
$100 - 125	264	28
$126 - 150	145	15
Over $150	81	9
Totals	**956**	**100**

[a]Respondents reporting a charge of $0 are excluded.

In comparing charges by state, we found that almost all Idaho facilities (97 percent) charged less than $100. This was a substantially higher percentage than in California (44 percent), Florida (54 percent), and Michigan (47 percent).

[2]About 2 percent of respondents, most of them HMOs, reported charging either nothing or only a nominal amount for screening mammography, presumably because it is a covered service for which there is no charge or a small copayment. We exclude no-charge cases from the remainder of this analysis.

Screening mammography charges were lower in mobile vans than in other settings. Sixty percent of the mobile vans reported charging $50 or less and none over $125. Typically, mobile vans concentrate on screening services, which allow them to take advantage of such procedural economies as batch reading of films (see p. 21). In contrast, no primary care physicians reported charging $50 or less, and a large percentage of hospitals and hospital breast clinics (31 and 37 percent respectively) charged more than $125. For additional information on charges by setting and by state, see table V.2.

In regard to location, rural facilities tended to charge somewhat less than facilities in urban/suburban locations, which may contribute to the lower charges in Idaho. Forty-seven percent of the urban/suburban facilities and 56 percent of the rural facilities charged less than $100. Conversely, 25 percent of the urban/suburban and 15 percent of the rural facilities charged over $125.

Limited Use of Economies of Scale in Screening Mammography Affects Charges

The medical community is at an early stage in distinguishing between screening mammography, a relatively new service, and diagnostic mammography. Almost two-thirds of the respondents to our survey reported that they began providing screening services after 1984 and almost half after 1985.

Over half of the 15 facilities we visited did not distinguish between the two kinds of mammography or differ in the way they provided these services or in their fees. This may account for the wide range of charges reported. In a 1989 report to Congress[3] on the cost of providing screening mammography, the Physician Payment Review Commission (PPRC) noted a similar relationship. In surveying 125 randomly selected mammography providers, PPRC found that at facilities that did not differentiate between screening and diagnostic mammography the average charge was $103. However, at providers that did make a distinction, the average charge for screening was $53 and for diagnostic mammography, $113.

The higher fees for screening mammography where providers do not distinguish between the two types of service may result from limited use of procedural efficiencies permitted by screening mammography. These include:

[3]PPRC, The Costs of Providing Screening Mammography, June 30, 1989.

- Batch reading of films. A major factor driving up the price of diagnostic mammography is the need for a radiologist to read the films while the patient is present. This does not apply to a screening situation.
- Maintaining a large volume of patients. This generates additional revenue without requiring additional investment in equipment.
- Requiring payment at time of service. This eliminates costs associated with billing and bad debt.

Mammography Volume Linked to Charges

Mammography experts have indicated that high volume is essential for providing screening mammography at lower fees. Many of our survey respondents reported a relatively low weekly mammography volume, and our analysis showed some association between higher volume and lower charges.

Generally Low Volume of Mammography Reported

The majority of facilities responding to our survey performed a relatively low volume of mammography.[4] The weekly volume ranged from 2 to 500 mammograms, but the average was 52 and the median 35, indicating a concentration at the lower end of the range. About one-third of respondents providing data on volume performed fewer than 25 mammograms per week, while only 21 percent did 75 or more weekly (see table 2.3).

Analysis by setting reveals great variation in mammography volume. At the lower end, 70 percent of the primary care physicians reported weekly volume under 25, and none performed more than 100 mammograms per week. Seventy-one percent of the hospitals reported a weekly volume under 50, with 7 percent doing over 100. In contrast, over half (58 percent) of the hospital breast clinics do at least 75 mammograms per week, with 37 percent doing over 100. (For additional information, see table V.3.)

[4]The volume data reported represent total mammography volume, including both screening and diagnostic mammography. Although we asked for separate data, some respondents provided only combined volume data and others used a definition of screening different from the one we provided. Our definitions of screening mammography and diagnostic mammography (that conducted on asymptomatic patients versus symptomatic patients) coincided with those of mammography experts, but some respondents evinced difficulty with these concepts. For example, one respondent stated that although many of the facility's patients were asymptomatic, it did not perform screening mammography.

Table 2.3: Survey Respondents' Weekly Mammography Volume

No. of mammograms performed weekly	Percent of respondents	No. of cases
1 - 24	34	336
25 - 49	28	269
50 - 74	17	167
75 - 100	10	100
Over 100	11	104
Totals	**100**	**976**

Higher Volume Associated With Lower Charges

Lower charges tended to be linked with a higher volume of mammography in our survey. The proportion of facilities charging $50 or less was almost three times greater among those performing over 100 mammograms weekly (15 percent) than among those doing fewer than 25 a week (6 percent). Another indication of this relationship is the fact that of the facilities performing more than 100 mammograms per week, over twice as many charged $50 or less (15 percent) as those that charged over $150 (7 percent). The relationship is reversed for facilities performing fewer than 25 mammograms per week. In that group, 6 percent charged $50 or less and 10 percent, over $150.

Experts on screening mammography emphasize that a key factor that makes screening for a lower fee possible is increased volume of service. To offer inexpensive mammography, one expert practitioner has stated, a provider must take advantage of certain economies of scale that require at least 15 patients daily. This minimizes periods when expensive equipment is idle. A break-even price for 16 patients a day of about $64, for 20 patients about $54, and for 25 patients about $46 was reported by a Florida physician who gave us information on the costs of a mobile van providing screening mammography.

At a stationary setting with average costs, the cost for providing one screening mammogram[5] ranges from about $34 at a volume level of 50 exams per day to $107 at a volume of 5 exams daily, PPRC said in its report. The unit cost at between 15 and 20 exams per day is around $50. Thus, PPRC concluded, $50 is sufficient payment for screening mammography if volume levels are high enough.[6]

[5]Includes nonphysician cost per exam and physician fee.

[6]PPRC also recommended increasing the Medicare payment to $60 in rural areas of low population density where it is not possible to generate sufficient volume to support a $50 payment.

High-Volume Providers Most Likely to Adhere to Quality Standards for Screening

Professional groups have developed quality standards for providers of screening mammography to follow. They include using dedicated equipment (i.e., equipment designed specifically for mammography instead of general purpose X-ray equipment), employing staff with proper credentials to perform and interpret mammograms, reporting and retaining records of mammographic results, and having an adequate quality assurance program. The primary goal of these standards is to produce a mammogram with good image quality, while limiting the patient's radiation dose, and to provide an accurate interpretation of the image. However, these standards are not uniformly followed, and there is great variation in image quality and radiation dose in current mammography practice.

Compliance with many of the professional quality standards, such as using equipment specifically designed for mammography, was widespread among the providers we surveyed. However, many did not comply with standards for quality assurance activities, such as annual inspection by a radiological physicist. Primary care physicians and multispecialty clinics reported the lowest rates of compliance with standards for quality assurance programs; in general, hospital breast clinics, HMOs, and mobile vans reported the highest.

Providers reporting higher levels of mammography volume showed a greater degree of compliance with quality standards than those performing fewer mammograms. Higher charges, however, did not necessarily buy higher quality. We found no consistent relationship between charge and adherence to quality standards.

Compliance With Professional Standards Important to Quality

Mammography is a complex process that requires providers' adherence to numerous quality standards to produce good results. Professional groups have established widely recognized quality standards to guide providers. Because of the complexity of the process, failure to comply with any of the standards can compromise the quality of the results. Some of the standards, such as using dedicated equipment and employing qualified personnel, relate directly to provision of mammography services. Others, such as daily inspection of the film processor, relate to the facility's quality assurance program. Adhering to quality assurance standards allows facilities to test their systems to ensure that they are providing high-quality mammograms and interpretations.

Most of the features considered necessary for quality screening mammography contribute to the goal of obtaining good image quality with

minimal risk to the patient. Because a mammogram is among the radiographic images most difficult to read, it must have optimal clarity. If image quality is poor or the interpretation faulty, the interpreter may miss cancerous lesions. This could delay treatment and result in an avoidable death or mastectomy. Problems with images or interpretation also can lead to unnecessary testing and biopsies if normal tissue is misread as abnormal.

The American College of Radiology has made a comprehensive effort to establish quality standards for screening mammography through its voluntary Mammography Accreditation Program (MAP). Started in 1987, it offers peer review and evaluation of a facility's equipment, staff qualifications, examination procedures, reporting practices, recordkeeping, and quality control and assurance programs. ACR also obtains information on image quality and radiation dose, which are evaluated through the use of a breast phantom[1] and dosimeter. A set of the facility's own mammographic images is also evaluated for image quality.[2]

A relatively small number of facilities have applied for and received accreditation. As of April 1989, 8 percent of facilities that responded to our questionnaire were accredited, according to data ACR supplied.[3] The setting with the highest proportion of accredited facilities was breast clinics (13 percent), followed by radiology practices (11 percent). Table V.4 provides additional information on respondents' ACR accreditation by setting and state. Other groups also have issued mammography guidelines. They include the National Council on Radiation Protection and Measurements (NCRP),[4] some of whose standards ACR incorporated

[1]Phantoms are objects designed to simulate breast tissue when exposed. The ACR phantom is a block with a wax insert containing fibers, specks, and masses that simulate growths that could be cancerous. The facility exposes the phantom with its equipment, and the visibility and clarity of the objects imbedded in the phantom are evaluated.

[2]When facilities submit clinical images to ACR as part of its MAP, the features that are assessed include proper patient positioning, acceptable image contrast, compression, and adequate visualization of structures within the breast.

[3]No Idaho facility was accredited, but 3 percent of the California, 6 percent of the Florida, and 19 percent of the Michigan respondents were. An ACR official said that participation in the accreditation program has been high in states where ACS chapters have required accreditation for participation in ACS screening programs. Michigan ACS and state officials have encouraged participation.

[4]NCRP, Mammography—A User's Guide, Report No. 85, Mar 1, 1986. The NCRP is a nonprofit corporation chartered by the Congress to make recommendations on radiation protection and related matters.

into its accreditation program, and the Conference of Radiation Control Program Directors (CRCPD).[5]

Problems in Meeting Image Quality, Radiation Dose Standards Revealed

Despite the existence of professional standards intended to result in optimal levels of image quality and radiation dose, ACR and state regulatory agencies have identified significant problems in current mammography practice. An analysis[6] of data collected from the ACR accreditation process revealed wide ranges of image quality and dose. The author of the analysis concluded that the underlying reason for these variations is the lack of universal compliance with quality assurance standards by mammography facilities.

The analysis was based on data collected from 647 providers that had completed the ACR accreditation process as of February 1, 1989. Twenty-nine percent of the applicants did not meet ACR's criteria and were not granted accreditation. Of these, about 36 percent failed because of poor clinical images, 38 percent because of poor phantom image quality, and 15 percent for both reasons. An additional 3 percent failed because of excessive radiation dose, and 8 percent failed to meet both dose and clinical image criteria. These findings were echoed in Michigan's inspection program, which also found significant problems when it evaluated equipment using ACR standards. (See pp. 37-38 for more detailed information.)

