The ACR's Mammography Accreditation Program: Ten Years of Experience Since MQSA

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The ACR's Mammography Accreditation Program has been helping facilities improve the quality of mammography through peer review and professional feedback since 1987. Initially conceived as a voluntary program, accreditation became mandatory when the Mammography Quality Standards Act (MQSA) of 1992 required all U.S. mammography facilities to become accredited and certified by October 1, 1994. Currently, the ACR is the largest of four accrediting bodies approved by the U.S. Food and Drug Administration, accrediting 12,729 units at 8325 facilities by October 1, 2004. Between 1987 and 1991, 70% of the mammography units applying for accreditation with the ACR passed on their first attempts. In 2003, 88.3% of the units passed on their first attempts, indicating a marked improvement in the quality of mammography in the United States since MQSA went into effect 10 years ago.

Key Words: Breast radiography, quality assurance

J Am Coll Radiol 2005;2:585-594.

INTRODUCTION

Radiologists and medical physicists on the ACR's Breast Task Force developed the Mammography Accreditation Program in 1987 to address documented concerns for inadequate and varying quality of mammography in the United States [1,2]. This voluntary program provided a means for facilities to demonstrate that they provided acceptable-quality mammography by showing that they met the ACR's mammography standards for personnel, equipment, quality assurance, clinical images, phantom images, and dose. If a facility could not pass the accreditation criteria, the ACR would provide feedback from experts in mammography to guide the facility in making improvements. The ACR's accreditation program gained wide acceptance among facilities and government agencies, even though it was a voluntary program. In 1991, approximately half of the estimated 10,000 mammography units in the United States had applied for accreditation; approximately one-quarter of the U.S. mammography units had successfully achieved accreditation [3].

Several states passed legislation requiring mammography facilities to meet quality standards and submit to regular inspections by state radiation control inspectors. In 1990, Congress passed legislation authorizing Medicare coverage of screening mammography. Facilities seeking Medicare reimbursement were required to register with the Health Care Financing Administration and meet quality standards similar to those of the ACR's Mammography Accreditation Program. Federal inspections of Medicare-registered screening facilities began in 1992. Although the goal of quality mammography was the same, this assortment of state, federal, and voluntary private efforts created a patchwork of mammography requirements across the United States, and much of the mammography being performed at that time was not subject to quality regulations of any type. Consequently, quality remained inconsistent.

Recognizing the need for uniform national standards that would apply to both screening and diagnostic facilities, Congress passed the Mammography Quality Standards Act (MQSA) in 1992 [4]. This act requires all mammography facilities to meet minimum quality standards for personnel, equipment, and recordkeeping and be certified by the U.S. Food and Drug Administration (FDA) or an FDA-approved state certifying body (CB) to legally operate in the United States. To become certified,

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0091-2182/05/$30.00 • DOI 10.1016/j.jacr.2004.12.005

facilities must be accredited by FDA-approved accrediting bodies. All mammography facilities in the United States had to be certified before October 1, 1994. (Although Veteran's Health Administration facilities were excluded from MQSA, they accredit with the ACR and meet equivalent standards.)

Because of the near impossibility of developing comprehensive regulations and simultaneously providing initial certification of more than 10,000 mammography facilities, the FDA developed interim rules based on existing standards from organizations such as the ACR, the Health Care Financing Administration, and state regulators. On December 21, 1993, the interim rules titled "Mammography Facilities—Requirements for Accrediting Bodies and Quality Standards and Certification Requirements" were published in the *Federal Register* [5]. They went into effect on February 22, 1994, and required that all facilities be certified by October 1, 1994.

The final regulations for implementing MQSA were published by the FDA [6] on October 28, 1997. In brief, the final rule established personnel requirements, clarified equipment standards, and outlined many performance-based equipment requirements in the quality assurance section of the regulations. Mammography facilities were also required to establish systems for communicating results of mammographic examinations and transferring the original mammograms at patients' requests. The majority of the final regulations became effective on April 28, 1999. Certain stricter equipment regulations became effective on October 28, 2002.

The FDA has designated the ACR as an accrediting body for both screen-film and full-field digital mammography (FFDM) units. The ACR is currently one of four FDA-approved accrediting bodies and is the only one that accredits nationally. The other three are the states of Iowa, Arkansas, and Texas. These states may accredit only facilities within their own borders; facilities within these states have the choice of accrediting with the ACR or with their states. Each accrediting body must have accreditation requirements that are identical or equivalent to the requirements outlined in the FDA's [6] final rules. The ACR's Mammography Accreditation Program is directed by radiologists and medical physicists through the Committee on Mammography Accreditation of the ACR Commission on Quality and Safety. This paper describes the current accreditation process and the results since all mammography facilities were required to be accredited and certified under MQSA 10 years ago.

