

Department of Health and Human Services

**OFFICE OF
INSPECTOR GENERAL**

**LESSONS FROM INSPECTIONS OF
MAMMOGRAPHY FACILITIES**



JUNE GIBBS BROWN
Inspector General

MAY 1994
OEI-05-92-00300

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EXECUTIVE SUMMARY

PURPOSE

This report examines the on-site inspection process of Medicare screening mammography facilities. The report also discusses lessons learned from Medicare that the Food and Drug Administration (FDA) should consider in the implementation of the Mammography Quality Standards Act (MQSA) of 1992.

BACKGROUND

There are approximately 11,000 mammography facilities in the United States today. Currently, these facilities operate under a patchwork of Federal, State, and voluntary programs that monitor the safety and quality of mammography services they provide.

Federal regulation of mammography is mainly the responsibility of FDA and the Health Care Financing Administration (HCFA). In the past, FDA provided limited oversight of mammography by ensuring the proper manufacture and installation of all mammography equipment. The HCFA regulates screening mammography by requiring facilities meet quality standards in the areas of equipment, personnel qualifications, and documentation. There are approximately 6,800 Medicare-certified screening mammography facilities. In August 1992, HCFA began conducting on-site inspections of mammography facilities through the States' survey and certification agencies.

In October 1992, Congress passed the Mammography Quality Standards Act (MQSA). Whereas Medicare's regulations only cover those facilities receiving Medicare reimbursement and only for screening mammography, MQSA mandates that all facilities providing mammography services, whether screening or diagnostic, meet minimum quality standards, or run the risk of fines and sanctions including the closure of the facility.

The FDA is responsible for developing the regulations and implementing the new legislation which will prohibit any mammography facility without a certificate from operating as of October 1, 1994. By October 1, 1994, HCFA plans to amend the Medicare screening mammography regulations to cross-reference FDA's MQSA standards.

METHODOLOGY

We gathered data from the people responsible for the inspection of mammography facilities. We obtained data about: 1) the number of Medicare-certified facilities; 2) the length of time and cost of doing on-site inspections; 3) the training the inspectors received; and, 4) the results of the inspections. We spoke with personnel from 87

inspected facilities and analyzed data from HCFA's Online Survey and Certification and Reporting system entered through August 31, 1993.

FINDINGS

States began routine on-site inspection of mammography facilities in September 1992; by August 1993, States inspected about 44 percent of the certified facilities.

The HCFA requires that 100 percent of facilities be inspected annually. Some States have completed 100 percent of their inspections while other have completed few inspections.

Eighty-six percent of the inspected facilities failed at least one requirement. Less than 5 percent of the deficiencies were considered serious. Most facilities corrected their deficiencies.

Fifteen facilities have been terminated from the Medicare program, while 228 have voluntarily dropped out. Three areas make up 79 percent of facility failures: duties of the physician consultant, aspects of quality assurance, and the written report sent to the patient and referring physician.

State inspectors say that facilities' unfamiliarity with Medicare's regulations is the biggest problem encountered during inspections.

Respondents from 34 States said that the facilities inspected so far were unfamiliar with Medicare's regulations. Thirty-nine of 87 facility respondents said they received no information about the inspection before it occurred.

The HCFA's experience with the Medicare program provides valuable lessons for FDA as they implement the Mammography Quality Standards Act. These lessons relate to:

- The FDA's plans to implement MQSA by October 1, 1994.
- The development and dissemination of the regulations for MQSA.
- The capacity to inspect all mammography facilities on an annual basis.
- The development of a management information system.

RECOMMENDATIONS

In light of our findings, we make recommendations both to HCFA and FDA regarding implementation of the Mammography Quality Standards Act. We believe that FDA has made significant progress towards the successful implementation of MQSA, including a public conference with the mammography community to discuss the implementation of MQSA. The FDA published interim final regulations for the quality standards and the accrediting bodies in December 1993. In addition to these

efforts, we believe that in the interim period before implementation, both HCFA and FDA need to coordinate their work to ease the transition for mammography facilities.

To ensure the smooth implementation of MQSA, HCFA and FDA should:

- reach agreement on the role of HCFA's screening mammography certification program in the interim period before full implementation of MQSA.

The HCFA inspections could be used to educate Medicare certified mammography facilities on the new requirements of MQSA. It would also allow inspectors to increase their familiarity with the MQSA requirements.

To effectively target current areas of concern while implementing MQSA, FDA should:

- ensure that facility personnel are aware of and thoroughly trained on MQSA's requirements;

While FDA has begun educating the mammography industry on MQSA's requirements, further efforts might be made to ensure that personnel involved in the day to day operation of the mammography units are trained on the requirements. For example if funds were available, FDA could provide training funds to States to educate the provider community on the new regulations, or work with private entities like the ACR, medical societies, and professional organizations to educate their members.

- examine ways to perform the most effective and cost-efficient inspections which still adequately enforce the regulations (given that the law requires an annual on-site inspection of all mammography facilities);

Potentially, inspections could be prioritized or targeted to ensure that the facilities with little prior regulation, or a history of problems, are inspected first. Another possibility includes designing streamlined inspections for facilities with a proven compliance record. The FDA should use current inspector's experiences in conducting HCFA's on-site inspections to develop FDA's inspection protocols.

- develop a management information system that allows for continuous monitoring of State inspections agency performance and facility compliance and distinguishes between documentation non-compliance and performance non-compliance.

We understand that FDA has begun developing a management information system for MQSA. We believe the system developed must be able to distinguish between documentation non-compliance and performance non-compliance.

AGENCY COMMENTS

We received comments on our draft report from FDA and HCFA. Both FDA and HCFA concur or concur in principle with the recommendations presented in our report. Many of the recommendations are already being implemented by FDA as part of their implementation of MQSA. Each set of comments are presented in Appendix C.

We have made a number of changes to the report based on the agencies' comments. We also have provided additional information which FDA requested.

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INTRODUCTION

PURPOSE

This report examines the on-site inspection process of Medicare screening mammography facilities. The report also discusses lessons learned from Medicare that the Food and Drug Administration (FDA) should consider in the implementation of the Mammography Quality Standards Act (MQSA) of 1992.

BACKGROUND

There are approximately 11,000 mammography facilities in the United States today. Currently, these facilities operate under a patchwork of Federal, State, and voluntary programs which monitor the safety and quality of mammography services.

State Standards and Voluntary Accreditation

Most States monitor the radiation safety of all X-ray imaging equipment including mammography units. Additionally, at least 10 States* have their own quality assurance standards for mammography. Although these standards are not identical, most set minimum quality standards in areas of radiation exposure, equipment specifications, quality control programs and personnel qualifications.

Since 1987, the American College of Radiology (ACR) has operated a voluntary accreditation program for screening and diagnostic mammography providers. As of April 4, 1994, ACR had accredited 6,184 facilities and had pending accreditation for 2,572 facilities. The accreditation process takes about 6 months to complete and occurs entirely by mail. The ACR has begun an on-site inspection audit of a sample of their accredited facilities.

