Public Citizen

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Joan Claybrook, President

July 2, 1996

Dockets Management Branch (HFA-305)
Food and Drug Administration
12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

RE: Proposed Requirements for Accreditation Bodies of Mammography Facilities
[Docket No. 95N-0192]

I. Introduction

On behalf of Public Citizen's Health Research Group, we offer the following comments about the Food and Drug Administration's proposed requirements for accreditation bodies of mammography facilities.

In addition to the comments on the specific issues addressed in the Federal Register, we believe that accreditation organizations must publicly release the information provided by mammography facilities to receive accreditation. In order for women to make intelligent decisions about which mammography facility to use, they need accurate information about each facility's practices. Even within the proposed standards, there can be differences in terms of radiation dosage delivered, equipment used, staff experience, and patient follow-up. We therefore recommend that accrediting agencies make available each facility's mean glandular dose of radiation, average number of mammograms interpreted by the facility per week, manufacturer of the mammography equipment used, and other baseline information accompanying accreditation applications.

II. Background

This proposed rule covers the procedures for application to FDA for approval as an accreditation body and the requirements and responsibilities of accrediting bodies.

III. Response to Specific Issues Raised in the Federal Register

§ 900.4 Standards for Accreditation Bodies

(a) Code of Conduct and General Responsibilities

(1) Circumstances where FDA believes there is a risk of substantial harm to the public

Under normal circumstances, accreditation bodies will deal directly with mammography facilities to oversee and correct deficiencies in operation. In this rule, however, FDA is proposing to require that an accreditation body take certain actions if the agency believes that the clinical image quality or other aspects of a facility's practice are seriously compromised and would pose an unreasonable risk of substantial harm to the public.

Although this process would reduce the autonomy of the accreditation bodies, it would ensure that FDA could intervene in situations where it knew of particular problems or had reason to doubt the accuracy of the accrediting body's review. Since a mammography facility cannot operate without both accreditation from an authorized accreditation body and FDA certification, it must therefore be subject to the requirements of both organizations. The additional monitoring proposed here is not only appropriate but serves as an excellent safety net for accreditation bodies.

(2) Equipment or practices that pose and unreasonable risk of substantial harm to the public

Under these proposed regulations, accrediting bodies would be required to notify FDA within 5 business days any time the accreditation body becomes aware that there has been actual loss of life or serious injury or illness associated with facility non-compliance with Mammography Quality Standards Act requirements.

We believe that if non-compliance with the MQSA leads to loss of life or serious injury or illness, the facility's accreditation and certification must be immediately suspended in order to protect the other patrons of the facility. The purpose of the legislation and regulations is to optimize the safety of mammography for women in the United States. Disregard of these rules can not be tolerated.

As soon as an accrediting body becomes aware that non-compliance has caused loss of life or serious injury or illness, the accrediting body must revoke the facility's accreditation and notify the FDA within 24 hours so that FDA can revoke its certification as well.

If, despite appropriate compliance with MQSA, a facility experiences loss of life or serious injury or illness, the 5-business day reporting requirement is appropriate.

(4) Quality assurance program

We support the proposed rules requiring accreditation bodies to have quality assurance programs including clinical and phantom image reviews.

(5) Conflict of interest

In this proposed rule, FDA calls for new measures to reduce the possibility of conflict of interest or bias on the part of an accreditation body. There are many inherent opportunities for conflict of interest in the proposed accreditation regulations. Some of these include bias with regard to reviewers evaluating images from known facilities or colleagues, professional organizations serving as accreditation bodies for their members, and health care organizations becoming approved to accredit their own facilities. The regulations propose to minimize this type of bias by prohibiting individuals from reviewing clinical or phantom images from or visiting a facility with which they maintain a financial or personal relationship.