ACCREDITATION PROCESS

The ACR's mammography accreditation process is summarized by the flowchart in Fig. 1. A new mammography facility must first complete an entry application to provide basic information on the facility, equipment, and personnel and submit a summary of the pass or fail results from its medical physicists' equipment evaluation, along with an application fee. The facility must apply for accreditation on all active mammography units. No clinical or phantom images are submitted with the entry application.

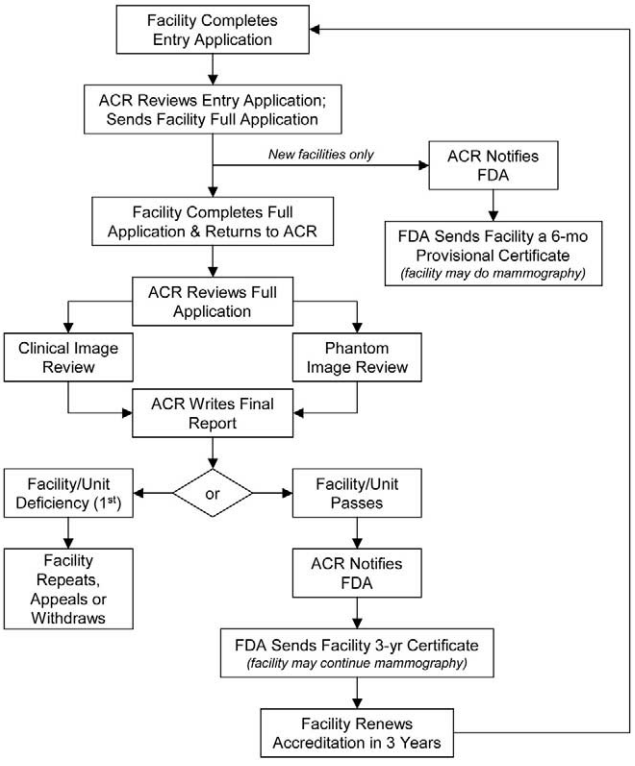

Fig. 1. Flowchart describing the ACR mammography accreditation process.

If a facility fulfills the criteria evaluated under the entry application, the ACR notifies the FDA (or state CB). The FDA (or state CB) issues the new facility a 6-month provisional certificate allowing it to legally perform mammography. The ACR then sends the facility a full application to obtain information on the qualifications of its radiologists, medical physicists, and radiologic technologists; quality control results; and other requirements of MQSA, along with the appropriate testing materials. Image quality and dose evaluations are an integral part of the process. Records of the quality control testing results for the film processor (or laser film printer) for a 30-day period are also requested for review by ACR staff members.

When all stages of the evaluation are completed, the ACR returns the original images and provides a final report (that includes specific assessments and recommendations) to the facility's lead interpreting physician. Those facilities successfully meeting all of the criteria are awarded 3-year accreditation certificates and unit decals

Table 1. Proceeding with accreditation if accreditation is not granted

Attempt at Accreditation	Accreditation Result	Facility Options
First	*Not granted* First deficiency Facility may continue performing mammography with the unit as long as it has a valid certificate.	• *Repeat* not acceptable area(s) (only if more than 60 days on MQSA certificate), • *Reinstate* by retesting all areas (if 60 days or less on MQSA certificate), • *Appeal* decision on original images or • *Withdraw*
Second	*Not granted* Second deficiency = first failure ACR strongly recommends that facility cease performing mammography with the unit.	• *Reinstate* by retesting all areas (with corrective action), • *Appeal* decision on original images (may not operate until the appeal is complete) or • *Withdraw*
Third	*Not granted* Third deficiency = second failure ACR strongly recommends that facility cease performing mammography with the unit.	• *Reinstate* after participating in scheduled on-site survey, • *Appeal* decision on original images (may not operate until the appeal is complete) or • *Withdraw*

Note: MQSA = Mammography Quality Standards Act.

for each approved mammography unit. The ACR notifies the FDA (or state CB) of each unit's accreditation approval so that it may issue the facility a 3-year MQSA certificate. Because the FDA (or state CB) certifies facilities rather than units, the accreditation for each unit within the facility must have the same expiration date, regardless of when it was accredited. The facility's MQSA certificate has the same expiration date as the ACR accreditation of the mammography unit. The ACR lists each accredited facility on its Web site so that a list of such facilities is available to patients and patient referral organizations.