Federal Role in Mammography

Various Federal agencies are involved in mammography issues. The National Institutes of Health perform and fund research on breast cancer as well as access to mammography services. The Centers for Disease Control and Prevention (CDC) provides grants to States for breast and cervical cancer screenings for low-income women. Facilities approved for CDC grant money must have Medicare certification as well as ACR accreditation. In addition, CDC has provided training for inspectors of

*Georgia, Indiana, Iowa, Kentucky, Maryland, Massachusetts, Michigan, North Carolina, Utah, and Vermont - as reported in the Committee on Labor and Human Resources Senate Report 102-448 on the Mammography Quality Standards Act of 1992.

mammography facilities. The Agency for Health Care Policy and Research is currently developing clinical guidelines for the provision of mammography.

Federal regulation of mammography is mainly the responsibility of FDA and the Health Care Financing Administration (HCFA). In the past, FDA provided limited oversight of mammography by ensuring the proper manufacture and installation of all new mammography equipment. The FDA did not routinely monitor the subsequent use of the equipment although FDA has obtained information from the Conference of Radiation Control Program Directors (CRCPD) concerning mammography use. Individual States, using CRCPD's Nationwide Evaluation of X-ray Trends survey protocols have measured patient radiation exposures and assessed phantom image quality.

The HCFA regulates facilities performing screening mammographies for Medicare patients. Screening mammography facilities must meet minimum quality standards to receive Medicare reimbursement. These minimum quality standards do not, however, apply to facilities performing diagnostic mammography.

The HCFA published interim final regulations on December 30, 1990, about 10 weeks after the passage of the legislation. The HCFA has not yet published final regulations for screening mammography for several reasons including Departmental concerns over Medicare's regulation concerning xerography equipment, and the enactment of MQSA.

According to the Medicare quality standards, facilities must use personnel who meet criteria on education, experience and certification. Mammography equipment must be dedicated (specifically designed for mammography), and meet other technical specifications. Film processing equipment must also meet certain standards, and be monitored daily. Facilities must also carry out an internal quality assurance program, which includes periodic testing of equipment, annual review by a qualified medical physicist, continuing education for personnel, and record keeping. Facilities must document that they meet all the requirements.

To receive reimbursement for screening mammograms after January 1, 1991, facilities had to meet Medicare's quality standards. To expedite the process of certifying facilities, HCFA allowed facilities to attest in writing that they met Medicare's standards. From January 1991 to September 1992, about 6,500 facilities attested that they met Medicare's quality standards. On-site inspections were only done in cases where a complaint was filed against a facility.

In August 1992, HCFA eliminated the attestation process and began conducting on-site inspections of mammography facilities through the States' survey and certification agencies. Because of the technical component of these inspections, HCFA encouraged the agencies to contract (or develop memorandums of agreement) with the radiation control units in their States to do all or some of the inspections.

In July and October 1992, HCFA provided a 1 week training course for the States on the inspection process. The FDA provided training on the technical aspects of testing mammography x-ray equipment. The HCFA trained attendees on the review of credentials and documentation. Training was also provided in May 1993 in cooperation with the Conference of Radiation Control Program Directors (CRCPD.)

The Mammography Quality Standards Act of 1992

In October 1992, Congress passed the Mammography Quality Standards Act. Congress felt that the current patch work of Federal, State, and voluntary programs did not ensure quality mammography to all women. Whereas Medicare's regulations only cover those facilities receiving Medicare reimbursement, and only for screening mammography, and whereas the ACR program only covers facilities that voluntarily apply for accreditation, MQSA mandates that all facilities providing mammography services, screening or diagnostic, meet minimum quality standards, or run the risk of fines and sanctions including the closure of the facility. The legislation also requires that all facilities be inspected by qualified inspectors.

The Senate Committee on Labor and Human Resources Report strongly suggested that responsibility for the new legislation be given to the Public Health Service. The FDA is responsible for developing the regulations and implementing the new legislation which will prohibit any mammography facility without a certificate from operating as of October 1, 1994.

By October 1, 1994, HCFA plans to amend the Medicare screening mammography regulations to cross-reference FDA's MQSA standards. Therefore, facilities that meet the mandatory MQSA standards will automatically be qualified to participate in the Medicare screening mammography program.

METHODOLOGY

Preinspection

In designing this study, we spoke with staff from HCFA, FDA, CDC, the General Accounting Office, the National Cancer Institute and the Assistant Secretary for Planning and Evaluation. In addition, we spoke with representatives from ACR, the CRCPD, the National Electronic Manufacturing Association, the American Cancer Society, the American Hospital Association, the Joint Commission for Accreditation of Health Organizations, a mammography machine manufacturer and a screening mammography provider. We attended mammography sessions at the Radiological Society of North America's national convention. We visited the State of Maryland and contacted the State of Illinois to discuss their Medicare inspection process. We reviewed literature about reimbursement, quality, and access for screening and diagnostic mammography. We also reviewed legislation involving the Medicare screening benefit and MQSA.

Data Collection

We gathered preliminary information from the 50 States, the Commonwealth of Puerto Rico and the District of Columbia (all referred to as States) about their Medicare mammography inspections. After that initial contact, we formally interviewed personnel responsible for the inspection of mammography facilities in 48 States - 45 by telephone and 3 on-site. We did not formally interview survey and certification agencies in four States because they had not yet done any inspections.

From the personnel responsible for the inspections, we obtained demographic information about the number of certified facilities, the length of time and cost of doing the inspections, information about the training the inspectors received, results of the inspections, the inspectors' impressions of the inspected facilities, and suggestions on areas of improvement.

We also requested complete data on the mammography facilities inspected including whether the facility originally attested to the Medicare requirements, name of a contact person and any conditions out of compliance. Not all the information received was complete. One State chose not to return this information.

We also contacted the radiation control agencies in the States and interviewed representatives in these agencies about their involvement with Medicare inspections, other mammography related inspections in the State, and the implementation of MQSA. One State did not have a radiation control agency.

We interviewed personnel in two inspected mammography facilities in each State where inspections were ongoing. In a few States, only one inspection had occurred and we contacted that one facility. We contacted a total of 87 facilities in 47 States. Fifty-one percent of these facilities were ACR accredited, 32 percent were in the ACR accreditation process and 7 percent were planning to apply for ACR accreditation. Ten percent of the facilities were not planning to apply for ACR accreditation. We spoke mainly with technicians and mammography administrative personnel - those staff who had the most contact with the surveyors at the time of the inspection.

We visited Georgia, Louisiana and Michigan. Where applicable, we interviewed staff at the State survey and certification agencies and at the radiation control agencies. We accompanied an inspector on an inspection of a mammography facility in each State. We conducted interviews at two inspected facilities in each State.

We also obtained screening mammography inspection data from HCFA's Online Survey and Certification and Reporting (OSCAR) system entered through August 31, 1993. This system allows for online data entry by State agencies and HCFA regional offices. The States are allowed up to 60 days after the inspection to input data in OSCAR. To check the OSCAR reliability, we randomly compared data collected directly from the States to OSCAR data. Our tests of the data revealed minor inconsistencies, omissions or other errors. However, when these data are viewed in

context with other available evidence, we believe the findings and recommendations in this report are valid.

SCOPE

This report discusses issues of the on-site inspection of mammography facilities under HCFA's Medicare screening quality standards. In addition, this report discusses issues that FDA must address to implement MQSA.

This report does not discuss what constitutes a quality mammogram, nor the appropriate cost of a mammogram.

This study was conducted in accordance with the *Quality Standards for Inspections* issued by the President's Council on Integrity and Efficiency in March 1993.

FINDINGS

States began routine on-site inspection of mammography facilities in September 1992; by August 1993, States inspected about 44 percent of the certified facilities.