The proposed regulations do not, however, discuss the potential for conflict of interest inherent in an accreditation body also being a product vendor for a mammography or quality-control related product. While we are less concerned with the software vendors trade association's assertion that an MQSA accreditation body's mammography reporting software might have a sales advantage, we are concerned that facilities purchasing this software will receive or appear to receive facilitated accreditation reviews. At the very least, facilities will feel coerced into purchasing reporting software that could ease their accreditation applications. At the worst, unqualified facilities could gain the knowledge and tools to circumvent the safe mammography requirements. We believe that facilities that produce mammography-related products should be banned from serving as accreditation organizations.

IV. Conclusion

FDA's proposed rules for accreditation bodies are marred by the lack of a regulation regarding disclosure of information contained in accreditation applications, inappropriate reporting of serious MQSA violations, and insufficient attention to issues of conflict of interest. Until these matters have been addressed, the rule regarding behavior of accreditation bodies should not be finalized.

Sincerely,

Laurel S. Mendelson

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RE: Quality Mammography Standards; General Preamble and Proposed Alternative Approaches
[Docket No. 95N-0192]

I. Introduction

On behalf of Public Citizen's Health Research Group, we offer the following comments about the Food and Drug Administration's ideas for the application of alternative performance and outcome-based standards to ensure quality mammography.

In summary, we support the Food and Drug Administration's efforts to strengthen the existing interim regulations on quality mammography standards. While the interim standards provided at least a minimal level of quality control over mammography services, more comprehensive regulations will produce further assurance of quality mammography for American women.

Although the proposed design and qualification-based standards are necessary, and will undoubtably improve mammography performance, we believe that the only way to ensure quality services is through the application of performance standards and outcome measures.

While we wholeheartedly support the development of performance standards and proficiency examinations, we recognize that the development of standards and proficiency examinations can take a considerable amount of time. While these processes are being developed, we urge FDA to adopt the proposed final standards (with minor revisions).

II. Background

The proposed final rule for Quality Mammography Standards outlines design specifications, training and educational requirements, and process requirements. FDA has recognized, however, that there can be means for ensuring quality mammography other than those presented in these proposals. In this request for comments, FDA has solicited comments addressing the application of specific performance or outcomes standards.

III. Response to Specific Issues Raised in the Federal Register

A. Mammography Equipment and Quality Control

The proposed regulations contain specific performance and design requirements for mammography equipment. While we urge FDA and others to identify complete system tests that would eliminate the need for other specific quality control tests, we do not believe that any of the currently-available tests are appropriate. Neither phantom image testing nor ongoing repeat-rate analysis offers sufficient assurance of quality mammography.

Since, we know of no existing outcome measure to adequately ensure high-quality mammography, we encourage FDA to implement the mammography performance and design requirements listed in this proposed rule.

B. Mammography Personnel: The Interpreting Physician and The Medical Audit

The proposed regulations require physicians to meet initial qualifications through board certification or training, mammography-specific training and experience, and continuing education and experience requirements. Despite all of these requirements, physicians may still have suboptimal mammography interpretation abilities.

We believe that appropriate physician qualifications must include three components: appropriate training and experience, ongoing medical outcomes analysis, and successful completion of a proficiency examination.

We propose that physicians be required to meet the education and experience qualifications discussed in § 900.12(a)(1). In addition, we believe that FDA, in collaboration with the National Mammography Quality Assurance Advisory Committee, should develop a proficiency examination that includes, among other components, clinical image interpretation. The physician should be required to pass this proficiency examination prior to commencing independent mammography interpretation. Finally, FDA should define performance standards for medical outcomes audit statistics. These standards should be used to continuously evaluate each physicians' performance. Those physicians whose performances drop below the defined

standards for an extended period of time should be required to cease independent interpretation until they have successfully completed remedial coursework and again passed a proficiency examination.