If a mammography unit does not pass, the ACR's final report provides specific recommendations for improvement so the facility may take corrective action on its own. After corrective action, the facility may reapply for accreditation by repeating only the deficient test or tests (e.g., clinical, phantom, dose). Facilities may appeal any denial of accreditation (Table 1).

After two consecutive unsuccessful attempts, a facility fails accreditation, and the ACR strongly recommends that the facility take the unit out of service. As an FDA-approved accrediting body, the ACR is required to notify the FDA (or state CB) of a failure. The ACR works with each facility to help it improve its image quality and to achieve accreditation. The facility must submit a corrective action plan to the ACR for approval and follow-up with documentation supporting this corrective action to reinstate. Once a facility has reinstated, the FDA (or state CB) will send it a 6-month provisional reinstatement certificate allowing it to resume mammography and reapply for accreditation.

If a mammography unit does not successfully obtain accreditation after three consecutive unsuccessful attempts, the ACR provides more personalized assistance and oversight as the facility reinstates. An ACR team (consisting of a radiologist reviewer, a medical physicist reviewer, and a mammography technologist who is a member of the ACR staff) conducts a scheduled on-site survey before reinstatement to assess the facility's independent corrective action and provide further advice on necessary improvements. This is an educational effort, and the ACR team works closely with the facility's radiologists, technologists, and medical physicists to achieve these goals. The facility may reinstate only after taking all corrective action recommended by the survey team.

Occasionally, clinical images submitted for accreditation are of such poor quality that the ACR reviewers

believe that more images should be reviewed to determine if the facility's practice may pose a "serious risk to human health" (as outlined in the FDA [6] regulations). In these rare cases, the ACR randomly selects 30 cases from the facility for review by a senior ACR clinical image reviewer. As a result of this review, if the senior reviewer believes that the facility's practice poses a serious risk to human health, the ACR notifies the FDA (or the state CB) and revokes the facility's accreditation. If the FDA (or state CB) determines that there is a serious risk to human health as a result of this and other information, it will usually require the facility to notify all patients (and their physicians) examined during the review period that the reliability, clarity, and accuracy of the interpretation of mammograms was compromised.

Eight months before the expiration of the ACR accreditation and the MQSA certificate, the ACR mails a renewal application to the accredited facility's lead interpreting physician. The renewal application process is essentially the same as the process for new facilities.

Clinical Image Evaluation

As part of accreditation, the facility must submit two sets of Breast Imaging Reporting and Data System (BI-RADS®) Assessment Category 1 [7] images for each mammography unit: one from a patient with fatty breasts and one from a patient with dense breasts. Fatty breast images may be composed almost entirely of fat (<25% glandular) or have scattered fibroglandular densities (25-50% glandular). Dense breast images may be heterogeneously dense (51-75% glandular) or extremely dense (>75% glandular). Because of the variations in patients' body habitus and their ability to cooperate, it is not possible to obtain ideal positioning and compression in all women [8]. Furthermore, mammography facilities across the United States have widely varying volumes and serve varied patient populations (e.g., younger, cooperative women at one extreme; fragile, elderly patients at the other). To enable all facilities to be equitably judged by the same criteria and to provide some flexibility for this variability in facility volume and patient demographics, the ACR instructs facilities to submit their best representative clinical images; they are given up to 45 days to provide these images. Facilities may not submit images that are performed on models or volunteers.

The clinical images are independently scored by at least two ACR-trained radiologist reviewers. If there is an outcome disagreement between the first two reviewers, the images are sent to a third for arbitration. The categories that are scored include positioning, compression, exposure level, sharpness, contrast, noise, examination identification, and artifacts [3,8]. The 1999 ACR *Mammography Quality Control Manual* [9] (provided to each new facility applying for accreditation) describes these eight categories in detail. Each case is scored on a 5-point, scale (1 = worst, 5 = best). A score of 1 or 2 is reserved for significant deficiencies; a score of 3 is given to marginally deficient or marginally acceptable imaging. A score of 1 or 2 in a single category or a score of 3 in multiple categories will generally fail an image [8].

To ensure that the evaluations are clinically relevant, reviewers are volunteers in current clinical practice from across the United States; they are not employees of the ACR. All clinical image reviewers must meet the following criteria: (1) meet the FDA's MQSA requirements for interpreting physicians; (2) if reviewing FFDM images, meet the FDA's MQSA requirements for FFDM; (3) be certified by the American Board of Radiology; (4) have at least 5 years of experience after residency in diagnostic radiology, with at least 50% of each year's practice in breast imaging; and (5) be currently actively practicing mammography (and FFDM, if reviewing FFDM) at a MQSA-certified and ACR-accredited facility. Reviewers are required to attend routine refresher courses, and the ACR monitors the performance of all reviewers on a semiannual basis. Furthermore, to ensure that there is no conflict of interest, no reviewer may evaluate images from a facility within the same state or from a facility with which he or she is affiliated.