Before September 1992, States only inspected facilities for HCFA in the case of a complaint. The HCFA now requires that inspections be performed annually at all facilities. By August 1993, States inspected about 44 percent (3,000/6,791) of Medicare certified mammography facilities. States conducted inspections ranging from a low of 2 percent to a high of 100 percent of their facilities. The reasons for this wide range vary. Some States were already conducting comprehensive reviews of mammography so enacting the Medicare surveys took little extra effort. Other States had never conducted extensive mammography reviews, had other surveys to conduct that competed with the mammography inspections, and/or experienced difficulty contracting with technical staff to conduct parts of the inspection.

In an August 1992 guidance to States, HCFA encouraged State survey and certification agencies to seek help from the radiation control agencies to conduct the inspections. Thirty-three States conduct inspections using a combination of staff from survey and certification and radiation control agencies. The survey and certification agency conducts the non-technical (documentation review) while the radiation control agency conducts the technical portion (machine review). The inspection is either completed as a joint review or as two separate reviews. For the remainder of the States, either the entire inspection process has been contracted to the radiation control agency or the survey and certification agency has hired or contracted with a radiological physicist. (See Appendix A.)

Most States choose facilities to inspect based on their geographic location. For example, they will inspect all the facilities within a given area, such as a county, or the northern region of their State. Originally per HCFA's instructions, inspections were unannounced. However, HCFA revised its policy, allowing up to 2 days notice because of complaints that unannounced inspections disrupted patient schedules. Some States will only announce the technical portion of the inspection and still conduct the non-technical portion unannounced.

During the technical portion of the inspection, the inspector measures radiation dosage, takes phantom images, and may perform other tests for the State that make the machine unavailable for patient use for at least 1 hour and up to 4 hours. In addition, the inspector reviews the quality control logs and manuals for the imaging equipment and the film processor. The inspector also reviews the policy and procedure manuals, staff credentials, and all other pertinent documents. A facility's mammography technician generally accompanies the inspector during these reviews. According to our facility respondents, there is a great deal of interaction between the technician and the inspector during the on-site inspection, which averages 7 hours.

The average for an overall inspection, which includes follow-up visits and paperwork, is 25 hours. The cost of an inspection averaged \$950 with a range of \$200 to \$2,800.

Few facility respondents expressed problems with the actual inspection. Furthermore, 61 facility respondents said the inspection helped their facility do some things better, such as preparing a policy and procedures manual. However, some complained that inspections interrupted patient care. In a few cases, unannounced visits were chaotic because the lead mammography technician was not in the facility that day.

Eighty-six percent of the inspected facilities failed at least one requirement. Less than 5 percent of the deficiencies were considered serious. Most facilities corrected their deficiencies.

Eighty-six percent of the inspected facilities failed to meet one or more of HCFA's requirements, with an average of 13 deficiencies per facility.** Less than 5 percent of all deficiencies found in the facilities are for conditional level (considered serious) deficiencies. The great majority of facilities correct their deficiencies and continue to supply screening mammography to Medicare beneficiaries.

According to recent HCFA information, 15 facilities have been terminated from the Medicare screening program, while 228 facilities have voluntarily dropped out because they could not correct their deficiencies or for other reasons. These facilities are still eligible to receive Medicare reimbursement for diagnostic mammography. Although as of October 1, 1994, all mammography facilities will be subject to quality standards regardless of reimbursement.

Few facilities are failing to meet HCFA's mammography requirements for safety and equipment specifications. Only two State respondents said that the common use of non-dedicated or unsafe imaging equipment was a problem. Overall, 20 percent of facilities failed to meet equipment standards, (most for not adhering to manufacturer's specified developer temperature) and 10 percent failed safety standards. This accounted for just under 1.5 percent of all conditional level deficiencies.

According to HCFA's OSCAR data, three areas in particular accounted for 79 percent of facility deficiencies. These were duties of a physician consultant, the written report sent to the patient and referring physician, and aspects of quality assurance. Each are explained below. (See Appendix B for a list of regulations and number of facilities out of compliance with a condition or standard.)

** We based our analysis of deficiencies on information contained in OSCAR. As of August 31, 1993, 1,394 facilities had at least one deficiency out of 1,615 facilities input into OSCAR. States are allowed up to 60 days after the inspection to input data into OSCAR.

Duties of the Physician Consultant

Sixty-three percent of inspected facilities in some way failed the physician consultant requirement. The HCFA requires that a screening mammography facility employ or contract with a physician consultant to oversee the entire mammography process. Six States reported that many facilities in their States were unaware of the physician consultant's responsibilities.

Among various duties, HCFA requires that the physician consultant observe the technicians' technique and positioning of a patient on a monthly basis. At 53 percent (859 facilities), this is the requirement most often failed. Thirty percent of our facility respondents told us they failed the physician consultant requirement because the physician consultant did not observe a technician on a monthly basis to evaluate their positioning and technique. In some cases, facilities reported that a physician consultant was observing the technician on a monthly basis but it was not documented in the procedures manual.

Some State and facility respondents thought there was little value added to the quality of a screening mammogram by having the physician consultant observe the technician. Some of these respondents said that the physician consultant was not sufficiently trained to comment on the technician's positioning and technique.

Typical of the comments we heard was one facility's letter to a State in which they wrote, "A radiologist is trained to interpret images and to evaluate the quality of the images based on the images themselves. The only current formal training available to a radiologist that allows actual hands-on position training for mammography is Tabar's Level 3 course, and even those of us who have taken that course are not qualified to critique our technologist's positioning technique except by review of the images themselves." Other facility respondents stated that many women feel uncomfortable having another person present while a technician performs a mammogram.

Other physician consultant duties that facilities often fail include:

- physician consultant signs off on the procedures manual, 39 percent;
- physician consultant verifies that equipment and procedures meet all Federal, State, and local regulations, 32 percent, and;
- physician consultant assures that safe operating procedures are used, 30 percent.

It is possible that physicians are performing these duties in their facilities. However, the documentation did not exist to verify it. Furthermore, although many facility respondents expressed frustration with specific required physician consultant duties, some of the technicians were pleased that the regulations required that the radiologist be involved with quality assurance activities in the facility.

Written Letter Sent to Patient and Referring Physician

Fifty-eight percent of facilities failed to meet the condition of interpretation of screening mammography results. A facility could fail to meet this requirement because: 1) the interpreting radiologist was not board certified or could not provide the board certificate, 14 percent; 2) the interpreting radiologist did not have enough continuing education or did not properly document their continuing education, 27 percent; and, 3) the interpreting radiologist did not provide a written interpretation of the mammography results to the referring physician and the patient, 46 percent. In particular, 31 percent of inspected facilities were cited for not providing a written statement to the patient.

Within a typical mammography practice, a radiologist provides a written interpretation of the mammography's results to the patient's referring physician. Rarely does a patient directly receive a written interpretation of the results. However, because a patient may receive a screening mammogram through Medicare without a physician's referral, the Medicare regulations require that in addition to the usual written interpretation for the referring physician, the radiologist must also provide a statement to the patient explaining the findings of the mammogram in lay terms. This statement may be sent directly to the patient or through the referring physician. Seventeen State respondents said that at the time of the inspection, many facilities were unaware of HCFA's requirement that a written statement be given to the patient.