For the states we reviewed, the following applicants who had completed the ACR process as of May 1989 had received accreditation, according to ACR:

- Michigan and Florida, about two-thirds of the 109 and 32 applicants, respectively;
- California, 82 percent of the 34 applicants; and
- Idaho, neither of 2 applicants.

[5]CRCPD, Mammography Screening Guide, Conference Publication 87-4, Feb. 1987 (prepared in cooperation with the Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration; it also uses NCRP standards). The CRCPD is an association of state radiation control officials that has worked to improve the quality of mammography.

[6]R. Edward Hendrick, Ph.D., "Quality Control in Mammography: The American College of Radiology's Mammography Screening Accreditation Program," Current Opinion in Radiology, Vol. I, 1989, p. 203.

Many Providers Do Not Meet Standards for Quality Assurance Programs

We found widespread compliance with many quality standards, particularly those directly related to providing mammographic services, such as employing certified or licensed technologists to perform the mammograms. But many facilities did not comply with standards for quality assurance programs, our survey showed. A comprehensive quality assurance program is essential to evaluate both equipment and staff performance, as problems in image quality and radiation dose have been attributed to the lack of such programs. Primary care physicians and multispecialty clinics reported the lowest levels of compliance with quality assurance standards; hospitals, hospital breast clinics, HMOs, and mobile vans generally reported the highest levels.

Almost all of our respondents reported adhering to a number of key quality standards (see table 3.1). Additional information about the importance of these practices and the results of our survey appears in appendix II. However, smaller percentages of providers reported complying with professional standards for quality assurance activities, as we discuss in more detail below.

Annual Inspection by Radiological Physicist Varies by Setting

ACR policy states that a mammography system should be inspected by a radiological physicist at least once a year. About two-thirds (69 percent)[7] of the facilities responding to our survey reported that either a staff or consultant radiological physicist conducts this annual inspection. Compliance with this standard varies greatly by setting, ranging from 43 percent of primary care physicians to 91 percent of mobile vans (see fig. 3.1). For a more detailed analysis by setting and state, see table V.5.

[7]Percentages by state were: California, 73; Florida, 62; Idaho, 52; and Michigan, 68.

Table 3.1: Survey Respondents' Compliance With Key Quality Standards for Screening Mammography

Quality standard	Percent of respondents reporting compliance
Service delivery standards:	
Taking medical history	100
Using dedicated mammography equipment	97
Taking 2 or more breast views	99
Certified or licensed mammography operator	97
Interpretation of mammograms by radiologist	99
Reporting results of abnormal mammograms to patient and/or physician:	
When patient has designated physician	99
When patient has not designated physician	99
Retention of original mammographic images:	
5 years or more	98
Over 10 years	49
Instructing patients on breast self-examination	90
Quality assurance standards:	
Annual inspection by radiological physicist	69
Annual physicist inspection of beam quality, average glandular dose, and phantom image quality	55
Daily processor sensitometry	35
Semiannual phantom image check by facility	46
Monitoring repeat mammograms and doing one other quality assurance activity[a]	44
Performing second reading of mammograms within facility	29
Following up on patient biopsies	76

[a]Other activities include second reading of mammogram within facility, peer review of readings, and follow-up on patient biopsies.

Fewer Providers Have Annual Inspection of Selected Features

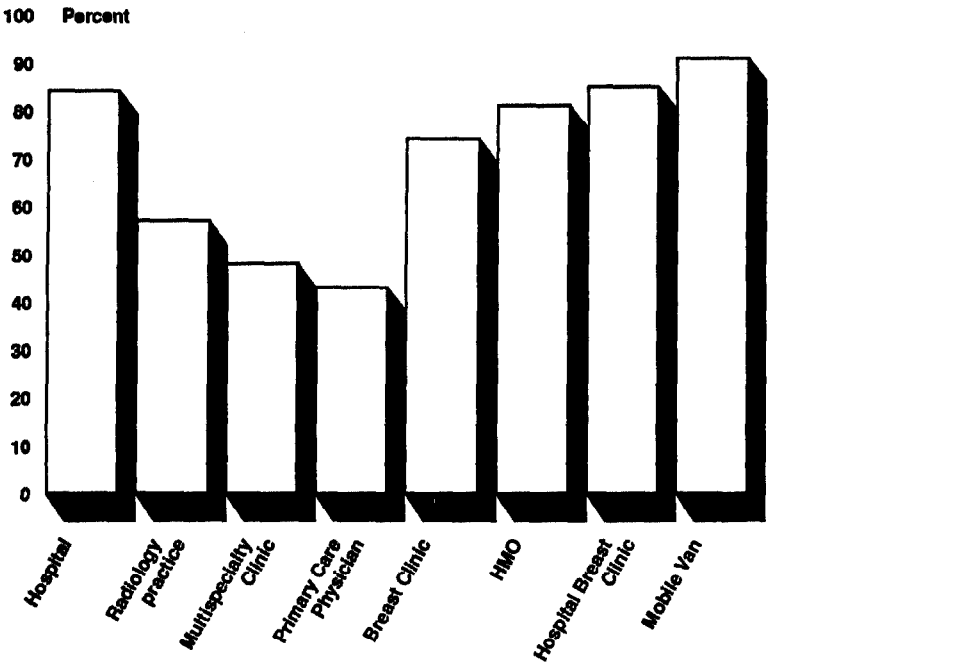
Three items that a radiological physicist should inspect annually are: (1) beam quality,[8] (2) average glandular dose,[9] and (3) phantom image quality. (Beam quality is related to both image quality and dose.[10]) About 55 percent of our respondents reported annual inspection of these three

[8]Beam quality is measured in terms of half value layer (HVL), which is the amount of filtration necessary to reduce the intensity of the beam to half of the original value.

[9]The measurement of radiation absorbed by the breast that best characterizes radiation risk from mammography, according to the NCRP.

[10]If the energy of the beam is too low, the radiation dose will be excessive; if too high, the contrast will be too low, resulting in poor image quality.

Figure 3.1: Annual Inspection Performed by Radiological Physicist, by Setting



Note: Total 1,026 respondents.

factors by a radiological physicist. As with overall inspection by a radiological physicist, primary care physicians and multispecialty clinics reported the lowest rates of compliance. Hospital breast clinics showed the highest rate of compliance (see fig. 3.2). There was considerable variation across states.[11] Table V.6 presents more detailed information.

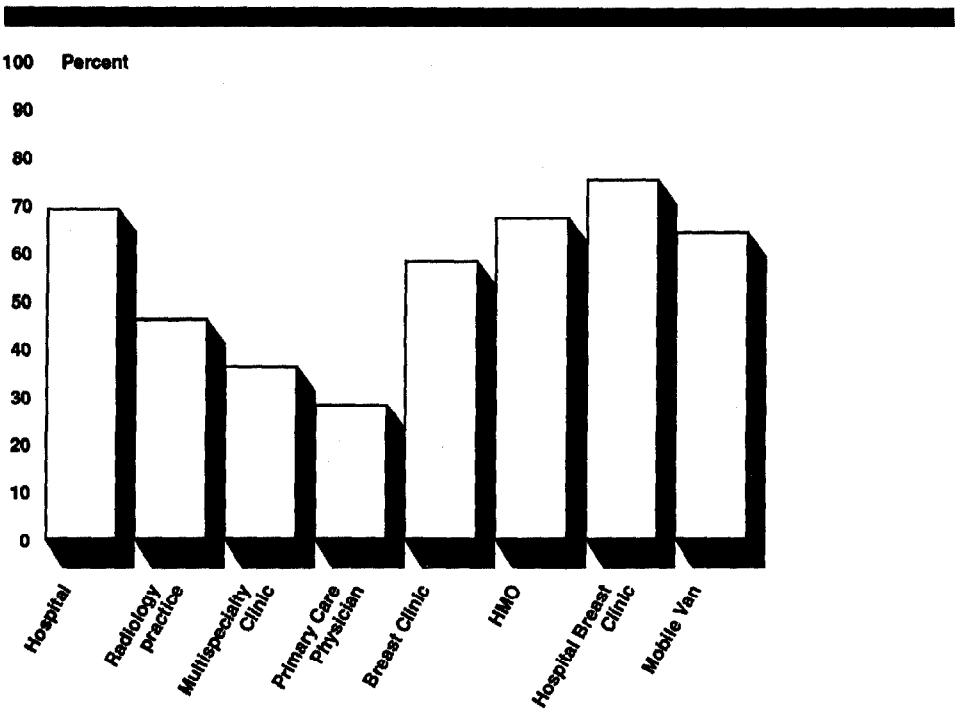
Daily Processor Sensitometry Advised

Some quality control procedures should be performed regularly by the screening mammography staff. There is a growing consensus that facilities doing screen-film mammography[12] need to do daily sensitometry of the film processor, a procedure that checks whether the processor that develops the film is operating properly. Of respondents using the screen-

[11]Percentages by state were: California, 59; Florida, 46; Idaho, 21; and Michigan, 59.

[12]The two principal techniques for performing mammography are the screen-film and xeroradiography methods. Of the facilities responding to our survey, 84 percent used only the screen-film method, 11 percent used xeroradiography, and 6 percent used both.

Figure 3.2: Annual Inspection of Selected Features by Radiological Physicist, by Setting



Note: These selected features include beam quality (HVL), average glandular dose, and phantom image quality. Total 1,026 respondents.

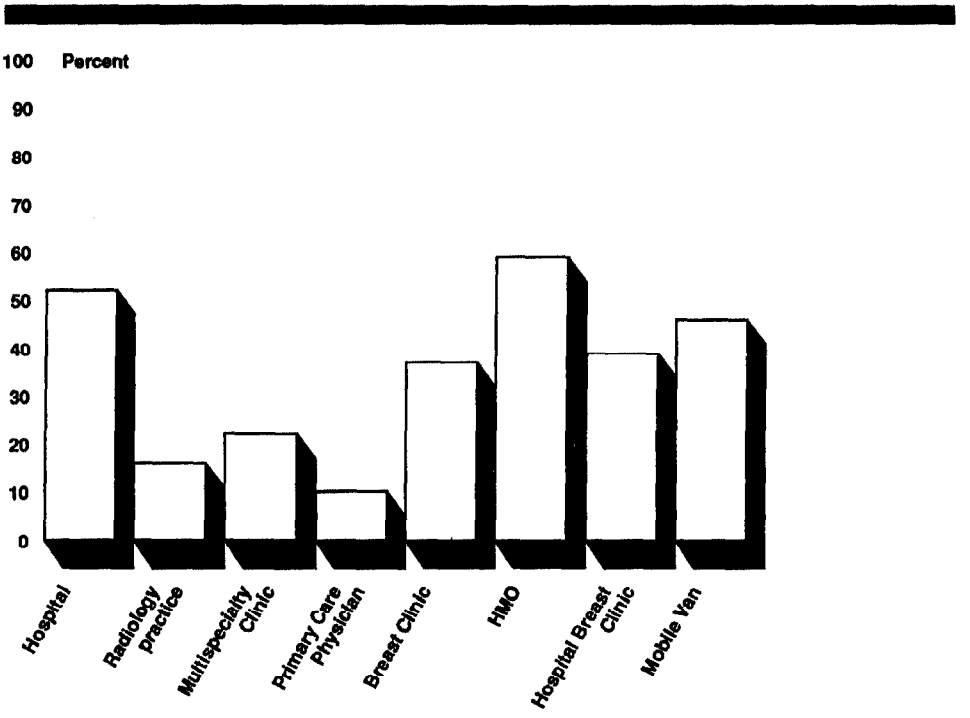
film method, 35 percent[13] reported doing daily processor sensitometry; an additional 17 percent did it at least weekly. By setting, there was wide variation in compliance with the daily sensitometry standard, ranging from 10 percent of primary care physicians to 59 percent of HMOs, as shown in figure 3.3.