(C) Mammography Personnel: The Radiologic Technologist

While we fully support the background, continuing education, and experiential components for qualifying radiologic technologists, we believe that training and experience do not always produce proficiency. We support the development and application of a proficiency examination to be administered before a technologist begins independent performance of mammography procedures. This proficiency examination should be repeated approximately every 3-5 years to ensure that technologists have sufficient competency with any current equipment and procedures.

(D) Mammography Personnel: The Mammography Medical Physicist

This rule would require medical physicists to meet initial qualifications and to have continuing experience and education. All medical physicists conducting surveys of mammography facilities would be required to have a state license or approval or have certification from an accreditation body approved by the FDA. In addition, medical physicists would be required to take specific coursework and attain certain educational levels.

While we agree that medical physicists must have a great deal of knowledge about general and imaging physics, we do not support the requirement for a master's degree in physical science. Instead, we believe that a proficiency examination should be developed that tests the critical issues in physics, physical science, and mammography. Any individual holding a bachelor's degree should be eligible to take this proficiency examination. Those who pass the examination would still be required to complete the other aspects of experience and continuing education proposed in this set of regulations.

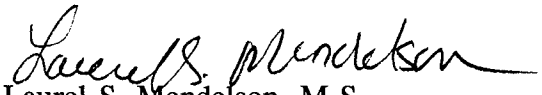
We suggest that medical physicists be required to pass both a physical science component and a practical survey component of a proficiency examination prior to beginning independent mammography equipment evaluations. We further suggest that the physical science component of the examination would not have to be repeated unless the medical physicist lost qualification because of failure to meet continuing education or experience requirements. Regular updates of the practical survey component of the examination should be required of all medical physicists every 3-5 years to ensure that they are sufficiently able to maintain quality assurance given current equipment and procedures.

IV. Conclusion

In these rules for mammography quality standards, FDA has proposed a complex set of

regulations for mammography facilities, personnel, equipment, and accrediting bodies. We support FDA's efforts and urge the implementation of final rules as quickly as possible. Furthermore, we recommend that FDA begin the process of developing additional outcomes measures for mammography personnel to include medical audit standards and proficiency testing.

Sincerely,



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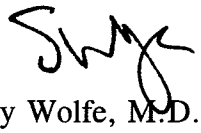

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12420 Parklawn Dr., Rm 1-23
Rockville, MD 20857

RE: Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements
[Docket No. 93N-0351]

I. Introduction

On behalf of Public Citizen's Health Research Group, we offer the following comments about the Food and Drug Administration's proposed rule modifying and adding to the quality standards and certification requirements for mammography facilities.

II. Background

This proposed rule establishes general certification requirements including mammography facility standards for record-keeping and reporting, medical outcomes audit, quality assurance, imaging of examinees with breast implants, and addressing consumer complaints.

III. Response to Specific Issues Raised in the Federal Register

§ 900.11 Requirements for Certification

All mammography facilities subject to the Mammography Quality Standards Act must obtain a certificate from FDA. New facilities beginning operation after October 1, 1994, are eligible to apply for six-month provisional certificates that allow them to operate while they obtain the clinical images needed to complete the accreditation process. If facilities fail to obtain a sufficient number of clinical images during the six-month provisional period or a single 90-day extension, their provisional certificates expire. Previously certified facilities that have allowed their full or provisional certificates to expire or have been refused renewals of their certificates by the FDA may apply to have their certificates provisionally reinstated once they have submitted a corrective action plan.

facility's quality assurance program. The medical outcomes audit is a systematic collection and analysis of mammography results and the comparison of those results with the physicians' recommendations and data from biopsy results. No specific methodologies are proposed for collection and use of this data; each facility would be given the flexibility to design an audit program that best serves its needs.