Some facility respondents were concerned that the written statement may interfere with the patient's relationship to her referring physician. These facility respondents said many referring physicians prefer to discuss the findings with their patient without the direct interpretation of the radiologist. Furthermore, many State respondents believe enforcing this requirement is difficult because they do not review whether the referring physicians are giving the radiologist's written statement to the patient.

Quality Assurance (QA) Monitoring

Sixty-two percent of inspected facilities were cited for quality assurance requirements. Most of the failures (42 percent) occurred because facilities were not routinely monitoring such things as automatic exposure (212 facilities), darkroom integrity (137), output reproducibility (133), and film storage adequacy (104).

Other failures in the quality assurance area include:

- direct assignment of quality assurance activities to responsible personnel (such as a technician), 29 percent;
- responsibility of overall quality assurance program to a qualified physicist (including an annual review), 26 percent, and;
- evaluation of monitoring results, 23 percent.

Unfortunately, it is difficult to determine if the number of quality assurance failures in HCFA's OSCAR data reflect a substantive problem in this crucial area of mammography. Few State inspectors told us that they saw actual problems with quality assurance in the facilities they had inspected.

It is possible that many of these procedures are being performed, but are not properly documented. The Medicare regulations, and thus the OSCAR data, does not make that distinction. Nevertheless, documentation of such activities are often the only way that inspectors have of determining the presence of quality assurance activities. Furthermore, a lack of documentation of QA process measurements prevents trend analysis which is essential to a QA program. The high number of deficiencies in this area warrants additional study.

State inspectors said that facilities' unfamiliarity with Medicare's regulations is the biggest problem encountered during inspections.

Thirty-four State respondents said inspected facilities were unfamiliar with the Medicare regulations before the inspection. Nineteen State respondents specifically said the reason for the unfamiliarity was that the radiologist or technician in charge of the mammography unit did not see the regulations or interpretive guidelines before the inspection. In many cases, these inspectors thought the attestation statement was signed by financial or administrative personnel but the attached regulations were never forwarded to the radiologist or technician in charge.

During two inspections we observed, the facility personnel were flustered and apparently unaware of the Medicare regulations. At one of the facilities, the State inspector gave the mammography technician a copy of the facility's attestation statement. The technician said it had been signed by someone in accounting. At the other facility, the State inspector gave a copy of the regulations and interpretive guidelines to the technician and radiologist who also claimed they had not seen them. In this case, the facility had many deficiencies that led to a denial of their initial application for Medicare certification.

Sixty-three percent of the facility respondents were aware that the State would inspect them for compliance with Medicare regulations. However, 45 percent of facility respondents (who were primarily mammography technicians and supervisors) said they had not received information about the regulations.

In addition, seven State inspectors said facilities were often confused and thought Medicare requirements were the same as ACR requirements. Many mammography facilities are freestanding clinics or doctors' offices that have never been regulated or undergone any kind of inspection.

Two State respondents said that special educational efforts by their States, such as seminars for the facilities, ensured that the facilities were prepared for the inspection.

These educational efforts took place after the first few inspections in their States showed that facilities were unprepared for a HCFA survey.

The facilities' initial unfamiliarity with Medicare requirements contributed to unnecessary noncompliance by the facilities. This in turn required that the State inspectors spend additional time and effort filling out paper work and conducting follow-up visits.

The HCFA's experience with the Medicare program provides valuable lessons for FDA as they implement the Mammography Quality Standards Act.

The FDA's plans to implement MQSA by October 1, 1994.

- What are FDA's current activities to implement MQSA?

The FDA was not given the authority to implement MQSA until June 1993. Since then, FDA has formed the Division of Mammography Quality and Radiation Programs within the Center for Devices and Radiological Health. In September, FDA sponsored a public conference on MQSA. The many issues discussed at this conference serve to illustrate the complexity of this legislation, and the need for careful MQSA implementation.

The FDA published interim final regulations for the requirements for accrediting bodies of mammography facilities and the quality standards and certification requirements for mammography facilities on December 21, 1993. These regulations took effect 60 days after their publication. The interim final regulations will be used as the basis for certifying mammography facilities - and all mammography facilities in the United States must be certified by October 1, 1994 in order to lawfully operate. Furthermore, under MQSA, facilities must be accredited by a private non-profit agency or a State agency which has been approved by the Secretary.

Because the FDA has based their interim regulations on the standards currently used by ACR, facilities with ACR accreditation automatically qualify for MQSA certification. (There are few States which are in a position to accredit facilities in their State.) Currently, 6,184 facilities have units that have been accredited by ACR and 2,572 more are in ACR review. However, according to our conversations with ACR, a thorough accreditation process takes about 6 months to complete. Therefore, approximately 2,000 or more facilities in the country will need to apply for ACR accreditation within the next few months and be accredited by October 1, 1994 in order to be certified under MQSA. This is a substantial challenge for ACR. The FDA must address how facilities that did not apply to the ACR (or perhaps their State) for accreditation will be handled after October 1, 1994.

Another issue that FDA faces is that some facilities may not be able to afford ACR or State accreditation fees and proposed inspection fees, in addition to the operating costs (which includes medical physicist charges) of providing mammography services.

In August 1993, FDA announced the formation of a national mammography advisory committee. This committee will advise FDA on various issues, including the cost of MQSA for facilities, the development of final MQSA quality standards and regulations for facilities and an accrediting body, and the development of sanctions.

Development and dissemination of the regulations for MQSA.

- What are the appropriate duties of the interpreting physician, the radiologic technician, and the medical physicist in ensuring quality mammography?

The OSCAR data we analyzed, as well as our interviews with State inspectors and facility personnel, indicate that HCFA regulations do not completely reflect current industry practice regarding the duties of the physician consultant. The data shows that facilities are not meeting Medicare's requirements for physician consultant duties. Specifically, our respondents questioned the need for physicians to observe a technician's positioning and technique on a monthly basis.

Respondents also questioned the need for a contract between a physician and a facility which outlines the required specific duties of the physician. They stated that in many cases physicians do not work on-site at facilities, but have films sent to them. However, a few mammography technicians we spoke with did express satisfaction with Medicare's strict requirements for the physician consultant. They were pleased that the radiologist finally had to get involved with quality assurance.

Our interviews and on-site observations at several facilities indicated the radiologic mammography technician has most day-to-day control over the production of clear images in the facility. These are the people who work with the patients, develop the film, and conduct the quality assurance monitoring. Facility respondents stressed the importance of the technician's qualifications and continuing education in the provision of mammography.

Also, some State inspectors and facility personnel were concerned with the lack of qualified medical physicists to review all mammography facilities. This concern was further complicated by Medicare's requirement that overall responsibility for an equipment quality control program be assigned to a medical physicist. Some medical physicists thought this made them liable for any problems, and therefore were reluctant to perform these duties for Medicare-certified facilities.

Although MQSA emphasizes image quality, MQSA also requires standards for personnel involved in the provision of mammography. The HCFA's experience regarding personnel qualifications and duties could provide useful lessons to FDA as they refine these regulations.

- How can FDA minimize the many and/or varied requirements that facilities must meet, but still ensure quality mammography?