Semiannual Phantom Image Checks Done by Half of Respondents

Although evaluating a phantom image is one component of the physicist's inspection, this procedure also may be done by trained personnel at the facility. As discussed on page 24, exposing a phantom shows the quality of image the system is producing and can indicate the existence of specific problems. Recommendations for frequency of this practice vary. Overall, 46 percent of the facilities responding to our survey reported doing a phantom image check at least every 6 months. By setting, the percentages ranged from 28 at primary care physicians to 70 at

[13]Percentages by state were: California, 40; Florida, 33; Idaho, 37; and Michigan, 25.

Figure 3.3: Daily Processor Sensitometry, by Setting



Note: Only repondents who perform screen-film mammography have been included in this analysis. Total 910 respondents.

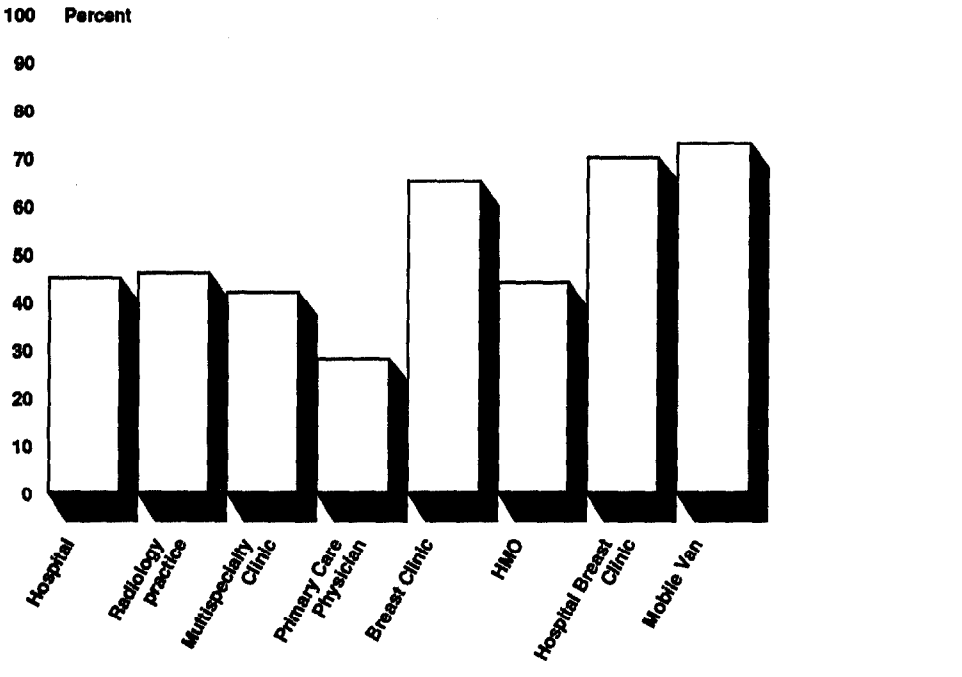
hospital breast clinics and 73 at mobile vans, as shown in figure 3.4. We also analyzed the extent to which facilities that did not report annual inspection by a radiological physicist performed semiannual phantom image tests. Although the need for such tests is probably greater at those facilities, the proportion performing them (30 percent) was smaller than for all facilities (46 percent).

Selected Quality Assurance Activities Analyzed

Significant findings on compliance with several other quality assurance activities emerged from our survey:

- Monitoring repeat mammograms. Monitoring the number of repeat mammograms and analyzing the reasons the original images had to be discarded provides information about possible problems with either the equipment or the work of the technologist, such as improper positioning.

Figure 3.4: Semiannual Phantom Image Checks, by Setting



Note: Total 1,026 respondents.

Just over half of our respondents (52 percent) reported doing such monitoring, ranging from 44 percent at primary care physicians to 67 percent at HMOs.

- Performing a second reading of mammograms within the facility. This provides a check on the radiologist's interpretation. About 29 percent of respondents reported doing second readings; responses varied by state.[14]
- Submitting mammograms to peer review panels for second readings. This practice provides feedback on the entire mammography process, both production and interpretation of the image. Eleven percent of respondents said they submit images for peer review.
- Following up on patient biopsies. This also provides feedback on the entire mammography process and was the most common quality assurance activity reported by respondents. Three-fourths indicated adhering to this standard. (See table V.7 for additional data on selected quality assurance activities by setting.)

[14]Percentages by state were: California, 34; Florida, 32; Idaho, 10; and Michigan, 21.

We analyzed the proportion of facilities that monitored repeat mammograms and did at least one of the other quality assurance activities discussed above. About 44 percent of respondents did this, ranging from 35 percent of primary care physicians to 64 percent of HMOs, as shown in figure 3.5.

High-Volume Providers More Often Adhere to Quality Standards

A strong relationship existed between the volume of mammography performed and the rate of compliance with many quality standards. Examples of quality practices where the facilities with the lowest rate of compliance were in the lowest volume range and those with the highest rate of compliance were in the highest volume range appear in table 3.2.

This association between high volume and adherence to quality standards is significant, because, as discussed on page 22, high volume is a critical factor in reducing the price of screening mammography. A recent report in the Journal of the Florida Medical Association[15] noted that not only is high volume necessary to lower costs, but it also contributes to quality by giving radiologists sufficient work to increase the proficiency of their interpretations.

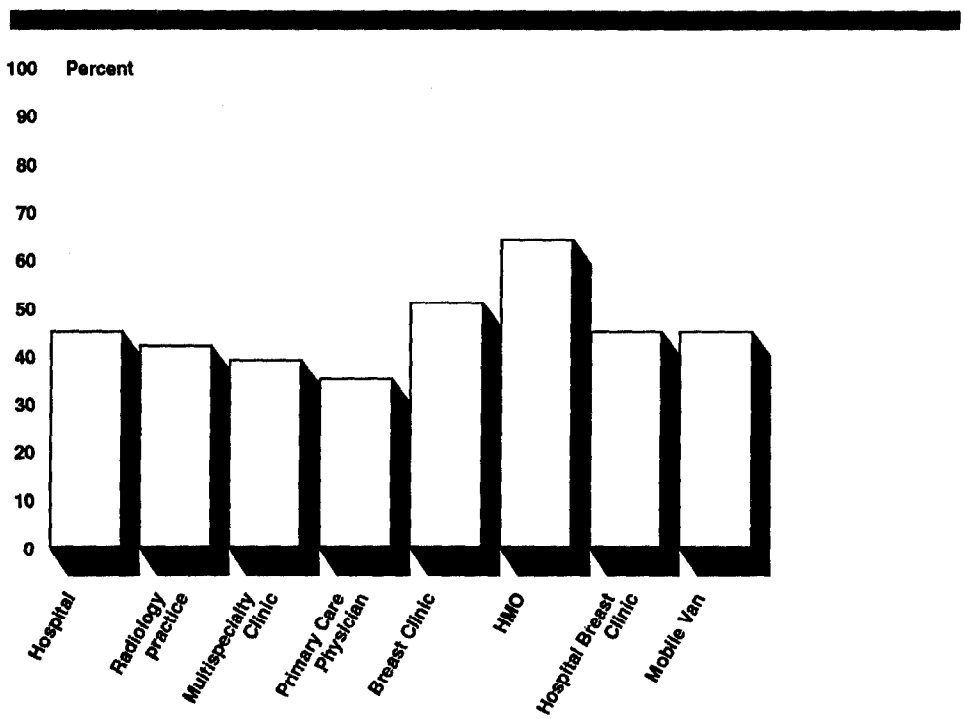
Compliance With Quality Standards Not Related to Charge

For several quality standards, we found no direct relationship between the charge for screening mammography and the degree of compliance with professional standards. For other standards, there was a relationship, but its direction was not consistent. That is, in some cases providers charging the lowest fees had the highest rate of compliance with a quality standard, while in other cases those with the highest fees had the highest rate of compliance.

For example, 44 percent of respondents charging over $150 reported doing semiannual phantom image checks, while 56 percent of those charging $50 or less said they did so. Similarly, 27 percent of the facilities charging $50 or less reported following the practice of both sending positive mammogram reports to the patient and/or physician and then reminding the patient to contact her physician. This proportion was at least twice as high as any other charge category. However, the charge category with the highest proportion of facilities inspected annually by a radiological physicist was those charging over $150 (79 percent). For

[15]Robert A Clark, M.D., et al., "Screening Mammography in the Tampa Bay Area: Current Status and Implications for the Next Decade," Journal of the Florida Medical Association, May 1989, pp. 449-453.

Figure 3.5: Selected Quality Assurance Activities, by Setting



Note: Activities are monitoring rate of repeat mammograms plus at least one of the following: (1) second reading of mammograms within facility, (2) peer review of interpretation, and (3) follow-up of patient biopsies. Total 1,026 respondents.

daily processor sensitometry, the highest rates were in the lowest (45 percent) and highest (44 percent) charge ranges.

Table 3.2: Relationship Between Volume and Providers' Compliance With Quality Standards

Quality standard[a]	Percent of respondents reporting compliance: Low-volume providers (<25/week)	High-volume providers (>100/week)
Annual inspection by radiological physicist	58	87
Annual physicist inspection of beam quality, average glandular dose, and phantom image quality	44	74
Daily processor sensitometry	24	50
Semiannual phantom image check by facility	33	73
Monitoring repeat mammograms and doing one other quality assurance activity[b]	40	60
Performing second reading of mammogram within facility	25	45
Following up on patient biopsies	70	89
Instructing patients on breast self-examination	84	97

[a]We did not include in this table the standards shown in table 3.1 with which almost all respondents reported complying.

[b]Other activities include second reading of mammogram within facility, peer review of readings, and follow-up on patient biopsies.