Phantom Image and Dose Evaluation

A facility must submit one phantom image with a thermoluminescent dosimeter to measure the dose from each mammography unit. At this time, the ACR has approved

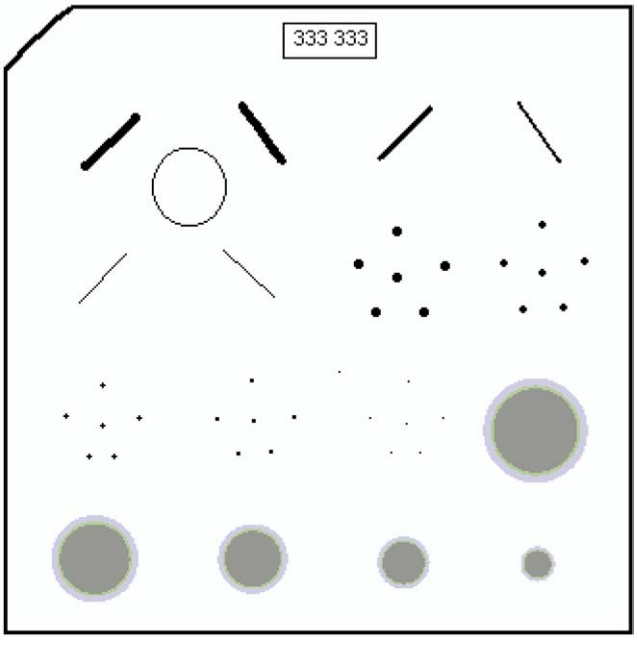

Fig. 2. Diagram of phantom used for mammography accreditation.

Table 2. Mammography units and MQSA-certified facilities

Year	Date and Data Reference	Certified Facilities[a]	Mammography Units[b]
1994	[11]	10,119	
1997	[11]	9956	
1998	10/1, [12]	9884	12,076
1999	1/1, [11]	9314	
2000	10/1, [13]	9933	12,956
2001	10/1, [13]	9558	13,173
2002	10/1, [13]	9306	13,173
2003	10/1	9114	
2004	10/1	9011	13,652

Note: MQSA = Mammography Quality Standards Act.
[a]Certified facilities include fully and provisionally certified.
[b]The number of mammography units is not available for each year.

RMI model 156, Nuclear Associates model 18-220, and CIRS model 015 phantoms for use in the Mammography Accreditation Program. The phantom must be exposed using the clinical technical factors (target, filter, kilovolt peak, grid, density control setting, etc.) currently used by the unit for a 4.2-cm compressed breast of average density [10]. At this time, all phantom (and clinical) images must be submitted to the ACR on hard copy, even if acquired with FFDM.

The phantom images are independently scored by at least two ACR-trained medical physicist reviewers. If there is an outcome disagreement between the first two reviewers, the images are sent to a third for arbitration. The four largest fibers, three largest speck groups, and three largest masses must be visible for the phantom image to pass (Fig. 2). The reviewers also subtract from the test object scores if artifacts look like test objects and are as apparent as the smallest test object scored. The ACR reviewers follow the detailed procedures outlined in the 1999 ACR *Mammography Quality Control Manual* [9] to score phantom images.

To ensure that phantom image reviewers have the valuable experience of surveying mammography equipment so that they may provide relevant feedback to facilities, reviewers are volunteers in current physics practice from across the United States and not employees of the ACR. All phantom image reviewers must meet the following criteria: (1) meet the FDA's MQSA requirements for medical physicists; (2) if reviewing FFDM images, meet the FDA's MQSA requirements for FFDM; (3) be certified by the American Board of Radiology or the American Board of Medical Physics in a diagnostic imaging area; (4) have at least 5 years of experience in diagnostic medical physics (in mammography), with at least 50% of their current practice in diagnostic medical physics; and (5) be currently in an active medical physics practice (including FFDM, if reviewing FFDM). Phantom image reviewers are also required to attend routine refresher courses and undergo semiannual performance review by the ACR. As with the clinical image reviewers, no phantom image reviewer may evaluate images from a facility within the same state or from a facility with which he or she is affiliated.