For the facility respondents who offered an opinion about MQSA, most said that the new regulations should complement State and ACR guidelines. Eighteen facility respondents expressed current frustration with trying to meet the varied requirements of different organizations and agencies. They wanted one requirement that would meet everybody's requirements and thus reduce the amount of needed documentation. By modeling the interim final regulations on current ACR standards, the FDA has addressed some of the facility respondents' concerns. The FDA is also familiar with various State standards. Because MQSA must set the national standard for mammography facilities, there may be some cases where a State's standards are significantly different or more stringent than MQSA. In these cases, the State inspectors (and perhaps the consulting physicist) will bear most of the responsibility for instructing the facilities in their State on what the facilities must do to meet both MQSA and State standards.

- What methods will successfully disseminate appropriate information about MQSA to involved groups and individuals?

The fact that some mammography facilities have experienced regulation and on-site inspection under Medicare (and perhaps their State) helped break ground for MQSA. Also, FDA has been working to alert facilities about MQSA. In December 1993, FDA's Commissioner Kessler spoke at the Radiological Society of North America's annual conference, and the FDA presented other materials there to many interested people and groups in the radiology community. The FDA's public conference in September 1993 also helped to disseminate some initial information. In February 1994, FDA sent a quarterly newsletter, entitled "Mammography Matters," to all known mammography facilities to alert them of their need to comply with MQSA. In addition, State involvement in educating facilities will increase the effectiveness of Federal education efforts.

However, thirty-eight percent of facility respondents we spoke with either have not heard about MQSA or are unfamiliar with its intent. Some confused the Medicare regulations and MQSA. In addition, approximately 35 percent of facilities providing mammography services in the country have not applied for Medicare certification nor undergone an inspection. It is unknown how many of these facilities will apply for Medicare certification or undergo an inspection before MQSA is implemented. Facilities with minimal State and no previous Federal or ACR monitoring will be especially unfamiliar with the regulatory process and inspections under MQSA.

Although we realize that facilities are ultimately responsible for their compliance with MQSA, to avoid similar problems encountered during the Medicare inspections, we agree with the 21 State inspectors who said that facilities should be thoroughly trained on MQSA's regulations before the inspection process begins. Ensuring that the mammography technicians are well-informed and instructed is especially crucial to successful MQSA implementation, not only to the letter but to the intent of the law.

Capacity to inspect all mammography facilities on an annual basis.

- What issues must FDA address to inspect all mammography facilities on an annual basis?

The regulations under MQSA will differ from those under HCFA's program. However, both programs require annual on-site inspection of 100 percent of facilities in their programs. Even if FDA significantly lowers the on-site and overall inspection time currently expended in the Medicare inspections, the additional 4,000 facilities covered by MQSA poses a substantial challenge.

To meet the 100 percent on-site inspection requirement, the FDA must use staff in the radiation control agencies in the States. However, these agencies vary their current capacities to fulfill that charge. Until their involvement in the Medicare program, some of these agencies only conducted minimal safety inspections of radiation equipment in their States once every three years. Even under the Medicare program, most of the States radiation control staff still only conduct the machine portion inspections. Other States conduct more comprehensive reviews of mammography facilities. Furthermore, these agencies must contend with competing priorities for inspections of radiological equipment in their States.

State radiation control personnel in 32 States said they will need additional staff to enforce MQSA. Fourteen radiation control respondents said they would need two or more additional staff to cover the MQSA inspections, while 12 said they would need between one and two additional people. Six said they would need more, but did not know how many. In addition, radiation control personnel in 33 States said they would need additional equipment.

Medicare inspection experience and the apparent shortage of qualified staff and resources should spark serious discussion over ways to prioritize and streamline the inspections while still ensuring quality mammography. The FDA will need to work closely with the individual State agencies in order to identify their current capacity, projected workload, and needed staff and equipment resources.

- Will States be able to hire extra inspectors to cover the workload required by MQSA inspections?

Most of the respondents we spoke with in the States' radiation control agencies said they could hire and had room for extra staff as long as the funds were readily available for salaries and other expenses. However, there may be a time lag in hiring new staff if these States have to wait for funds generated from user fees.

However, radiation control personnel in 16 States said that there were possible constraints to expanding the staff in their agencies. Of these States, half thought that a current State hiring freeze would prevent them from expanding their agency. The

FDA may have to use their own inspectors in those States where additional staff cannot be hired or in those States where the inspectors need extensive training.

- How will FDA train all the inspectors needed to conduct the inspections?

The MQSA legislation requires that only qualified inspectors conduct on-site inspections of mammography facilities. The FDA is currently designing a two-week training course for inspectors which includes field training. Furthermore, experienced inspectors will be given the opportunity to "test out" of certain portions of the training.

Some of the State inspectors currently conducting Medicare inspections commented on the training they received from HCFA and FDA. Most expressed the need for more training in unfamiliar areas. In particular, radiation control personnel wanted more practical training on conducting paper reviews. Also, our observation of inspections and interviews with inspectors revealed that some inspectors had different ideas about their role as inspector - some inspectors viewed themselves as educators in a facility, whereas others were more concerned with strict compliance with the regulation. We hope the FDA will consider these issues when designing their training curriculum.

Development of a management information system.

- What data should be collected from MQSA inspections? How could FDA use this data to better implement and manage MQSA?

The MQSA legislation requires that States prepare and submit an annual report on the facilities inspected. We believe that such information, if continually collected and analyzed, could be highly useful for providing feedback and assistance to State inspection agencies and facilities as well as revealing the state of quality in mammography facilities. The FDA is currently developing a management information system to handle the mass of data which MQSA will generate, as well as help prepare the required reports.

The HCFA's OSCAR system is an example of such a database. The OSCAR system, however, does not always differentiate between a substantive problem as opposed to a documentation technicality. To illustrate, facilities were cited for having the operator's initials on the patient's record, as opposed to the operator's full name. The OSCAR system does not capture the fact that the operator is identified on the patient's record but failed to record their full name. The FDA's management information system should capture such differences. The HCFA's experience with inspections and with OSCAR could provide valuable information in helping to design FDA's system.

RECOMMENDATIONS

In light of our findings, we make recommendations both to HCFA and FDA regarding implementation of the Mammography Quality Standards Act. We believe that FDA has made significant progress towards the successful implementation of MQSA, including a public conference with the mammography community to discuss the implementation of MQSA. The FDA published interim final regulations for the quality standards and the accrediting bodies. In addition to these efforts, we believe that in the interim period before implementation, both HCFA and FDA need to coordinate their work to ease the transition for mammography facilities.

To ensure the smooth implementation of MQSA, HCFA and FDA should:

- reach agreement on the role of HCFA's screening mammography certification program in the interim period before full implementation of MQSA.

The HCFA inspections could be used to educate Medicare certified mammography facilities on the new requirements of MQSA. It would also allow inspectors to increase their familiarity with the MQSA requirements.

To effectively target current areas of concern while implementing MQSA, FDA should:

- ensure that facility personnel are aware of and thoroughly trained on MQSA's requirements;

While FDA has begun educating the mammography industry on MQSA's requirements, further efforts might be made to ensure that personnel involved in the day to day operation of the mammography units are trained on the requirements. For example if funds were available, FDA could provide training funds to States to educate the provider community on the new regulations, or work with private entities like the ACR, medical societies, and professional organizations to educate their members.

- examine ways to perform the most effective and cost-efficient inspections which still adequately enforce the regulations (given that the law requires an annual on-site inspection of all mammography facilities);

Potentially, inspections could be prioritized or targeted to ensure that the facilities with little prior regulation, or a history of problems, are inspected first. Another possibility includes designing streamlined inspections for facilities with a proven compliance record. The FDA

should use current inspector's experiences in conducting HCFA's on-site inspections to develop FDA's inspection protocols.