Our site visits also tended to dispel the concern that quality would be compromised at facilities charging lower fees for screening mammography. We visited three facilities that reported complying with many quality standards and that charged $50 or less for screening mammograms. All reported volume levels of at least 200 mammograms per week. One used a significant amount of volunteer labor to lower operating costs, but the other two did not. The quality standards and recommended practices present at these facilities include

- trained, experienced radiologists and certified radiologic technologists;
- inspection by a radiological physicist at least annually;
- daily processor sensitometry;
- phantom image checks at least semiannually;
- monitoring of repeat mammograms and following patients with abnormal findings;
- proper record retention and reporting practices; and
- extensive instruction on breast self-examination.

Federal and State Regulation of Screening Mammography Is Limited

Currently, both the Food and Drug Administration and the states have responsibility for regulating mammography equipment and services. FDA's role is to ensure the proper manufacture and installation of equipment, so it has no standards for mammographic image quality or patient radiation dose. Of the states we reviewed, only Michigan has a law requiring the use of dedicated mammography equipment and the setting of image quality and radiation dose standards. The lack of such standards in the other three states limits their ability to regulate screening mammography services. Even with limited oversight of mammography, both FDA and state inspections have found noncompliance with performance standards.

The limited scope of FDA and state regulation and the problems found by inspectors underscore the importance of the quality standards that Congress required the Secretary of HHS to issue for Medicare-funded screening mammography. On September 1, 1989, HHS published proposed regulations that closely parallel the professional quality standards we discussed in chapter 3. However, HHS plans to withdraw the regulations due to the repeal of the Medicare Catastrophic Coverage Act of 1988.

State Oversight of Mammography

State regulation of mammography equipment in the four states we visited is limited. Only Michigan requires use of dedicated equipment and has established standards for image quality and radiation dose. Idaho does not regulate operators of mammography equipment, and the other three states we visited vary in the qualifications required for persons interpreting mammograms. State inspections have found image quality problems at mammography providers, but narrow legal authority often limits state enforcement efforts.

Regulation of Mammography Equipment and Personnel Limited

In three of the four states we reviewed, state regulation applies to use of all X-ray equipment, and emphasizes protecting the equipment operator and bystanders. These states have no separate standards for mammography services. In June 1989, Michigan enacted legislation adopting ACR standards for mammographic image quality and radiation dose, becoming the only one of the states we reviewed to require the use of equipment specifically designed for mammography.

Each of the states we reviewed has an office responsible for the oversight of all types of X-ray equipment. The states require registration of X-ray equipment at the time of installation, as well as periodic reregistration.

The competence of the person operating the mammography equipment is critical to producing a useful image. Both California and Florida have requirements for and license operators of X-ray equipment, including mammography equipment. Idaho neither licenses the people who take mammograms nor sets minimum qualifications they must meet. The legislation enacted by Michigan in June 1989 requires state regulators to set standards for mammography operators. (For additional information on licensing requirements in these states, see app. IV.)

The four states also differ in their regulation of persons who interpret mammograms, another critical component of the screening process. Michigan has no law governing who may interpret mammograms. According to state officials, Florida and Idaho permit any licensed physician to interpret mammograms. California requires interpreters to have a state license in the healing arts.

Frequency and Content of Inspections Vary

Each state we visited has an inspection program for all X-ray equipment, including mammography machines. The programs vary with regard to frequency of inspection, staffing, and contents of the inspections, although some equipment features are examined in all four states.

The criteria of the Conference of Radiation Control Program Directors call for state inspections of new facilities within the first year of operation. In Florida and Idaho, newly registered equipment is inspected within 1 year, and Michigan will begin inspecting new equipment within 60 days. Subsequent periodic inspections occur annually in Florida and every 3 years in California. Michigan's new law will increase subsequent inspections there from every 3 years to at least annually.

Idaho bases inspection priorities on the setting in which the X-ray equipment is used. After the initial inspection during the first year, the schedule calls for inspection of mammography equipment in hospitals once every year and in physicians' offices once every 2 to 3 years. Hospitals are given priority, state officials told us, because most X-ray examinations are performed in that setting. Because of a staffing shortage, however, Idaho is not completely adhering to this inspection schedule. Of Idaho's three state inspector positions, two have been vacant for over 1 year. Consequently, equipment in hospitals is being checked about once every 2 years and in physicians' offices, about once every 3 years.

The inspection procedures of the four states include a number of common elements. For example, all measure the beam quality (HVL) and

average glandular dose. California, Idaho, and Michigan use a phantom (see footnote 1, p. 24) to inspect image quality, and Florida plans to begin this procedure in early 1990. Both California and Michigan use the phantom ACR uses in its accreditation program. Except for Michigan, the states lack legally binding standards regarding use of dedicated mammography equipment, limitations on the radiation dose received by patients, and minimum image quality. Although California uses the same phantom to evaluate image quality that ACR uses in its accreditation program, it does not have image quality standards.

Florida and Michigan focus on whether the facility is using equipment specifically designed for mammography. Until recently, neither state prohibited the use of nondedicated equipment, although both encouraged facilities to use only dedicated equipment. As a result of Michigan's efforts, the number of facilities using general purpose machines for screen-film mammography dropped from 25 to 3 between May 1987 and November 1988. Now, as indicated earlier, Michigan law requires use of dedicated equipment. (For additional information on inspection personnel, see app. IV.)

State Inspections Find Problems

Of the states we visited, only Michigan had analyzed inspection data on mammographic image quality and radiation exposure, basing its evaluations on ACR standards. Between January and November 1988, Michigan inspected 95 mammography machines, over 20 percent of those in the state. As shown in table 4.1, 35 percent of the 95 machines produced poor image quality and 11 percent registered excessive radiation dose.

To determine if there were differences in adherence to certain quality standards in different settings, the Michigan inspection program categorized the inspection data by facility type. Mammography machines located in medical offices were more than twice as likely to produce poor image quality than machines located in hospitals and had more problems than those located in radiology offices.

Table 4.1: Michigan Mammography Equipment With Image Quality and/or Radiation Problems, by Facility Type (Jan.-Nov. 1988)

Equipment problem	Percent experiencing problem			
		By facility[a]		
	All equipment inspected	Hospital	Radiology office	Medical office
Poor image quality	35	23	36	57
High radiation exposure	11	9	10	14

[a]Michigan's principal facility categories are hospital, radiology office, and medical office. A clinic could be included as either a radiology or medical office.

In compiling data on compliance with state law and regulations concerning mammography (see table 4.2), Florida officials did not distinguish between minor and serious violations, even though some of the types of noncompliance cited could affect patient dose. California and Idaho officials were unable to provide summary data from their inspections.

Table 4.2: Florida Mammography Equipment Not in Compliance (Fiscal Year 1988)

Facility	No. of inspections	Percent of noncompliance
Hospital	173	9
Medical doctor[a]	216	11
Osteopath	3	0
Mobile lab	15	0

[a]This category includes both physicians and clinics.

Absence of Legal Authority Hinders Enforcement Efforts

Officials from all four states told us that when they find violations of state standards, facilities usually respond readily to efforts to bring about compliance. Steps such as court action are rarely necessary. However, because there are few state regulations pertaining to mammography, state officials have limited authority to require providers to correct problems. When there is no legal requirement in effect, such as for use of dedicated equipment or limiting radiation dose to the patient, state officials must depend on persuasion to correct the problem. Officials told us they are often successful in these compliance efforts, even without the force of law. However, if a provider chooses not to comply with a recommendation, state radiation control officials have no authority to apply sanctions.

The problems this situation can create are illustrated by our site visit to a California mobile van. A June 1988 inspection report by Los Angeles County noted several deficiencies, including unacceptable temperature of the developing solution in the film processor and poor phantom image

quality. No follow-up actions occurred, and since there is no legal standard for image quality, the state could not require the facility to upgrade its technique. The facility has to repeat 10 percent of its mammograms, a facility official told us; this rate is five times that considered acceptable by the Conference of Radiation Control Program Directors. (See pp. 30-31 for a discussion of the quality assurance purpose of monitoring repeat mammograms.)

FDA Regulates Manufacture, Assembly of Mammography Equipment

FDA regulates the manufacture and initial assembly of mammography equipment. Its standards, which govern all types of X-ray machines, not just mammography equipment, apply to manufacture and installation. Although FDA inspects only a small percentage of mammography equipment, it has found noncompliance with its standards.

FDA's Performance Standards Apply to Manufacturer, Not User

FDA's role is to ensure that diagnostic X-ray equipment (including mammography equipment) is correctly manufactured and installed. Consequently, its standards apply only to the manufacturer and assembler of the equipment, not to the user, such as the mammography provider.

FDA performance standards cover such factors as equipment alignment and measurement of radiation leakage. There is no standard for the radiation dose received by the patient, as FDA considers that to be a practice of medicine issue not within its purview. FDA evaluates compliance with the standards during inspections of newly installed radiographic equipment.

Relatively Few Inspections Performed

Partially through contracts with 34 state radiological health agencies, including those of California and Florida, FDA arranges for field testing of newly installed diagnostic X-ray equipment. In states without contracts, FDA staff do the inspections. Inspectors test to determine whether the equipment complies with FDA's performance standards, focusing on equipment installed within the past 12 months. Only within this time frame does FDA take regulatory action, and few inspections occur beyond the first year.

States decide which X-ray facilities to inspect, with some guidance from FDA as to the percentages of each type of equipment to check. The FDA

goal is to inspect up to 30 percent of new X-ray equipment within 1 year of installation, but the proportion of mammography machines inspected in the four states we visited was much lower (see table 4.3). This is because FDA gives priority to general purpose equipment, the type most frequently used.

Table 4.3: FDA Inspections of Newly Installed Mammography Equipment in Four States (1986-1988)

	1986			1987			1988		
	Installed	Inspected		Installed	Inspected		Installed	Inspected	
State	(no.)	No.	Percent	(no.)	No.	Percent	(no.)	No.	Percent
California	207	11	5	193	16	8	79	35	44
Florida	100	12	12	113	4	4	41	8	20
Idaho	5	0	0	7	0	0	6	0	0
Michigan	84	5	6	88	0	0	33	0	0

Substantial Noncompliance With Standards Found

FDA's inspections in the four states we visited have found a substantial amount of noncompliance with its performance standards (see table 4.4). If noncompliance is found within 1 year of equipment installation, FDA assumes it is due to improper installation. The assembler is responsible for correcting the problem unless obvious misuse is apparent. FDA sends a notice of noncompliance to the assembler instructing repair within 30 days. The assembler must then notify the FDA district office when the problem has been corrected.

Table 4.4: Noncompliances Identified by FDA in Four States (1982-1989)

State	No. of inspections[a]	No. of noncompliances	Percent of noncompliances
California	86	9	10
Florida	35	8	23
Idaho	1	1	100
Michigan	8	1	13

[a]Between Jan. 1982 and Feb. 1989.

Problems with image receptor alignment are the most frequent type of noncompliance found. If the beam and image receptor are not properly aligned, part of the body that should not be exposed to radiation is exposed, and part that should be included in the image is not.