MAMMOGRAPHY FACILITIES AND UNITS IN THE UNITED STATES

On October 1, 2004, the FDA reported that there were 13,652 mammography units at 9011 MQSA-certified facilities in the United States. This count included both fully and provisionally certified facilities. Since 1994, the number of mammography facilities in the United States has declined by 10.9% (Table 2 and Fig. 3). A 2001 report by the Eastern Research Group [11] stated that the "1994 facility counts were inflated due to duplicate listings of facilities that had received more than one accred-

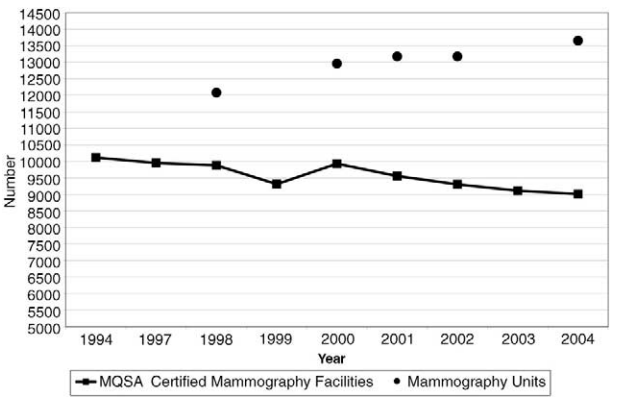

Fig. 3. Mammography units and MQSA certified facilities since 1994 (includes full and provisionally certified facilities.)

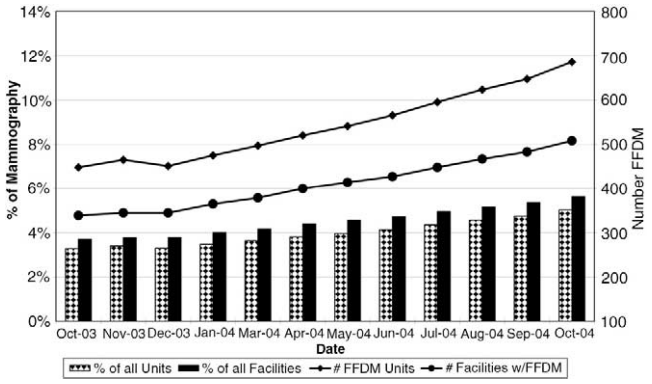

Fig. 4. The growth of full-field digital mammography units and facilities in the U.S.

itation." Assuming that the 1997 data in the Eastern Research Group's [11] study were more accurate, there was a 9.5% drop in the number of facilities, still a significant amount. Despite this drop in the number of mammography facilities, there has actually been an increase in the number of mammography units. In 1998, the U.S. General Accounting Office [12] reported that there were 12,076 units; in 2004, the FDA reported 13,652 units, a 13.1% increase over 6 years. In recent years, much of this increase has been related to the introduction of FFDM units. On October 1, 2004, there were 686 FFDM units at 508 facilities, representing 5% of the mammography units and 5.6% of the mammography facilities in the United States. The number of FFDM mammography units has grown by about 4% each month over the past year. (Fig. 4).

Since April 2001, the ACR has tracked the number of ACR-accredited facilities closing their doors and their reasons for doing so. Although Table 3 breaks out the reasons for closure, most causes are certainly related to hard financial decisions. Facilities report that the main reason they close is due to unspecified financial reasons (33.5%). Many facilities also seem to be consolidating their mammography activities to save resources by closing single-unit facilities and moving the unit to a sister facility (23.7%). Over 11% closed due to equipment problems (most likely an inability to meet the FDA regulations). An inability to find qualified staff has been a reason to close for 10.3% of these facilities. Over 1560 ACR-accredited facilities closed between April 2001 and October 2004. (The ACR does not include facilities switching their accreditation from the ACR to states in this count.)

Table 3. Reason for facility closures since April 2001 (as of October 2004)

Reason	Number of Facilities Closed	% of Total
Financial	523	33.5
Moved to sister site	370	23.7
Equipment	173	11.1
Staffing	161	10.3
Unknown	159	10.2
Other	84	5.4
Bankruptcy	34	2.2
Change in ownership	30	1.9
Mobile unit merged with another site	29	1.9
Total	1563	*

It is also important to note that 938 new facilities accredited with the ACR during this time period. These "new" facilities include 127 California-accredited facilities (which had never been accredited with the ACR before) who transferred their accreditation to the ACR after the state of California ceased accreditation activities in May 2004. Excluding these California facilities, this represents a net loss of 752 facilities since April 2001.

Although there are currently three other FDA-approved accrediting bodies, the ACR's Mammography Accreditation Program is by far the largest, accrediting over 90% of the mammography facilities in the United States. As of October 1, 2004, 13,188 mammography units at 8482 facilities are actively participating in the ACR mammography accreditation process; 12,729 units at 8325 facilities are fully accredited by the ACR.