While we fully support the concept of a medical outcomes audit, and indeed believe it to be critical to a facility's ongoing quality assurance program, we believe the proposed regulations do not sufficiently address how the data should be collected, interpreted, or used. Furthermore, there are no standards for the optimal results of medical outcomes audits. We recommend that FDA define specific features of the outcomes audit, including positive predictive value, cancer detection rate, and percent of minimal cancers found, and determine standards for each feature. Once this has been accomplished, medical outcomes audits should be performed for each physician on a quarterly basis. Those physicians whose performance falls below the acceptable standard or more than 10% below previous performance levels should be required to participate in remedial training. Physicians whose performance falls below set standards for two consecutive quarters should be prohibited from independently interpreting mammograms until they have passed a proficiency examination.

This proposed rule does not require that all mammograms should be read a second time by a second qualified physician to increase the accuracy of diagnoses. We continue to believe that dual reading is the optimal situation and should be encouraged wherever possible.

(g) Mammography Procedure and Techniques for Mammography of Examinees with Breast Implants

The Mammography Quality Standards Act specifically requires facilities to establish procedures to identify examinees with breast implants. The proposed rule would require mammography facilities to inquire if an examinee has a breast implant at the time of mammogram scheduling. Although we agree that this should be sufficient in most cases, we fear that occasional breakdowns in communication can occur along any part of the information transmission from examinee to desk clerk to technician.

Because of the adverse consequences of the technician not knowing about the implants, we suggest an additional safety net: in addition to inquiring about breast implants at the time of mammogram scheduling, we recommend that mammography facilities also post signs reminding women to tell mammography technicians that they have breast implants <u>before</u> their mammograms.

We agree that facilities should be allowed to obtain subsequent six-month provisional certificates once they have effectively corrected their deficiencies. However, we believe that there must be a limit to the number of times facilities can apply for provisional certificates since repeated lapses in meeting requirements may indicate patterns of substandard operation. We recommend that facilities be allowed no more than 3 provisional certificates in any five-year period.

§ 900.12 Quality Standards

(c) Medical Records and Mammography Reports

The proposed regulations would establish requirements for the content and terminology of mammography examination reports, the manner of communicating results to examinees and to health care providers, and the duties of facilities for maintaining records of examinees.

We support the proposed regulations with the exception of those addressing communication with the examinee and with health care providers about the results of the mammogram. The proposed rules would require that all examinees receive notification of results expressed in lay terms. Examinees without health care providers would receive actual mammography reports along with the notification. Examinees who do have health care providers would have their reports sent directly to their health care providers.

We believe that each woman should be allowed to receive a copy of her own mammography report. Rather than automatically sending reports to health care providers, facilities should be required to design their intake questionnaires to ask whether the examinee would like a copy of her full report. In a situation, where the women cannot or does not answer the question, the report should be sent to both the woman and her health care provider.

(d) Quality Assurance--General

The proposed rule states that each mammography facility shall designate a lead interpreting physician who will have the general responsibility for assuring that quality assurance requirements are met. Although we agree that in a best-case situation, this role should be filled by an interpreting physician, we believe that the person responsible for total facility quality assurance must be a full-time employee of the facility. Those facilities that do not employ full-time physicians would be better served by assigning primary quality assurance responsibilities to a qualified full-time employee.

(f) Quality Assurance--Mammography Medical Outcomes Audit

The proposed rule requires a mammography medical outcomes audit program to be part of each

IV. Conclusion

In summary, although we support the increased regulation of certification requirements and standards, we believe that the regulations regarding reporting, medical outcomes audits, and examinees with breast implants must be strengthened. Once these deficiencies have been corrected, the proposed rule for general facility requirements will offer a comprehensive and safe framework for mammography.

Sincerely,

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12420 Parklawn Dr., Rm 1-23
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RE: Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements
[Docket No. 95N-0215]

I. Introduction

On behalf of Public Citizen's Health Research Group, we offer the following comments about the Food and Drug Administration's proposal to amend the mammography facility standards by modifying and adding to the personnel requirements for interpreting physicians, radiologic technologists, and medical physicists who perform mammography services.

II. Background

This proposed rule establishes the personnel qualification standards that the staff of each mammography facility must meet in order to comply with requirements under the Mammography Quality Standards Act.