- develop a management information system that allows for continuous monitoring of State inspections agency performance and facility compliance and distinguishes between documentation non-compliance and performance non-compliance.

We understand that FDA has begun developing a management information system for MQSA. We believe the system developed must be able to distinguish between documentation non-compliance and performance non-compliance.

AGENCY COMMENTS

We received comments on our draft report from both HCFA and FDA. The HCFA agrees with our recommendation that they reach an agreement with FDA on the role of HCFA's screening mammography program. Instructions on ensuring a smooth transition from HCFA's management of the screening mammography program to FDA's management of MQSA will be sent out shortly to HCFA regional offices, Medicare State agencies and State radiation control agencies.

The FDA concurs fully or in principle with our recommendations. As part of the implementation of MQSA, FDA is already implementing or in the process of implementing our recommendations. They have held public meetings to discuss the quality standards of MQSA, provided initial training to some State inspectors, have reached an agreement with CRCPD for the States' input into the inspection process and have plans to develop a management information system. Each set of comments are presented in full in Appendix C.

We also have made a number of changes to the report based on the agencies' comments. The FDA requested additional information on some areas of our report; we have provided that information separately to FDA.

APPENDIX A

LIST OF STATES AND HOW THEY PERFORM INSPECTIONS OF SCREENING MAMMOGRAPHY FACILITIES

STATE	COMBINED AGENCY	RADIATION CONTROL AGENCY	SURVEY & CERTIFICATION AGENCY
Arkansas	X		
Arizona	X		
Alabama	X		
Alaska	X		
California		X	
Colorado		X	
Connecticut	X		
District of Columbia		X	
Delaware			X
Florida	X		
Georgia			X
Hawaii	X		
Iowa		X	
Idaho	X		
Illinois	X		
Indiana	X		
Kansas		X	
Kentucky			
Louisiana	X		
Massachusetts	X		
Maryland		X	
Maine	X		
Michigan		X	
Minnesota	X		
Missouri		X	
Mississippi	X		

STATE	COMBINED AGENCY	RADIATION CONTROL AGENCY	SURVEY & CERTIFICATION AGENCY
Montana	X		
North Carolina		X	
North Dakota	X		
Nebraska	X		
New Hampshire	X		
New Jersey	X		
New Mexico	X		
Nevada	X		
New York		X	
Ohio	X		
Oklahoma			
Oregon	X		
Pennsylvania	X		
Puerto Rico	X		
Rhode Island	X		
South Carolina	X		
South Dakota			X
Tennessee		X	
Texas			X
Utah	X		
Virginia	X		
Vermont	X		
Washington	X		
Wisconsin		X	
West Virginia	X		
Wyoming			X

APPENDIX B

**NUMBER OF FACILITIES OUT OF COMPLIANCE WITH ONE OR MORE
CONDITIONS OR STANDARDS UNDER THE SCREENING MAMMOGRAPHY
REGULATIONS.**

We obtained data from OSCAR on the results of all inspections entered through August 31, 1993. A total of 1,615 inspected screening mammography facilities were entered. Inspectors found deficiencies in 1,394 facilities. The following table breaks out the number of mammography facilities failing one or more standards or conditions after their initial inspection. Conditional level requirements are bolded.

The HCFA assigns identification numbers for data input (known as tag numbers) to various conditions and standards. The HCFA can assign more than one tag number to a standard or condition. For example, the standard for personnel orientation has 12 different tag numbers assigned for various portions of the standard. We chose to combine the tag numbers under a standard or condition. The facilities out of compliance represent a unique count of facilities failing one or more of these tags under a standard or condition. Conditions are in bold text, while standards are in normal text.

Regulation	Facilities out of compliance	Percent out of compliance
General - Must meet all the conditions in the regulations.	146	9%
Compliance with Federal, State and local laws and regulations.*	68	4%
Consultation with a qualified physician.	123	8%
Qualifications for the physician consultant.	195	12%
Physician consultant's duties	1003	62%
Interpretation of the results of screening mammography procedures.	99	6%
Board certification of interpreting physician.	232	14%
Experience and continuing education of interpreting physician.	437	27%
Written and signed report	742	46%
Qualifications and orientation of technical personnel and retention of employee records.	72	4%
Qualifications of operators of screening mammography equipment.	233	14%

Regulation	Facilities out of compliance	Percent out of compliance
Personnel orientation for mammography operators.	621	38%
Qualifications of individuals furnishing diagnostic X-ray physics support.	162	10%
Maintenance of employee records.	119	7%
Obtaining and preserving records.	108	7%
Records of screening mammography services performed by the supplier.	660	41%
Preservation of mammography records.	165	10%
Equipment Standards.	8	.4%
Equipment specifically designed for mammography.	2	.1%
FDA standards for x-ray system.	26	2%
Image receptor systems designed appropriately for mammography.	5	.3%
Developer temperature.	224	14%
kV-target-filter combinations.	38	2%
Focal spot size.	23	1%
Devices to immobilize and compress the breast.	43	3%
Standard: Anti-scatter grids.	15	1%
Automatic exposure control.	9	1%
Control panel indicators.	17	1%
Recalibration of mobile units after each relocation.	24	1%
Safety standards.	11	1%
Safety precautions.	58	4%
Exposure badges to measure radiation exposure.	27	2%
Equipment inspection.	75	5%
Protection against electrical hazards.	43	3%

Regulation	Facilities out of compliance	Percent out of compliance
Quality assurance.*	387	24%
Responsibility for the quality assurance program.	423	26%
Calibration of equipment.	119	7%
Performance monitoring.	684	42%
Evaluation of monitoring results.	378	23%
Retake analysis.	218	13%
Responsible personnel for monitoring must be assigned.	476	29%

* More than one tag number was rolled up into these conditional level requirements.

APPENDIX C

AGENCY COMMENTS



Memorandum

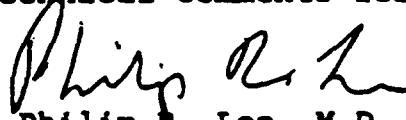
Date .APR 10 1994

From Assistant Secretary for Health

Subject Office of Inspector General (OIG) Draft Report "Lessons From Inspections of Mammography Facilities," OEI-05-92-00300

To Inspector General, OS

Attached are the Public Health Service comments on the subject draft report. We concur fully or in principle with the report's recommendations and our comments describe the actions taken or planned to implement these recommendations. We also offer a series of technical comments for your consideration.


Philip R. Lee, M.D.

Attachment

PUBLIC HEALTH SERVICE (PHS) COMMENTS ON THE OFFICE OF
INSPECTOR GENERAL (OIG) DRAFT REPORT "LESSONS FROM
INSPECTIONS OF MAMMOGRAPHY FACILITIES," OEI-05-92-00300

General Comments

OIG's recommendations present important "lessons" that the Food and Drug Administration (FDA) should be aware of as the Mammography Quality Standards Act (MQSA) of 1992 is implemented. The Health Care Financing Administration's (HCFA) experience in the inspections of Medicare screening mammography facilities is important. However, the emphasis on providing facilities with sufficient information to understand what is required of them prior to the first inspection is a tall order. The time frames required of FDA to properly certify all facilities prior to the October 1, 1994 deadline, and the resources available to accomplish the tasks, will require FDA to focus on the certification process rather than any extensive facility education program.