HHS Proposed Standards for Screening Mammography

The 1988 Medicare Act required the Secretary of HHS to develop regulations to ensure that screening mammography reimbursed by Medicare would meet safety and accuracy standards. The law specifically called for requirements on equipment, personnel, and film retention. On September 1, 1989, HHS published its proposed regulations. These included standards closely paralleling those developed by professional organizations, such as ACR. Such standards, along with an adequate enforcement mechanism, would help to assure the provision of high quality screening mammography. However, since the Medicare Catastrophic Coverage Act of 1988 was repealed, HHS plans to withdraw its proposed regulations.

Conclusions

Breast cancer is increasing in American women, and mammography is the best method of detecting breast cancer at its earliest, most curable stage. Symptom-free women who follow recommended guidelines for periodic screening mammography can lower their risk of dying from breast cancer by 30 percent. Despite broad agreement in the medical community on the importance of regular screening, relatively few women participate in screening mammography programs.

A Medicare screening benefit such as that provided in the Medicare Catastrophic Coverage Act of 1988 would make millions of high-risk women eligible for low-cost screening mammography. However, some members of Congress were concerned that the act's $50 limit on what providers could charge might reduce the availability of high-quality services.

We found facilities that charged $50 for screening mammography and reported complying with quality standards. Providers can better do so if they distinguish between screening and diagnostic mammography and operate high-volume screening practices. This enables them to use such procedures as batch reading of films and make more efficient use of equipment to lower the cost of providing screening services. The Physician Payment Review Commission, which found that providers that make a distinction between screening and diagnostic services charge less for screening, concluded that $50 is an appropriate charge if volume is sufficiently high.

High volume also was associated with high quality in our survey. The facilities that reported the highest rates of compliance with many quality standards were those providing the highest volume of mammography services. However, we found no consistent relationship between charge and compliance with quality standards.

Quality standards are not always adhered to in current mammography practice, our survey and other studies have found. Oversight of mammography services by the states and FDA is limited. Of particular concern, there is little regulation of mammographic image quality and the radiation dose patients may receive.

In conclusion, Medicare coverage for screening mammography would bring a valuable life-saving tool to a large population of women at risk of developing breast cancer. The evidence we found suggests that limiting charges to $50 should not jeopardize the quality of care available to Medicare beneficiaries. To the contrary, the charge limit would

encourage provision of screening mammography in high-volume settings, which we found were most likely to comply with quality standards. By reinforcing the trend to high-volume settings, which can best provide high quality at lower prices, such a charge limit also could increase the accessibility of screening mammography for younger women eligible for screening.

At the same time, we found a need for strong federal standards to assure the quality of screening mammography. Although there are professional standards for acceptable image quality and radiation dose, there have been few legal mechanisms to enforce them. The result is a wide range of image quality and patient dose in current mammography practice. The regulations that were proposed by HHS would have helped to fill this regulatory gap.

GAO's Survey Methodology

In January 1989, we mailed a questionnaire to all facilities identified by state radiological health departments in California, Florida, Idaho, and Michigan as having mammography equipment. We assumed that these facilities were currently in business in the respective states. This appendix contains a technical description of our questionnaire design, pretest procedures, and response rate.

The questionnaire was designed to obtain information concerning the practices and procedures of facilities performing screening mammography. It was reviewed by officials from the National Cancer Institute and American College of Radiology.

Questionnaire Pretested in Two Areas

Before distributing the questionnaire, we pretested it in person with officials at nine facilities in the Washington, D.C., metropolitan area and two facilities in Providence, Rhode Island. These facilities represented the types of settings likely to be found among the facilities to be surveyed. Pretesting the questionnaire assured us that the questions were generally understandable and free of confusion and error. During the pretest, the officials completed the questionnaire as if they had received it in the mail. Our staff noted the time it took to complete each question and any difficulties the respondents experienced. Once the questionnaire was completed, we used a standardized approach to elicit descriptions of difficulties and issues encountered with each item.

Using the pretest results, we revised the questionnaires to ensure that (1) the potential respondents could and would provide the information requested and (2) all questions were fair, relevant, easy to answer, and relatively free of design flaws that could introduce bias or error into the study results. In addition, we tested the questionnaire to ensure that the task of completing it would not place too great a burden on the respondent.

Adjusted Response Rate at 82 Percent

Of a total of 1,485 questionnaires mailed to facilities in four states, 1,242 were returned. We adjusted our universe to 1,369 to exclude questionnaires that (1) were mailed to facilities no longer in operation, (2) were duplicates,[1] or (3) were returned as nondeliverable.[2] This resulted

[1]The list the state provided indicated a different address or contact person, but the recipients informed us the facilities were identical.

[2]After making several unsuccessful attempts to contact these facilities by telephone and mail, we assumed they were not currently in business.

in an overall response rate of 82 percent. The initial and adjusted universe and the number of responses are shown by state in table I.1.

Table I.1: Response to GAO Questionnaire, by State

State	Initial universe of facilities	No longer in operation, undeliverable questionnaires	Duplicate facilities	Adjusted universe	No. of usable responses
California	757	10	70	677	553
Florida	313	6	9	298	239
Idaho	35	0	1	34	30
Michigan	380	3	17	360	304
Totals	**1,485**	**19**	**97**	**1,369**	**1,126**

GAO Questionnaire on Mammography

United States General Accounting Office
Screening Mammography Survey

The United States General Accounting Office (GAO), an agency of the U.S. Congress, is conducting a survey of facilities identified by state offices of radiologic health or radiation control as having equipment used to perform mammography. The purpose of this questionnaire is to obtain information about mammography conducted on asymptomatic patients. In this questionnaire, we refer to such mammography as screening mammography.

This questionnaire should take about 20 minutes to complete. Your responses will be kept confidential. We will report your responses only in summary with those of other facilities that respond to this questionnaire. Your responses will not be made known to anyone outside of the GAO.

This questionnaire should be completed by the person(s) most familiar with your facility's screening mammography practices. Before you begin, because of the variety of information requested, you may want to briefly review the questionnaire to determine the necessary sources of information you will need and whom you may want to consult.

In the event you receive more than one questionnaire, please complete only one questionnaire for each facility where mammography is performed, mark the additional questionnaire(s) "duplicate", and return all questionnaires in the same business reply envelope provided. It is possible that your state records both individual ownership as well as facility location. Therefore, since we sent a questionnaire to each address provided, we may have included in our survey the owner of the equipment as well as the facility. In order for us to report accurate information to the Congress, it is very important that all questionnaires be returned.

LABEL

Please provide the name, title, and telephone number of the primary person we may contact if additional information is required concerning your responses.

Name of Primary Contact Person: _____

Official Title: _____

Telephone Number: ( )_____

Please return the questionnaire in the enclosed business reply envelope, or if the envelope is misplaced, send it to the address shown on the back of the questionnaire. If you have any questions, please call Helene Toiv at (202) 426-0842 (or 426-0800).

BACKGROUND

1. Is mammography performed at your facility? (CHECK ONE.)

   a. ( ) Yes

   b. ( ) No —>**(Stop! PLEASE RETURN THIS QUESTIONNAIRE. IT IS IMPORTANT THAT YOU RETURN THIS QUESTIONNAIRE.)**

2. Does your facility provide mammography to -- (a) asymptomatic patients (referred to **as screening mammography**), (b) symptomatic patients (referred to as **diagnostic mammography**), or (c) both asymptomatic and symptomatic patients? (CHECK ONE.)

   a. ( ) Screening mammography only —>**(SKIP TO QUESTION 5.)**

   b. ( ) Diagnostic mammography only

   c. ( ) Both diagnostic and screening mammography —>**(SKIP TO QUESTION 5.)**

3. Using the categories provided below, please indicate the **one** kind of setting where the **majority** of your diagnostic mammograms are performed. (CHECK ONE.)

   a. ( ) Primary care physician's office (e.g., gynecologist, internist, surgeon)

   b. ( ) Radiology private practice

   c. ( ) Hospital -- Radiology Department

   d. ( ) Hospital -- Outpatient clinic/ Ambulatory Care Center

   e. ( ) Breast Center/ Clinic (i.e., freestanding facility for screening and/or treatment of breast disease)

   f. ( ) Health Maintenance Organization (HMO)

   g. ( ) Multispecialty clinic (e.g., multispecialty group practice, outpatient clinic)

   h. ( ) Mobile van -- Affiliated with a hospital, clinic, or physician's practice

   i. ( ) Mobile van -- Not affiliated with a hospital, clinic, or physician's practice

   j. ( ) Other (PLEASE SPECIFY) _____

4. How would you describe the physical location of your facility? (CHECK ONE.)

a. ( ) Urban
b. ( ) Suburban ——>(GO TO QUESTION 46.)
c. ( ) Rural

5. Using the categories provided below, please indicate the **one** kind of setting where the majority of your screening mammograms are performed. (CHECK ONE.)

a. ( ) Primary care physician's office (e.g., gynecologist, internist, surgeon)

b. ( ) Radiology private practice

c. ( ) Hospital -- Radiology Department

d. ( ) Hospital -- Outpatient clinic/ Ambulatory Care Center

e. ( ) Hospital -- Breast Screening clinic (i.e., screening clinic located in hospital, but for outpatients only)

f. ( ) Breast Center/ Clinic (i.e., freestanding facility for screening and/or treatment of breast disease)

g. ( ) Health Maintenance Organization (HMO)

h. ( ) Multispecialty clinic (e.g., multispecialty group practice, outpatient clinic)

i. ( ) Mobile van -- Affiliated with a hospital, clinic, or physician's practice

j. ( ) Mobile van -- Not affiliated with a hospital, clinic, or physician's practice

k. ( ) Other (PLEASE SPECIFY) _____

THE RESPONSES YOU GIVE FOR THE FOLLOWING QUESTIONS SHOULD BE BASED ON THE ONE SETTING YOU IDENTIFIED IN QUESTION 5.

6. How would you describe the physical location of your facility? (CHECK ONE.)

   a. ( ) Urban

   b. ( ) Suburban

   c. ( ) Rural

7. Approximately during what month and year did your facility begin providing screening mammography services?

   |__||__| 19 |__|__|
   (Month) (Year)

8. During a normal week for each day listed below, indicate the total number of hours your facility provides screening mammography.

   Total Number of Hours Screening Mammography Is Provided

   a. Monday _____ Hours

   b. Tuesday _____ Hours

   c. Wednesday _____ Hours

   d. Thursday _____ Hours

   e. Friday _____ Hours

9. During a normal week, does your facility provide screening mammography after 6:00 p.m.? (CHECK ONE.)

   a. ( ) Yes

   b. ( ) No —>**(SKIP TO QUESTION 11.)**

10. Approximately how many **evening hours (after 6:00 p.m.)** during a normal week does your facility provide screening mammography?