ACCREDITATION RESULTS

Between 2001 and 2003, 15,477 mammography units completed their first attempt at accreditation either for the very first time (initial accreditation) or for renewal. Over 86% of all first-attempt final reports between 2001 and 2003 passed. Over 13% were deficient. After a second attempt, 88.2% of the applicants that completed the process passed resulting in a 96.7% overall pass rate for the 15,477 units (Table 4).

McLelland *et al.* [3] reported that 70% of the 2954 mammography units completing the accreditation process between 1987 and 1991 (when the program was still voluntary) passed on their first attempt. This first-attempt pass rate did not change significantly in 1994 and 1995, as all facilities in the United States were required to accredit their mammography units under the FDA's interim rules (Table 5). This is surprising because it would be reasonable to assume that facilities voluntarily seeking accreditation would be the higher performers. It is also interesting to note that, when the program was voluntary, 31.3% of the units that did not pass accreditation dropped out rather than correct the identified deficiencies and reapply for accreditation. There are no data

Table 4. Unit pass rates for all accreditation (i.e., initial plus renewal)

	First Attempt			Second Attempt		
		Pass		Pass		
Report Year[a]	Total[a]	No.	%	No.	%	% Pass Overall[b]
2001	4563	3771	82.6	516	87.5	94.0
2002	5448	4769	87.5	538	88.5	97.4
2003	5466	4828	88.3	541	88.7	98.2
Sum	15,477	13,368	86.4	1595	88.2	96.7

[a]Units with first-attempt accreditation reports written in designated year. Although repeat attempt reports may be written in following years, their results are included in the first-attempt report year.
[b]Overall pass rate for all units with first-attempt reports written in designated year [(first + second)/total issued first-attempt reports].

available to determine if the facilities continued to perform mammography with these units. In 1994, a smaller percentage (22.2%) of units not passing their first accreditation attempt dropped out. Because FDA regulations at this time [5] required all units to be accredited, it is reasonable to assume that these units were not used for mammography. In 1994, those units repeating accreditation had a markedly higher pass rate (94.4%) relative to those repeating accreditation from 1987 to 1991 (87.5%).

After 1996, when the vast majority of mammography facilities had become accredited and certified under MQSA, there was a marked increase in first-attempt pass rate (85.7%). Although there has been some fluctuation in pass rates since 1996, this higher pass rate has generally been maintained to the present. The slight decrease in pass rate noted in the late 1990s may partially be due to the tighter clinical image review criteria described in the 1999 ACR *Mammography Quality Control Manual* [9] and the tighter requirements for equipment published in the new FDA regulations [6]. In 2003, 88.3% of the 5466 mammography units completing the accreditation process passed on the first attempt. This 18% improvement in pass rate is indicative of an overall improvement in the quality of mammography in the United States as a result of ACR mammography accreditation and MQSA. It is also important to note that accreditation standards for passing had not been lowered over this time.

Another important aspect of accreditation is whether the facilities that did not pass on their first attempt sufficiently improve their performance to pass on their second attempt. McLelland *et al.* [3] reported that 609 of the units that failed to pass between 1987 and 1991 reapplied for accreditation after correcting their deficiencies and 87.5% passed. Overall, 88.1% of the units applying for accreditation passed after their first or their second attempt. Of the units that did not pass in 2003, 610 reapplied after correcting their deficiencies and 88.7% of them passed resulting in an overall pass rate of 98.2%. Since the beginning of the program, there is a higher pass rate among units reapplying for accredita-

Table 5. ACR Mammography Accreditation Program unit pass rate history

	First Attempt			Second Attempt			
		Pass			Pass		
Year of First-Attempt Report	Total	No.	%	Total	No.	%	% Pass Overall
1987 to 1991 [3]	2954	2068	70.0	609	533	87.5	88.1
1994	3929	2751	70.0	917	866	94.4	92.1
1995	5712	4162	72.9	1248	1129	90.5	92.6
1996	4736	4061	85.7	620	545	87.9	97.3
1997	4706	3934	83.6	680	643	94.6	97.3
1998	5428	4275	78.8	949	794	83.7	93.4
1999	5305	4166	78.5	766	632	82.5	90.4
2000	4923	3995	81.1	722	640	88.6	94.1
2001	4563	3771	82.6	590	516	87.5	94.0
2002	5448	4769	87.5	608	538	88.5	97.4
2003	5466	4828	88.3	610	541	88.7	98.2

Table 6. ACR Mammography Accreditation Program unit pass rates: initial vs. renewal