At the same time, FDA recognizes that the intent of the MQSA is to bring facilities into compliance rather than forcing mammography facilities out of business. To that end, FDA will implement the law fairly. Facilities will be given the opportunity to comply fully with the MQSA; however, if facilities refuse or are unable to comply, FDA will enforce the law and move to assure that these facilities do not operate unlawfully.

The dilemma identified in this report (the education versus enforcement role of the inspector) is one that is always an issue for regulatory programs. There is no question that inspectors must be responsible for the objective, unbiased evaluation of the facility. This enforcement role is the most important. However, it is also possible for these inspectors to provide some assistance to the facilities to help them determine how to come into compliance. When this assistance is provided it must be provided in a lawful, fair, uniform manner and the inspector must not provide information that could be construed as providing specific details about how to comply with the regulations. The regulatory programs in the States have historically worked out for their own purposes how this issue should generally be handled. FDA will not encourage the inspectors to take on responsibilities that appropriately belong to the facility's medical physicist.

OIG Recommendation

1. The HCFA and FDA should have a written agreement on the role of HCFA's screening mammography certification program in the interim period before full implementation of MQSA.

PHS Comment

We concur in part. The FDA and HCFA are already working to provide a smooth transition between the Medicare program and the MQSA program. It is our intention to go as far as is possible to make these changes through administrative actions. However, it is not yet clear that all of the issues can be resolved within the Department. A conforming amendment to the Medicare program may still be required to resolve this issue completely. If the Department determines that Congressional action is necessary to complete the task, all possible lawful steps will have been taken within the Department by the October deadline.

In this light, FDA suggests the following alternative language for OIG's first recommendation:

To ensure the smooth implementation of MQSA, HCFA and FDA should ~~have a written~~ reach agreement on the role of HCFA's screening mammography certification program in the interim period before full implementation of MQSA.

OIG Recommendation

2. The FDA should ensure that facility personnel are aware of and thoroughly trained on MQSA's requirements.

PHS Comment

We concur in principle. OIG recommends FDA provide training funds to States to improve the knowledge of MQSA requirements among the provider community. Although this approach could be useful, the suggestion is unrealistic in light of existing budget constraints. FDA does not have sufficient funds this year to fully fund the first year of the MQSA inspection program. Given this constraint, FDA's highest priority for applying the limited available funds is to assure that the inspection program is funded as completely as possible.

However, FDA has worked to alert facilities to the requirements. FDA has sent the interim final rules to individual facilities, it has worked to alert the professions by attending their professional meetings, holding public meetings to invite interested parties, and finally, it has established a quarterly newsletter, entitled "Mammography Matters." The first edition of this newsletter was sent to all known mammography facilities in February 1994. Its purpose is to alert facilities not only to the need to comply with the MQSA, but to answer some additional more involved issues, explain the differences between the existing American

College of Radiology (ACR) and HCFA programs and the MQSA, and emphasize the need to be accredited by an approved accrediting body.

In addition, on March 7, 1994 FDA provided a Level II training for 20 mammography inspectors who are senior staff from the States.

OIG Recommendation

3. The FDA should examine ways to perform the most effective and cost-efficient inspections which still adequately enforce the regulations (given that the law requires an annual on-site inspection of all mammography facilities.)

PHS Comment

We concur. The recommendation to utilize the experience of the State inspectors in the development of the MQSA inspection program has been implemented. In February 1994, the Conference of Radiation Control Program Directors and FDA agreed to a process by which the States will have input in the inspection procedures as they are developed. However, the timing required to implement the program will limit the opportunity for an involved iterative process here.

OIG Recommendation

4. The FDA should develop a management information system that allows for continuous monitoring of State inspections agency performance and facility compliance and distinguishes between documentation non-compliance and performance non-compliance.

PHS Comment

We concur. FDA will develop a management information system (MIS) that will allow continuous monitoring of State inspections and facility compliance. The MIS will focus on facility performance, including documentation necessary to assure adequate performance.

Technical Comments

The following comments are related to specific sections of the report, as noted.

- 1) Page i, paragraph 5: MQSA's effective date should be revised to state that MQSA prohibits any mammography facility from operating after October 1, 1994 without a certificate issued by FDA. The current wording suggests that facility

certification might start after October 1, 1994; should this be the case, all mammography facilities would be unlawfully providing mammography services since no facility would have the required certificate. Additionally, MQSA did not replace Medicare's current regulations. The question is whether the Department has the authority to modify the approach taken under the Omnibus Budget and Reconciliation Act of 1990 (OBRA '90) to effect the replacement, or whether Congress will have to pass a conforming amendment to correct the situation. In the meantime, FDA and HCFA are working to assist facilities in the transition. HCFA is working with their contractors in the State health departments to inform facilities inspected under the Medicare program that inspection after September 1994 will be against MQSA requirements. As MQSA inspection procedures are developed, State inspectors can use these methods rather than the Medicare survey methods and will evaluate facilities against MQSA's interim final regulations where appropriate.

2) Page 1, paragraph 4: The report seems to confuse the numbers of facilities accredited by ACR with the number of x-ray units. This common point of confusion results from one of the differences between what ACR has historically done, i.e. accredit individual x-ray units, and what is required under the statute, that facilities rather than individual x-ray units be accredited. The number stated in this paragraph appears to represent the number of units accredited not the number of facilities. This will demonstrate a larger difference between those facilities accredited by ACR and the total number in the U.S.. As of February 1994, ACR had accredited 7,742 units in 6,029 facilities.

3) Page 2, paragraph 1: The wording of this paragraph should be modified to reflect the proper ownership of the NEXT program. This is a program that is conducted by the Conference of Radiation Control Program Directors. FDA, under the terms of a cooperative agreement covering several areas, receives the results of the States' program and has published analyses of the NEXT program results. FDA would prefer the following language: "...although FDA has obtained information from the Conference of Radiation Control Program Directors (CRCPD) concerning mammography use. Individual States, using the NEXT protocol, have measured patient radiation exposures and assessed phantom image quality...."

4) Page 2, paragraph 3: It is not clear that the reason for HCFA's delay in publishing the final regulations is totally related to the xerography issue. We believe there were other substantive issues as well, one of which was the enactment of MQSA about 22 months after the interim final mammography screening rules were published by HCFA.

- 5) Page 3, 2nd whole paragraph: See technical comment number 1.
- 6) Page 4, paragraph 1: Information from the 4 States that had not yet done any inspections would be helpful to FDA in its negotiation of inspection contracts with these States. This information might point to issues that should be considered before negotiations begin so that if there are problems that need to be resolved, FDA will have some opportunity to work to that end and assure adequate inspectional programs in each State.
- 7) Page 6, paragraph 2: As in Technical Comment number 6, FDA would like to have the information the OIG has obtained regarding the number of inspections performed by each State.
- 8) Page 7, paragraph 4: Although the statement is true that under OBRA '90, the Medicare program could reimburse facilities for providing diagnostic mammography services, it would nevertheless be useful here to reiterate that under MQSA any facility that does not have an FDA certificate after October 1, 1994 can not lawfully provide mammography services of any type regardless of whether federal reimbursement is involved.
- 9) Page 9, section on "Quality Assurance Monitoring": The fact that documentation of quality control (QC) practices was not available for the State inspector should be considered a demonstration that QC practices are not implemented. The evaluation of the processes, i.e., making objective measurements of the process, and recording those measurements is central to any QC program. This is a rather generic process whether it is used in an industrial setting or a medical one. The lack of documentation of the process measurements would prevent trend analysis which is essential to process control. Without this essential element, the process controls are limited to correcting bad processes rather than preventing them which is the fundamental goal of a quality assurance (QA) program. If measurements are being taken but not documented for trends analysis, this should not be considered a QA program.
- 10) Page 11, last paragraph: The concern mentioned here regarding the cost of accreditation should be placed in perspective with the other aspects of the program. If facilities cannot afford to pay the accreditation fee, how can they afford to pay for the annual physics survey required by MQSA, and, if the inspections are to be self funding through fees as required by MQSA, these will be new costs to facilities that they have not previously incurred. These are among the issues that are assigned by the statute to the

National Mammography Quality Assurance Advisory Committee.