    _____ Total **evening** hours screening mammography provided

<< Answer only with respect to the one setting you identified in question 5 >>

11. Check below when, if at all, your facility is open to provide screening mammography during the weekend. (Saturday and/or Sunday) (CHECK ONE.)

a. ( ) Every weekend

b. ( ) 3 weekends a month

c. ( ) 2 weekends a month

d. ( ) 1 weekend a month

e. ( ) Not open during the weekend

12. During a normal week, how many diagnostic and/or screening mammograms does your facility perform?

a. _____ Number of **diagnostic** mammograms

b. _____ Number of **screening** mammograms

13. Listed below are various pieces of information which might be collected from a patient as part of the screening mammography process. Indicate the information you **usually** collect. (CHECK ALL THAT APPLY.)

a. ( ) Demographic data (e.g., age, marital status, ethnic background)

b. ( ) Current breast symptoms (e.g., breast tenderness, pain, lump, or nipple discharge)

c. ( ) Previous mammography information (e.g., date, where performed)

d. ( ) Surgical history -- breast surgery

e. ( ) Family history of breast cancer

f. ( ) Current medication history (e.g., hormone)

g. ( ) Other (PLEASE SPECIFY) _____

h. ( ) Do not collect information

<< **Answer only with respect to the one setting you identified in question 5** >>

14. At the time a screening mammogram is performed at your facility, is a breast physical examination (palpation) **routinely** conducted? (CHECK ONE.)

    a. ( ) Yes

    b. ( ) No —>**(SKIP TO QUESTION 17.)**

15. When a breast physical examination is performed at your facility, who usually does the examination? (CHECK ONE.)

    a. ( ) Radiologist (who interprets the films)

    b. ( ) Radiologist (not necessarily interpreter)

    c. ( ) Other physician

    d. ( ) Technologist who performs the mammogram

    e. ( ) Nurse

    f. ( ) Other (PLEASE SPECIFY) _____

16. Does your facility charge a separate fee for the breast physical examination? (CHECK ONE.)

    a. ( ) Yes ——> Please indicate **fee** charged $ _____

    b. ( ) No

<< **Answer only with respect to the one setting you identified in question 5** >>

17. Indicate what mechanism(s) is used by your facility to inform the patient about breast self-examination. (CHECK ALL THAT APPLY.)

    a. ( ) Video

    b. ( ) Pamphlet

    c. ( ) Staff person instructs the patient

    d. ( ) Other (PLEASE SPECIFY) _____

    e. ( ) No information provided

MAMMOGRAPHY

18. For screening mammography, indicate if your facility performs screening mammograms using (a) dedicated mammography equipment (i.e., equipment manufactured for the sole purpose of mammography **or** general radiographic equipment that is modified for mammography only and cannot be used for general radiographic purposes), (b) general purpose radiographic equipment, or (c) both dedicated mammography and general purpose radiographic equipment? (CHECK ONE.)

    a. ( ) **Dedicated** mammography equipment only (i.e., equipment manufactured or modified for mammography only)

    b. ( ) **General purpose** radiographic equipment

    c. ( ) **Both** dedicated mammography and general purpose radiographic equipment

19. Indicate the type of screening mammography your facility uses. (CHECK ONE.)

    a. ( ) Screen-film mammography

    b. ( ) Xeromammography

    c. ( ) Both screen-film and xeromammography

<< **Answer only with respect to the one setting you identified in question 5** >>

20. Which views does your facility usually do for a screening bilateral mammogram? (CHECK ALL THAT APPLY.)

a. ( ) Cranio-caudal or Cephalo-caudal (1 view per breast)

b. ( ) True Lateral (1 view per breast)

c. ( ) Oblique--Mediolateral (1 view per breast)

d. ( ) Other (PLEASE SPECIFY) _____

21. Listed below are various categories representing individuals who might perform screening mammography. Indicate the **one** category which represents the individual at your facility who usually **performs** the screening mammograms. (CHECK ONE.)

a. ( ) ARRT registered radiologic technologist

b. ( ) State licensed radiologic technologist

c. ( ) Radiologic technician

d. ( ) Nurse

e. ( ) Radiologist

f. ( ) Technician trained to perform mammography

g. ( ) Other (PLEASE SPECIFY) _____

22. Does any **other** individual(s) perform screening mammograms at your facility? (CHECK ONE.)

a. ( ) Yes

b. ( ) No —>**(SKIP TO QUESTION 24.)**

<< **Answer only with respect to the one setting you identified in question 5** >>

23. Indicate each category which represents the other individual(s) who **performs** screening mammograms at your facility. (CHECK ALL THAT APPLY.)

a. ( ) ARRT registered radiologic technologist

b. ( ) State licensed radiologic technologist

c. ( ) Radiologic technician

d. ( ) Nurse

e. ( ) Radiologist

f. ( ) Technician trained to perform mammography

g. ( ) Other (PLEASE SPECIFY) _____

24. Listed below are categories representing individuals who might interpret screening mammograms. Indicate the category which represents the individual at your facility who usually does the **final interpretation** of the screening mammograms. (CHECK ONE.)

a. ( ) Radiologist

b. ( ) Other physician

c. ( ) Nurse

d. ( ) Technologist

e. ( ) Other (PLEASE SPECIFY) _____

25. Is the final interpretation of the screening mammogram done by any **other** individual(s)? (CHECK ONE.)

a. ( ) Yes

b. ( ) No **—>(SKIP TO QUESTION 27.)**

<< **Answer only with respect to the one setting you identified in question 5** >>

26. Indicate each category which represents the other individual(s) who **interprets** screening mammograms at your facility. (CHECK ALL THAT APPLY.)

a. ( ) Radiologist

b. ( ) Other physician

c. ( ) Nurse

d. ( ) Technologist

e. ( ) Other (PLEASE SPECIFY) _____

27. Does your facility accept self-referred patients? (CHECK ONE.)

a. ( ) No —>**(SKIP TO QUESTION 31.)**

b. ( ) Yes, but the patient must provide the name of her personal physician or select a physician from a list provided by the facility —>**(SKIP TO QUESTION 31.)**

c. ( ) Yes, even if the patient does not designate a personal physician

28. If a patient has a **negative** mammogram **and** has not designated a personal physician, what is usually done with the mammogram report? (CHECK ONE.)

a. ( ) Report sent to the patient

b. ( ) Report sent to the patient and patient telephoned about the results

c. ( ) Report not sent, but patient telephoned about the results

d. ( ) Report not sent, but filed at the facility

e. ( ) Other (PLEASE SPECIFY) _____

<< **Answer only with respect to the one setting you identified in question 5** >>

29. If a patient has a **positive** mammogram **and** has not designated a personal physician, what is usually done with the mammogram report? (CHECK ONE.)

a. ( ) Report sent to the patient

b. ( ) Report sent to the patient and patient telephoned about the results

c. ( ) Report not sent, but patient telephoned about the results

d. ( ) Report not sent, but filed at the facility

e. ( ) Other (PLEASE SPECIFY) _____

30. List in the space below, any other actions your facility takes when a patient has a **positive** mammogram **and** has not designated a personal physician.

31. For a patient who has a personal physician and has a negative mammogram, what is usually done with the mammogram report? (CHECK ONE.)

a. ( ) Report sent to the patient

b. ( ) Report sent to patient's physician

c. ( ) Report sent to the patient and patient's physician

d. ( ) Report not sent, but patient telephoned about the results

e. ( ) Report not sent, but patient's physician telephoned about results

f. ( ) Report not sent, but patient and patient's physician telephoned about the results

g. ( ) Report not sent, but filed at the facility

h. ( ) Other (PLEASE SPECIFY) _____

<< Answer only with respect to the one setting you identified in question 5 >>

32. For a patient who has a personal physician and has a positive mammogram, what is usually done with the mammogram report? (CHECK ONE.)

a. ( ) Report sent to the patient

b. ( ) Report sent to patient's personal physician

c. ( ) Report sent to the patient and patient's physician

d. ( ) Report not sent, but patient telephoned about the results

e. ( ) Report not sent, but patient's personal physician telephoned about results

f. ( ) Report not sent, but patient and patient's physician telephoned about the results

g. ( ) Report not sent, but filed at the facility

h. ( ) Other (PLEASE SPECIFY) _____

33. What actions, if any, does your facility take in addition to sending or filing the mammogram report when a patient has a positive mammogram and has a physician? (CHECK ALL THAT APPLY.)

a. ( ) No other actions taken

b. ( ) Telephone patient's designated or personal physician to discuss mammogram results

c. ( ) Contact patient to remind her to contact her physician

d. ( ) Other (PLEASE SPECIFY) _____

<< Answer only with respect to the one setting you identified in question 5 >>

34. For each item listed below, check in:

Column 1: Whether your facility keeps the item as part of the patient's record.

Column 2: If yes, how long the item is kept. (CHECK ONE FOR EACH ITEM.)

Item	Column 1: Item kept?			Column 2: How long is the item kept?				
	No	Yes		1 Yr	2-4 Yrs	5 Yrs	6-10 Yrs	Over 10 Yrs
a. Mammogram report			If Yes -->					
b. Original mammogram images			If Yes -->					
c. Patient information provided at the time of the mammogram			If Yes -->					
d. Other (Specify) _____			If Yes -->					

35. How much does your facility generally charge for a screening bilateral mammogram? The mammogram charge should include charges for the mammogram **and** interpretation of the mammogram.

$_____ Charge for Screening Bilateral Mammogram

<< **Answer only with respect to the one setting you identified in question 5** >>

QUALITY ASSURANCE

36. Does your facility periodically have someone inspect all or part of your mammography system? (CHECK ONE.)

    a. ( ) Yes

    b. ( ) No ——>**(SKIP TO QUESTION 42.)**

37. Listed below are various individuals who might inspect a mammography system. Indicate in:

    Column 1: Whether your mammography system is inspected by each individual.

    Column 2: If yes, how frequently each individual inspects your system. (CHECK ONE.)

	Column 1			**Column 2**				
	Does Inspect?			How frequently mammography system inspected. (CHECK ONE.)				
Individual	No	Yes		Every 6 Months	Every Year	Every 2 Years	Every 3- 5 Yrs	Over 5 Years
a. Consultant Radiological Physicist (i.e., physicist not at facility)			**If Yes->**					
b. Federal/State/ Local Radiation Control Inspector			**If Yes->**					

<< **Answer only with respect to the one setting you identified in question 5** >>

38. For each of the items listed below, check in:

Column 1: Whether the consultant radiological physicist or radiation control inspector you identified in **question 37** inspects the item.

Column 2: If yes, which individual(s) inspects the item. (CHECK ALL THAT APPLY.)

	Column 1			Column 2	
	Inspect item?			Who inspects item? (CHECK ALL THAT APPLY)	
Item	No	Yes		Consultant Radiological Physicist	Fed/State Local Control Inspector
a. Beam quality (Half value layer)			If Yes-->		
b. Focal spot size			If Yes-->		
c. Average glandular dose			If Yes-->		
d. Phototimer			If Yes-->		
e. Consistency of mA station			If Yes-->		
f. KVP			If Yes-->		
g. Phantom image quality			If Yes-->		
h. Other (SPECIFY) _____			If Yes-->		

<< **Answer only with respect to the one setting you identified in question 5** >>

39. Is there a radiological physicist on staff at your facility? (CHECK ONE.)

a. ( ) Yes

b. ( ) No ——>**(SKIP TO QUESTION 41.)**

40. Listed below are various items a staff physicist might inspect as part of his/her overall quality assurance duties. Check in:

Column 1: Whether the staff physicist at your facility inspects each item.