Year of First-Attempt Report	First Attempt: Initial Accreditation			First Attempt: Renewal Accreditation		
		Pass			Pass	
	Total	No.	%	Total	No.	%
1994	3879	2707	69.8	50	44	88.0
1995	5256	3788	72.1	456	374	82.0
1996	1694	1412	83.4	3042	2649	87.1
1997	2017	1721	85.3	2689	2213	82.3
1998	2455	1995	81.3	2973	2280	76.7
1999	2267	1851	81.6	3038	2315	76.2
2000	1644	1369	83.3	3279	2626	80.1
2001	1625	1420	87.4	2938	2351	80.0
2002	1937	1717	88.6	3511	3052	86.9
2003	1747	1550	88.7	3719	3278	88.1

tion, suggesting that facilities do improve their performance once deficiencies have been pointed out (Table 5).

Table 6 and Fig. 5 show that during the early years of MQSA, there was a significantly higher pass rate for units renewing their accreditation relative to units undergoing initial accreditation. For example, in 1994, renewing units had an 88% pass rate, whereas those undergoing initial accreditation passed at a rate of only 69.8%. This also supports the conclusion that accreditation and MQSA have improved mammography quality. In 1994, the units undergoing initial accreditation were primarily located at facilities that had never been accredited and were mandated by regulation to seek accreditation. However, a shift occurred after 1997; units applying for initial accreditation now had a slightly higher pass rate than those renewing. At this point, many older, poorer quality mammography units were being replaced at existing, accredited and certified facilities by newer, higher quality units that met all of the FDA regulations. These new units had to undergo initial accreditation and contributed to the higher pass rates. For example, in 2001, the year before the new FDA equipment requirements went into effect [6], 1625 units completed initial accreditation and 88.6% passed. The vast majority of these were new units. During the same year, only 80% of the units renewing their accreditation passed.

Another indication of quality improvement is the number of scheduled on-site surveys conducted at facilities after a third unsuccessful attempt at accreditation. In 1996, when the policy was initiated, the ACR needed to conduct 32 site visits. Although the numbers are low and fluctuate each year (possibly for reasons described above) there have been fewer scheduled on-site surveys required for repeated unsuccessful accreditation attempts during recent years. In 2003, only 6 were necessary (Table 7 and Fig. 6).

In the early years of the program (1987–1991), 37% of units not passing accreditation on their first attempt had only clinical deficiencies, 42% had only phantom deficiencies, 13% had both clinical and phantom deficiencies, and 7% did not pass because of high dose [3]. Currently, the primary reason that units do not pass accreditation is a deficiency in clinical

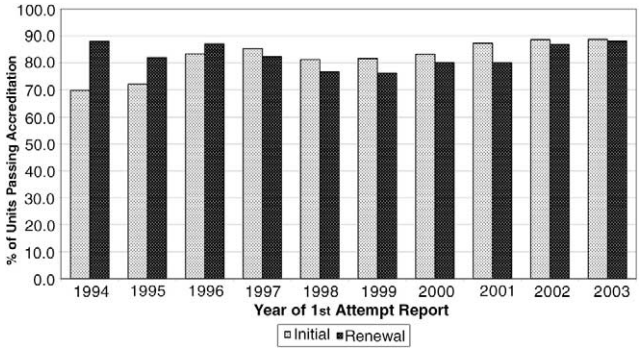

Fig. 5. Initial and renewal first-attempt pass rates since 1994.

Table 7. Scheduled on-site surveys after three unsuccessful attempts at accreditation

Year	Scheduled On-Site Surveys
1996	32
1997	18
1998	20
1999	29
2000	30
2001	15
2002	11
2003	6

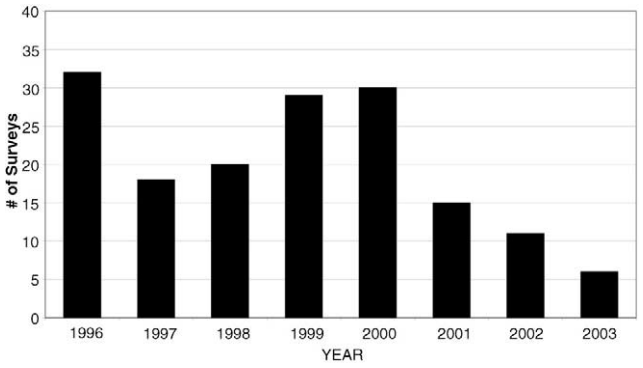

Fig. 6. Scheduled On-Site Surveys after three unsuccessful attempts at accreditation.