III. Response to Specific Issues Raised in the Federal Register

§ 900.12 Quality Standards

(a)(1) Personnel--Interpreting Physicians

This rule would require interpreting physicians to meet initial qualifications and to have continuing experience and education. Specifically, all physicians interpreting mammograms would be required to have a state license to practice medicine, either have achieved certification in an appropriate specialty area or have had at least 3 months of documented formal training in mammography, have a minimum of 60 hours of documented medical education in mammography, and have interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within the previous 6-month period. In order to maintain qualifications to interpret mammograms, physicians would have to continue to

interpret an average of at least 40 mammograms per month over each 24 month period, complete continuing education requirements, and receive training in each new modality used in their practices.

We fully support the background, continuing education, and experiential components for qualifying interpreting physicians. These regulations will ensure that most physicians have received adequate training to interpret mammograms. But we continue to believe that training, no matter how intensive, does not prove proficiency.

In addition to the training and experience proposed in these regulations, we support the development and application of a proficiency examination that includes the interpretation of clinical images. This examination should be administered both before a physician begins independent interpretation of mammograms and following any lapse in qualifications.

Furthermore, the proposed rule contains a loophole for the least experienced physicians. While most physicians would be required to have interpreted at least 240 mammograms in the 6-months immediately prior to becoming qualified, physicians who are just completing a diagnostic radiology residency are only required to interpret 240 mammograms in the 2 years prior to becoming board certified (if they become board certified at the first allowable time). Interpretation of mammograms is a highly complex procedure that must be performed nearly daily in order to maintain sufficient skills. Physicians who have had a 1 1/2 year lapse in reading mammograms cannot sufficiently maintain their skills and should be required to repeat the supervised portion of their training before interpreting independently.

We believe that physicians who are just completing diagnostic radiology residencies should be required to meet the same standards as all other physicians.

(a)(2) Personnel--Radiologic Technologists

This rule would require radiologic technologists to meet initial qualifications and to have continuing experience and education. All radiologic technologists would be required to be licensed or certified to perform radiologic examinations, have undergone 40 contact hours of documented training specific to mammography under the supervision of a qualified individual, meet continuing education requirements, and perform at least 100 mammography examinations per year.

While we fully support the background, continuing education, and experiential components for qualifying radiologic technologists, we believe that training and experience do not always produce proficiency.

We therefore support the development and application of a proficiency examination to be administered before a technologist begins independent performance of mammography procedures.

(a)(3) Personnel--Medical Physicists

This rule would require medical physicists to meet initial qualifications and to have continuing experience and education. All medical physicists conducting surveys of mammography facilities would be required to have a state license or approval or have certification from an accreditation body approved by the FDA. In addition, medical physicists must have a master's degree or higher in a physical science from an accredited institution including at least 20 semester hours of college-level physics, have 20 contact hours of documented specialized training in conducting surveys of mammography facilities, and have the experience of conducting surveys of at least 5 mammography facilities and 10 mammography units. Medical physicists must also fulfil continuing education and experience requirements.

While we agree that medical physicists must have a great deal of knowledge about general and imaging physics, we do not support the requirement for a master's degree in physical science. Instead, we believe that a proficiency examination should be developed that tests the critical issues in physics, physical science, and mammography. Any individual holding a bachelor's degree should be eligible to take this proficiency examination. Those who pass the examination must still complete the other aspects of experience and continuing education proposed in this set of regulations.

IV. Conclusion

FDA has taken some important steps toward ensuring appropriate qualifications for mammography personnel. However, as we have explained above, experience and education do not necessarily equate proficiency. In addition to the requirements proposed here, we support the development of proficiency tests that include both tests of knowledge and clinical abilities.

Sincerely,

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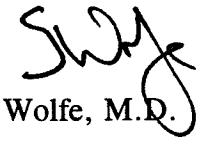

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