Column 2: If yes, how frequently he/she performs the inspection. (CHECK ALL THAT APPLY.)

	Column 1			**Column 2**				
	Inspect item?			How frequently item inspected? (CHECK ALL THAT APPLY)				
Item	No	Yes		Every 3 Months	Every 6 Months	Every Year	Every 2 Years	Every 3-5 Yrs
a. Beam quality (Half value layer)			**If Yes—>**					
b. Focal spot size			**If Yes—>**					
c. Average glandular dose			**If Yes—>**					
d. Phototimer			**If Yes—>**					
e. Consistency of mA station			**If Yes—>**					
f. KVP			**If Yes—>**					
g. Phantom image quality			**If Yes—>**					
h. Other (SPECIFY) _____			**If Yes—>**					

<< **Answer only with respect to the one setting you identified in question 5** >>

41. Listed below are additional items that might be inspected as part of your facility's quality assurance program. Check in:

Column 1: Whether each item is inspected as part of your quality assurance program.

Column 2: If yes, how frequently the item is inspected. (CHECK ONE.)

	Column 1			Column 2					
	Inspect Item?			How frequently is the item inspected? (CHECK ONE.)					
Item	No	Yes		Daily	Weekly	Monthly	Every 6 Months	Annually	Less Often Than Annually
a. Grids			If Yes->						
b. Screens			If Yes->						
c. Processor Sensitometry			If Yes->						
d. Phantom image quality			If Yes->						
e. Other (SPECIFY) _____			If Yes->						

<< **Answer only with respect to the one setting you identified in question 5** >>

42. A facility might include some of the following procedures as part of its quality assurance program. Which procedures, if any, does your facility usually perform. (CHECK ALL THAT APPLY.)

a. ( ) Review film quality

b. ( ) Perform a second reading of mammograms within the facility

c. ( ) Submit mammograms for second reading by peer review panel outside the facility

d. ( ) Follow up on patient biopsies

e. ( ) Monitor number of repeat mammograms due to equipment, patient, and/or technologist problems

f. ( ) Other (PLEASE SPECIFY) _____

g. ( ) No procedures performed

43. In question 5, did you identify **mobile van,** either affiliated or not affiliated with a hospital, clinic, or physician's practice, as the one kind of setting where the majority of your screening mammograms are performed? (CHECK ONE.)

a. _____ Yes —>**(SKIP TO QUESTION 46.)**

b. _____ No

44. Does your facility provide any mammography services using a mobile van? (CHECK ONE.)

a. _____ Yes

b. _____ No —>**(SKIP TO QUESTION 46.)**

45. During a normal week, how many diagnostic and/or screening mammograms are performed in the mobile van?

a. _____ Number of **diagnostic** mammograms

b. _____ Number of **screening** mammograms

46. If you have any comments regarding this questionnaire or issues relating to mammography, please write them in the space provided below.

**** THANK YOU FOR YOUR COOPERATION ****

Selected Quality Standards for Mammography and Related Survey Results

This appendix contains more detailed information about the quality standards discussed in chapter 3, as well as additional survey results.

Use of Dedicated Equipment

To obtain the best mammographic image with the smallest dose of radiation, it is essential to use dedicated mammography equipment—that specifically designed for mammography. Its features enable the operator to obtain high-quality images with much lower radiation exposure than is possible with general X-ray equipment. Use of dedicated equipment is one of the standards the Congress had mandated for screening mammography reimbursed by Medicare.

Taking Two Breast Views

State-of-the-art screening mammography practice in this country is to take two views of each breast. About 82 percent of responding facilities indicated they take two views, 17 percent take three views, and only 1 percent do one view. Although almost all respondents reported taking at least two views, we did find one problem. The NCRP recommends that screen-film mammography consist of the craniocaudal (CC)-oblique combination, and specifically advises using an oblique view instead of a true lateral view.[1] However, about 11 percent of the respondents doing only screen-film mammography reported using the CC-true lateral combination instead of CC-oblique. The settings in which this was more likely to occur were primary care physicians' offices and hospitals; no mobile vans reported this practice.

Performance and Interpretation of Mammograms by Certified or Licensed Personnel

The person taking the mammogram plays an essential role in providing quality mammography. Proper positioning of the patient and adjustment of the equipment are vital to producing a good image. ACR's accreditation standards require, and the CRCPD recommends, that radiologic technologists operating mammography systems be registered with the American Registry of Radiologic Technologists (ARRT)[2] and/or state-licensed and have specialized training in mammography.

Of the 97 percent of facilities reporting that the person who usually performs their screening mammograms is ARRT-certified, state-licensed, or both, about 9 percent indicated that another type of staff member (see app. II) sometimes performs screening mammography. The settings with

[1] In xeroradiography, the true lateral view is appropriate.

[2] CRCPD recommends registration with either ARRT or the American Registry of Clinical Radiographic Technologists (ARCRT).

the largest proportions reporting this were primary care physicians (17 percent), radiology practices (11 percent), and hospital breast clinics (10 percent). HMOs and multispecialty clinics had the smallest proportions (6 percent).

The CRCPD states that American Board of Radiology-certified radiologists with documented training in mammographic image interpretation should interpret mammograms. ACR requires a board-certified radiologist to supervise accredited programs and interpret the mammograms. The radiologist also must have specific training and experience.[3] About 99 percent of providers responding to our survey reported that the person who interprets the mammogram is a radiologist, and 99.9 percent reported that it is a radiologist or other physician.

Reporting Positive Mammogram Results and Following Up

Guidelines for screening mammography programs stress the importance of a system for reporting test results—particularly for "positive" mammograms, those with a finding of possible abnormality—to the patient and/or her physician. It is especially important for the facility or radiologist to ensure that women without personal physicians are referred for appropriate care when their mammograms are positive.

When the woman has designated a personal physician, about 93 percent of respondents reported that they send positive mammogram reports to the physician. An additional 5 percent send the report to both the patient and her physician.[4] When the patient has not designated a physician, 99 percent of respondents take action to inform her of the results and/or arrange for her to receive medical care.

Experts also recommend telephoning the patient's physician to ensure that the written report is not accidentally overlooked. Two-thirds of our respondents reported following this practice. Radiology private practices (81 percent), hospital breast clinics (79 percent), and breast clinics (78 percent) were among the settings most likely to take this extra step, and hospitals (61 percent) among the least likely.

[3]The radiologist supervising the program and/or interpreting mammograms must have (1) completed a residency program after 1982, when mammography was added to the radiology board examination; or (2) 3 years' experience reading at least 10 cases per week; or (3) 40 hours of mammographic education in the past 2 years. ACR is now phasing in additional criteria regarding training and experience.

[4]Due to rounding, table 3.1 shows a total of 99 percent of respondents reporting the results to the patient and/or physician.

We also asked survey participants whether they contacted patients with positive mammograms who have designated physicians to remind them to contact their physicians. Eleven percent of all respondents reported that they both send the radiologist's report to the patient and/or physician and contact the patient with a reminder. The settings that most often reported following this practice were mobile vans (36 percent), primary care physicians (29 percent), and hospital breast clinics (26 percent).

When a patient with abnormal findings has not designated a physician, many respondents said they take additional steps beyond reporting the mammogram results to her. These include referring the patient to a surgeon or other physician and sometimes making the appointment for the patient, calling the physician to confirm that the patient was seen, and contacting the patient to ensure that she has sought medical care.

Record Retention

Retention of the original mammographic image is extremely important for quality screening. Comparison with a previous film can indicate whether a suspected abnormality is a benign structure in the woman's breast or confirm that a new lesion has appeared. ACR policy calls for providers to keep mammograms and positive reports for at least 5 years, and the CRCPD recommends that images be maintained indefinitely.

Our survey found that 98 percent of all respondents keep original images for at least 5 years, and 49 percent for over 10 years. (See table V.8 for information by setting.) Almost all respondents told us they retain the mammogram report, with 99 percent reporting they keep it for at least 5 years.

Taking Patient's Medical History

Information collected about the patient's medical history

- helps identify women who are not candidates for screening mammography but instead should be considered diagnostic patients, such as women with current breast symptoms, and
- can be used to identify patients who are at greater risk for developing breast cancer, which may be a factor in determining how often they should be screened.

With one exception, every respondent to our survey reported collecting some patient information.

Instruction on Breast Self-Examination

Because breast self-examination (BSE) is considered another critical element of breast cancer screening, there is consensus that a good screening program should include information on how to perform BSE. As the ACS will provide free instructional pamphlets for distribution to patients, cost should not be a barrier to facilities providing this service. At least one form of BSE instruction is available at 90 percent of the facilities that gave us information on this subject. Three-fourths of responding facilities (78 percent) give pamphlets to patients, 42 percent show a video tape, and instruction by a staff person occurs at 41 percent.

When analyzed by setting, the data show that 100 percent of breast clinics, hospital breast clinics, and mobile vans provide information on self-examination, while 83 percent of hospitals and 85 percent of radiology practices do so. However, when the analysis includes only facilities that accept self-referred patients, where the need for such information might be greatest, the overall rate of facilities that provide information increases to 96 percent, and the rates for hospitals and radiology practices rise to 93 and 95 percent, respectively.

State Oversight of Screening Mammography

This appendix contains more detailed information about the state oversight programs described in chapter 4.

Staffing of State Programs

California has 32 inspectors, including those in the Radiological Health Branch of the Department of Health Services (DHS) and those in certain counties. The latter are counties with which DHS contracts for inspection and enforcement of radiation control regulations in their jurisdictions. Inspectors must be certified radiologic technologists with supervisory experience. In addition, they must pass a competitive examination and complete 1 year of on-the-job training prior to becoming an inspector.

In Florida's Office of Radiation Control, the Department of Health and Rehabilitative Services has 35 inspectors. The X-ray Machine Registration and Control (XMRC) Section is responsible for inspecting the state's 25,000 X-ray machines (as of July 1988), of which 463 are mammography machines. According to the manager of XMRC, all inspectors have the education and training necessary to oversee and regulate mammography equipment. They are public health physicists, which requires either

- a bachelor's degree with a major in radiologic health or radiologic science, and 1 year of experience in radiologic health, a physical or natural science, radiation control, X-ray technology, or health physics; or
- a bachelor's degree with a major in engineering, mathematics, or one of the physical or natural sciences, and 2 years of the experience described above.

A master's degree and/or doctorate in one of the educational areas described above can substitute for 1 year of required experience. Also, experience can be substituted for education. About one-fourth of the inspectors have a master's degree.