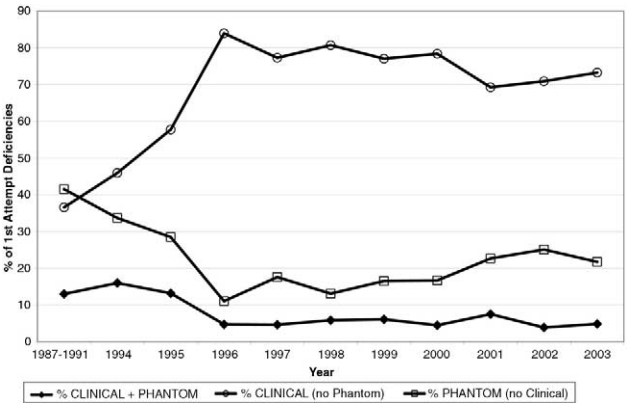

Fig. 7. Reasons for first attempt deficiencies: 1987-2003.

image quality. Over 70% of the units that were unsuccessful in their first attempt at accreditation between 2001 and 2003 had only clinical image quality deficiencies. Over 23% had only phantom image quality deficiencies and 5.5% had both clinical and phantom image quality deficiencies. Fewer than 1% did not meet the 300-mrad dose limit (Table 8 and Fig. 7). This relative decrease in the percentage of deficient phantom images is most likely due to the ACR's early educational efforts to improve quality. The most notable of these are the publication of the 1990, 1992, 1994, and 1999 editions of the *Mammography Quality Control Manual* [9]. Although problems in clinical image quality have become the leading obstacle to accreditation since 1994, Fig. 7 shows that phantom deficiencies were proportionally much higher from 1994 to 1995, suggesting that facilities have further improved characteristics tested by the phantom (e.g., contrast, resolution, and artifacts).

CONCLUSIONS

The ACR's Mammography Accreditation Program has been one of the most successful quality improvement programs in radiology. Since its inception as a voluntary program in 1987, it has improved the quality of mammography performed at facilities throughout the United States, as illustrated by the increasing pass rates described above. The FDA's regulations under MQSA that mandated accreditation ensured that these improvements not only occurred at facilities with the interest and dedication, but also at facilities that might not or would not have made this effort on their own. This ensures that all women in the United States benefit from these improvements.

Although the number of mammography units has increased since 1994, the number of mammography facilities has clearly diminished. Most facility closures have been due to financial reasons. One way of dealing with

Table 8. Reasons for unit deficiencies: first-attempt final reports

Year	Total Unit Deficiencies	Clinical and Phantom		Clinical (No Phantom)		Phantom (No Clinical)		Only Dose	
		No.	%	No.	%	No.	%	No.	%
1987 to 1991	886	115	13.0	324	36.6	368	41.5	64	7.2
1994	1164	186	16.0	535	46.0	392	33.7	2	0.2
1995	1534	202	13.2	886	57.8	437	28.5	8	0.5
1996	681	32	4.7	572	84.0	75	11.0	1	0.1
1997	780	36	4.6	603	77.3	137	17.6	4	0.5
1998	1132	66	5.8	914	80.7	148	13.1	4	0.4
1999	1151	70	6.1	887	77.1	190	16.5	4	0.3
2000	852	38	4.5	668	78.4	142	16.7	4	0.5
2001	817	61	7.5	566	69.3	185	22.6	5	0.6
2002	674	26	3.9	478	70.9	169	25.1	1	0.1
2003	640	31	4.8	469	73.3	139	21.7	1	0.2
2001 to 2003	2131	118	5.5	1513	71.0	493	23.1	7	0.3

these pressures is by consolidating mammography operations to one location. Many facilities are taking this approach. Further research needs to be done to determine if women in communities no longer being served because of these closed facilities have access to other mammography facilities within a reasonable distance.

In 2003, the National Cancer Institute's [14] *Annual Report to the Nation on the Status of Cancer, 1975-2001* reported that the incidence of breast cancer had increased by 0.4% per year between 1987 and 2001. The institute attributed this to the increased use of mammography and possibly an increased prevalence of obesity and use of hormone replacement therapy. The institute also reported that there had been a 12.5% gain in 5-year survival for breast cancer patients since the mid-1970s. The improvement in survival rate was partly attributed to early detection and partly to the use of hormonal and adjuvant chemotherapies. In addition, Taplin *et al.* [15] investigated the association between clinical image quality (using similar criteria to those described in this paper) and breast cancer occurrence within 24 months of a negative mammogram. The authors concluded that failures in positioning (and sharpness in some cases) were associated with subsequent interval cancers and may reduce the sensitivity of mammography. There is reasonable evidence to support the position that the improved quality of mammography in the United States as a result of accreditation and MQSA coupled with an increase in annual screening compliance have contributed to this early detection and improved survival.

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