- 11) Page 12, paragraph 3: The comment in the last line of this paragraph regarding the requirement for radiologists to "finally get involved with quality assurance" is an interesting contrast to the complaints by some facilities regarding the need for the physician consultant on page 8, paragraph 1. It appears that the team did find some support for the concepts behind physician involvement in establishing and monitoring the quality of mammography performed in the facility. This comment should be strengthened to put the complaints reported on page 8 into better context.
- 12) Page 12, paragraph 4: The comments in this paragraph regarding the question of sufficient medical physics support and the concern of some physicists for liability and the speculation that this might cause some to refuse to work under these conditions is an important issue for the Advisory Committee to evaluate. Any specific information the authors of this report could provide to clarify these issues would be important for the Advisory Committee to have available to them.
- 13) Page 13, paragraphs 3 & 4: We are concerned that the OIG seems to place nearly all of the responsibility on FDA for alerting facilities to the need to comply with MQSA. The limited time provided to implement the program severely limits the opportunities for facilities to fully understand what is expected of them prior to the compliance deadline. The HCFA experience suggests that many of the people involved in mammography facilities do not take these requirements seriously in the first place. Even the strongly worded letter from HCFA warning against false attestations resulted in a very high percentage of facilities making attestations of compliance without understanding the requirements. Clearly, this is a difficult task that will finally be resolved only during the inspection program.

The FDA has worked to alert facilities to the requirements, not only by sending the interim final rules to individual facilities, but has also worked to alert the professions by attending their professional meetings, holding public meetings to invite interested parties, and finally, a quarterly newsletter has been established and the first edition sent to all known mammography facilities in February 1994. This first newsletter was written to alert facilities not only to the need to comply but to answer some additional more involved issues, explain the differences between the existing Advisory Committee and HCFA programs and this new one, and emphasize the need to be accredited by an approved accrediting body.

The FDA is aware of activities on the part of some States to provide information on MQSA to mammography providers (e.g., Connecticut recently made such efforts with assistance from the FDA Regional Radiological Health Representative). State efforts will clearly increase the effectiveness of federal educational efforts.

14) Pages 14 & 15, re: inspector training: FDA began the training program for inspectors in February 1994. The training program will provide inspectors with much more extensive training than the HCFA program did, with three 2-week training sessions interspersed with mentored inspection work and culminating with a practical qualification examination. Once potential inspectors have been qualified, they will be permitted to conduct the MQSA inspections. Then, their performance will be monitored through the statutorily required audit program.

**Memorandum**

Date **APR 1 1994**

From **Bruce C. Vladeck** *Bruce Vladeck*
Administrator

Subject **Office of Inspector General (OIG) Draft Report: Lessons From Inspections of Mammography Facilities (OEI-05-92-00300)**

To **June Gibbs Brown**
Inspector General

We reviewed the subject draft report which describes inspections of mammography facilities under the Medicare screening mammography program. The report also discusses the implementation of the Mammography Quality Standards Act (MQSA).

We agree with OIG's recommendation that the Health Care Financing Administration (HCFA) and the Food and Drug Administration (FDA) have a written agreement on the role of HCFA's screening mammography certification program. HCFA and FDA have agreed on an approach to surveying screening mammography facilities between now and the time MQSA becomes effective after September 30. This approach will include continued onsite inspections of Medicare approved screening mammography facilities through September 30, after which the FDA will assume responsibility for all certification activity. Instructions to implement the agreement between HCFA and FDA will be sent shortly to the HCFA Regional Offices, the Medicare State agencies, and the State radiation control agencies. These instructions will ensure a coordinated transition from HCFA's management of the screening mammography program to FDA's management of the MQSA. HCFA will also issue a regulation to accept FDA's quality standards for Medicare facilities that provide mammography services.

Additional comments are attached for your consideration. Thank you for the opportunity to review and comment on this draft report. Please advise us if you would like to discuss our comments at your earliest convenience.

Attachment

Comments of the Health Care Financing Administration (HCFA)
on the Office of Inspector General's (OIG) Draft Report:
"Lessons From Inspections of Mammography Facilities"
(OEI-05-92-00300)

General Comments

- The report states that it is unknown how the Mammography Quality Standard Act (MQSA) will affect the Medicare program and inspections. We have determined that there is no conflict between the Medicare screening mammography law and the interim regulations promulgated by the Food and Drug Administration (FDA) on December 21, 1993. As a result, we are amending the interim final Medicare screening mammography regulations to cross-reference the FDA standards by the effective date of those rules (October 1).

- The second finding of the report includes a statement that mammography facility deficiencies were not serious. The basis for this finding appears to be on page 7, where it states that "Less than 5 percent of all deficiencies found in the facilities are for conditional level (considered serious) deficiencies."

Minor deficiencies typically greatly outnumber serious deficiencies in any type of quality survey, and, thus, serious deficiencies as a percentage of all deficiencies would typically be small. Therefore, we do not believe this is a valid analysis or finding and request that it be deleted from the report.

- The last recommendation, addressed to FDA, is to develop a system that distinguishes between "documentation noncompliance" and "performance noncompliance." The report does not provide a further explanation of what either condition means, nor does it provide a rationale for this recommendation. We suggest that the final report further develop an explanation and justification for this recommendation.

A significant difficulty with this recommendation is that "documentation noncompliance" and "performance noncompliance" appear to be intertwined. For example, if corrective action documentation is missing ("documentation noncompliance") for a problem that may have caused inaccurate test results, the surveyor would then check patient records for any unusual test results. This examination of patient records may result in the discovery of a "performance noncompliance" when in fact the investigation started as a "documentation noncompliance" issue.

Technical Comments

Page 2, third full paragraph -- The report states that "HCFA has not yet published final regulations for screening mammography because of departmental concerns over Medicare's regulation concerning xerography equipment." We suggest that the statement be revised to read as follows:

"HCFA has not published final regulations for screening mammography under the Medicare program for a number of reasons, including the enactment of the Mammography Quality Standards Act (MQSA) of 1992, which the Food and Drug Administration is responsible for implementing by October 1, 1994, and which HCFA believes will supersede the Medicare standards at that time."

Page 7, last sentence -- The report states that "HCFA based the screening mammography regulations on the portable x-ray regulations that require that a physician supervisor oversee the x-ray process." We suggest that the statement be revised to read as follows:

"HCFA modeled its Medicare screening mammography regulations, in part, after the American College of Radiology Accreditation guidelines and the Medicare portable x-ray regulations, both of which require that a physician supervisor oversee the x-ray process."