A background in radiology would allow a new inspector to begin working independently sooner than protocol would dictate. A trainee generally goes through 4 to 6 months of on-the-job training before being allowed to conduct an inspection alone.

In Michigan, the Division of Radiological Health (DRH) in the Department of Public Health has nine inspectors, who are radiological physicists with a B.S. degree in physics. According to the chief of the DRH Investigation and Compliance Section (ICS), in 1988 Michigan had about 20,000

X-ray machines located in 8,655 facilities. Of these, 446 were mammography machines located in 381 facilities. State inspectors participate in FDA training courses, the chief of ICS told us, and have on-the-job training that includes observing an experienced inspector for a few months and then conducting inspections under direct supervision for several additional months. Usually after 6 months, new inspectors may perform inspections without direct supervision. Due to a June 1989 law requiring annual inspection of mammography equipment, the ICS chief estimates he will need three additional inspectors on his staff.

Persons Performing Mammography

In California, radiologic technologists must graduate from a state-approved school of radiologic technology and pass state-approved examinations in diagnostic radiation protection and safety and diagnostic radiologic technology. There is no specific requirement for training in mammography, although an official of the Joint Review Committee on Education and Radiologic Technology said that mammography training is considered a standard part of the curriculum of accredited radiologic technology programs. A California official told us that the California examination has no questions on mammography.

The Florida Office of Radiation Control issues six different licenses to technologists; mammographers must have the general radiographer license, which is the most advanced level. Generally, licenses must be renewed every 2 years. General radiographers must graduate from a radiologic technology program that meets the guidelines of the Committee on Allied Health, Education, and Accreditation, an arm of the American Medical Association. They also must pass either the national ARRT examination or Florida's examination. The ARRT examination covers mammography.

Additional Results From GAO's Screening Mammography Survey

Table V.1: Settings of Respondents Performing Screening Mammography, by State

	Distribution of settings, by state							
	CA		FL		ID		MI	
Setting	**%**	**No.[a]**	**%**	**No.[a]**	**%**	**No.[a]**	**%**	**No.[a]**
Hospital	38	195	36	79	55	16	45	119
Radiology practice	28	144	25	55	7	2	22	58
Multispecialty clinic	11	55	11	23	14	4	8	22
Primary care physician	7	35	7	15	3	1	14	38
Breast clinic	7	35	15	32	7	2	6	16
HMO	6	32	1	1	0	0	1	3
Hospital breast clinic	2	9	1	3	14	4	2	4
Mobile van	1	6	1	3	0	0	1	2
Other	1	3	3	6	0	0	2	4
All settings	**50**	**514**	**21**	**217**	**3**	**29**	**26**	**266**

[a]Respondents that reported performing screening mammography.

Table V.2: Respondents' Charges for Screening Mammogram, by Locale and Setting

Locale/setting	No. of respondents	Distribution of amounts charged,[a] by locale/setting (percent) $1-50	$51-99	$100-125	$126-150	Over $150
All states						
Hospital	379	7	38	25	16	15
Radiology practice	255	5	48	30	14	4
Multispecialty clinic	98	8	24	45	19	3
Primary care physician	85	0	45	31	18	7
Breast clinic	83	17	55	19	6	2
HMO	14	21	29	7	29	14
Hospital breast clinic	19	11	37	16	32	5
Mobile van	10	60	30	10	0	0
Other	11	0	55	27	9	9
All settings	**954**	**7**	**41**	**28**	**15**	**8**
California						
Hospital	181	8	34	20	18	20
Radiology practice	142	3	46	30	16	4
Multispecialty clinic	52	8	15	44	29	4
Primary care physician	35	0	34	34	17	14
Breast clinic	34	24	50	15	9	3
HMO	10	20	10	10	40	20
Hospital breast clinic	9	11	44	11	33	0
Mobile van	6	67	17	17	0	0
Other	2	0	0	100	0	0
All settings	**471**	**8**	**36**	**27**	**18**	**11**
Florida						
Hospital	72	6	40	28	14	13
Radiology practice	55	11	47	25	13	4
Multispecialty clinic	22	5	27	55	14	0
Primary care physician	14	0	57	43	0	0
Breast clinic	31	13	58	26	0	3
HMO	1	100	0	0	0	0
Hospital breast clinic	3	0	33	33	33	0
Mobile van	2	50	50	0	0	0
Other	6	0	83	17	0	0
All settings	**206**	**8**	**46**	**30**	**10**	**6**

(continued)

Locale/setting	No. of respondents	Distribution of amounts charged,[a] by locale/setting (percent) $1-50	$51-99	$100-125	$126-150	Over $150
Idaho						
Hospital	16	13	81	6	0	0
Radiology practice	2	0	100	0	0	0
Multispecialty clinic	4	0	100	0	0	0
Primary care physician	1	0	100	0	0	0
Breast clinic	2	100	0	0	0	0
HMO	0	0	0	0	0	0
Hospital breast clinic	3	33	67	0	0	0
Mobile van	0	0	0	0	0	0
Other	0	0	0	0	0	0
All settings	**28**	**18**	**79**	**4**	**0**	**0**
Michigan						
Hospital	110	5	36	33	15	11
Radiology practice	56	4	50	34	11	2
Multispecialty clinic	20	15	30	45	5	5
Primary care physician	35	0	49	23	26	3
Breast clinic	16	0	69	19	13	0
HMO	3	0	100	0	0	0
Hospital breast clinic	4	0	0	25	50	25
Mobile van	2	50	50	0	0	0
Other	3	0	33	0	33	33
All settings	**249**	**4**	**43**	**31**	**15**	**7**

[a]For mammogram and interpretation. Facilities charging $0 were excluded from analysis.

Table V.3: Volume of Mammograms Performed, by Setting

Setting	No. of respondents[b]	Distribution of no. of mammograms[a] performed weekly, by setting (percent) 1-24	25-49	50-74	75-100	Over 100
Hospital	383	37	34	13	9	7
Radiology practice	251	31	27	23	9	10
Multispecialty clinic	98	37	29	17	12	5
Primary care physician	86	70	15	8	7	0
Breast clinic	79	15	16	27	15	27
HMO	35	6	20	17	14	43
Hospital breast clinic	19	11	16	16	21	37
Mobile van	10	20	20	10	20	30
Other	12	17	25	42	0	17
All settings	**973**	**34**	**28**	**17**	**10**	**11**

[a]Screening and diagnostic.

[b]Total number of respondents in setting category.

Table V.4: Survey Respondents Accredited by ACR Mammography Accreditation Program, by Setting and State (As of April 1989)

Setting	Percent of respondents accredited CA	FL	ID	MI	All 4 states
Hospital	2	4	0	21	8
Radiology practice	6	11	0	26	11
Multispecialty clinic	2	9	0	14	6
Primary care physician	0	0	0	5	2
Breast clinic	6	9	0	38	13
HMO	0	0	0	0	0
Hospital breast clinic	11	0	0	0	5
Mobile van	17	0	0	0	9
Other	0	0	0	0	0
All settings	**3**	**6**	**0**	**19**	**8**

Table V.5: Survey Respondents Reporting Annual Inspection by Radiological Physicist, by Setting and State

	Percent and no.[a] of respondents									
	CA		FL		ID		MI		All 4 states	
Setting	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**
Hospital	88	195	82	79	56	16	82	119	84	409
Radiology practice	60	144	46	55	0	2	64	58	57	259
Multispecialty clinic	55	55	52	23	25	4	32	22	48	104
Primary care physician	43	35	47	15	0	1	42	38	43	89
Breast clinic	83	35	53	32	100	2	94	16	74	85
HMO	81	32	0	1	[b]		100	3	81	36
Hospital breast clinic	89	9	67	3	75	4	100	4	85	20
Mobile van	100	6	67	3	[b]		100	2	91	11
Other	67	3	83	6	[b]		25	4	62	13
All settings	**73**	**514**	**62**	**217**	**52**	**29**	**69**	**266**	**69**	**1,026**

[a]Total number of respondents in setting category.

[b]No respondents in category.

Table V.6: Survey Respondents Reporting Annual Physicist Inspection of Beam Quality (HVL), **Average Glandular Dose, and Phantom Image Quality, by Setting and State**

	Percent and no.[a] of respondents									
	CA		FL		ID		MI		All 4 states	
Setting	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**
Hospital	73	195	60	79	25	16	73	119	69	409
Radiology practice	48	144	33	55	0	2	53	58	46	259
Multispecialty clinic	38	55	44	23	0	4	27	22	36	104
Primary care physician	29	35	33	15	0	1	26	38	28	89
Breast clinic	66	35	41	32	0	2	81	16	58	85
HMO	66	32	0	1	[b]		100	3	67	36
Hospital breast clinic	89	9	33	3	50	4	100	4	75	20
Mobile van	67	6	33	3	[b]		100	2	64	11
Other	67	3	67	6	[b]		0	4	46	13
All settings	**59**	**514**	**46**	**217**	**21**	**29**	**59**	**266**	**55**	**1,026**

[a]Total number of respondents in setting category.

[b]No respondents in category.

Table V.7: Survey Respondents Reporting Compliance With Selected Quality Assurance Standards, by Setting

	Percent and no.[a] of respondents									
	Daily processor sensitometry[b]		Semiannual phantom image check		Monitoring of repeat mammograms		Second reading of mammogram in facility		Follow-up of patient biopsies	
Setting	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**
Hospital	52	361	45	409	54	398	37	398	82	398
Radiology practice	16	226	46	259	51	257	22	257	71	257
Multispecialty clinic	22	95	42	104	50	101	21	101	70	101
Primary care physician	10	79	28	89	44	85	20	85	69	85
Breast clinic	37	76	65	85	62	84	33	84	75	84
HMO	59	32	44	36	67	36	44	36	75	36
Hospital breast clinic	39	18	70	20	55	20	25	20	85	20
Mobile van	46	11	73	11	64	11	27	11	82	11
Other	33	12	54	13	62	13	23	13	54	13
All settings	**35**	**910[c]**	**46**	**1,026[c]**	**53[d]**	**1,005[c]**	**29**	**1,005[c]**	**76**	**1,005[c]**

[a]Total number of respondents in setting category.

[b]Analysis excludes respondents who do xeromammography only.

[c]Numbers of total cases differ because of different numbers that responded to specific questions.

[d]Total differs by 1% from percentage in report because latter is based on all cases, including those who did not identify setting.

Table V.8: Survey Respondents' Retention of Original Mammographic Images, by Setting

	Percent of respondents		
Setting	**Images kept at least 5 years**	**Images kept over 10 years**	**No.[a]**
Hospital	98	49	394
Radiology practice	96	50	252
Multispecialty clinic	98	34	101
Primary care physician	99	56	86
Breast clinic	99	63	83
HMO	100	42	33
Hospital breast clinic	100	55	20
Mobile van	91	55	11
Other	100	27	11
All settings	**98**	**49**	**991**

[a]Total number of respondents in setting category.

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