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Mammography Quality Standards; Proposed Rules

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0192]

RIN 0910–AA24

Quality Mammography Standards; General Preamble and Proposed Alternative Approaches

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its interim regulations issued under the Mammography Quality Standards Act of 1992 (the MQSA). In addition, FDA is also setting forth ideas for the application of alternative performance and outcome-based standards to ensure quality mammography. FDA is soliciting comments on these alternatives as possible ways of meeting the objectives of Executive Order 12866, which requires Federal agencies to, where feasible, specify performance objectives, rather than specifying the behavior and manner of compliance and to avoid duplicative regulations. Elsewhere in this issue of the Federal Register, FDA is proposing amendments to the requirements for accreditation bodies, procedures for facility certification and quality standards for mammography personnel, equipment and practices, including quality assurance. These actions are being taken to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis.

DATES: Written comments on the proposed rule by July 2, 1996. Written comments on the information collections should be submitted by May 3, 1996.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Building, 725 17th St. NW., rm. 10235, Washington DC 20503, ATTN: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. General Preamble

The MQSA (Pub. L. 102–539) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that, to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA.

The MQSA was enacted in response to the growing incidence of breast cancer and its associated mortality rate. Breast cancer is now the most common nonskin cancer and is the second leading cause of cancer deaths among women, after lung cancer. The American Cancer Society projects that in 1995 there will be 180,000 new cases of breast cancer among women in the United States (Ref. 1). Of these new cases, it is estimated that approximately 46,000 of these women will die from the disease. The lifetime risk of developing breast cancer is increasing. In 1993, breast cancer was projected to affect 1 in 8 women in their lifetime, as compared to 1 in 11 in 1980, 1 in 14 in 1960, and 1 in 20 in 1940 (Ref. 2).

Early detection of breast cancer, typically involving breast physical examination and mammography, is the best means of preventing deaths that can result when the diagnosis is delayed until the onset of more advanced symptoms. The value of undergoing screening mammography is that it can detect cancers that are asymptomatic. Mammograms can reveal breast cancer up to 2 years before a woman or her doctor can feel a lump. In addition, over 90 percent of these early stage cancers can be cured (Ref. 3).

However, according to the General Accounting Office, a mammogram is among the most difficult radiographic images to read. It must be of high quality for the image to be interpreted correctly. If the image quality is poor, the interpreter may miss an incipient cancerous lesion. This false negative diagnosis could delay early treatment and result in an avoidable death or mastectomy. Further, it is equally true that poor quality images or faulty interpretations can lead to a false positive diagnosis when normal tissue is misread as abnormal. This can lead to needless anxiety for the examinee, costly additional testing, and painful biopsies.

The Senate Committee on Labor and Human Resources held hearings on breast cancer in 1992 and found a wide range of problems with mammography practice in the United States: (1) Poor quality equipment, (2) a lack of quality assurance procedures, (3) poorly trained radiologic technologists and interpreting physicians, and (4) a lack of facility inspections or consistent governmental oversight.

A. Provisions of the MQSA

The MQSA legislation was enacted to address these deficiencies in mammography practice. Under the MQSA, Congress established a comprehensive statutory scheme for the certification and inspection of mammography facilities to ensure that, after October 1, 1994, only those facilities that comply with minimum Federal standards for safe, high-quality mammography services may lawfully continue to operate. Operation after that date is contingent on receipt of an FDA certificate attesting that the facility meets the minimum mammography quality standards issued under section 354(f) of the Public Health Service Act (the PHS Act)(42 U.S.C. 263b(f)). These standards are intended to apply equally to screening and diagnostic mammography.

Specifically, the MQSA required the following:

(1) Accreditation of mammography facilities by private, nonprofit organizations or State agencies that have met the standards established by FDA for accreditation bodies and have been approved by FDA. The MQSA requires a direct Federal audit of the accreditation bodies through facility inspections by Federal inspectors. It also requires that, as part of the overall accreditation process, actual clinical mammograms from each facility be evaluated for quality by the accreditation body.

(2) An annual mammography facility physics survey, consultation, and evaluation performed by a qualified medical physicist.

(3) Annual inspection of mammography facilities, to be performed by FDA-certified Federal or

State inspectors. If State inspectors are used, the MQSA requires a Federal audit of the State inspection program by direct Federal inspections of a sample of State-inspected facilities.

(4) Establishment of initial and continuing qualification standards for interpreting physicians, radiologic technologists, medical physicists, and mammography facility inspectors.

(5) Specification of boards or organizations eligible to certify the adequacy of training and experience of mammography personnel.

(6) Establishment of quality standards for mammography equipment and practices, including quality assurance and quality control programs.

(7) Establishment by the Secretary of a National Mammography Quality Assurance Advisory Committee (NMQAAC). Among other things, the NMQAAC is required to advise FDA on appropriate quality standards for mammography facilities and accreditation bodies.

(8) Standards governing recordkeeping for examinee files and requirements for mammography reporting and examinee notification by physicians.

The MQSA replaced a patchwork of Federal, State, and private standards in order to guarantee sufficient oversight of mammography facilities to ensure that all women nationwide will receive high quality mammography services.

B. Interim Regulations

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting interim rule authority to the Secretary (and by delegation, to FDA) to issue interim quality standards under MQSA. This authorization was provided in recognition of the fact that FDA certification of the over 10,000 mammography facilities in the United States could not be accomplished by the October 1, 1994, statutory deadline without streamlining the rulemaking process for issuing the initial standards. Because of the urgent public health need for national mammography standards, Congress decided to grant this interim rule authority rather than extend the deadline to develop standards.

Under the interim rule legislation, FDA was authorized to issue temporary interim regulations setting forth standards for approving accreditation bodies and quality standards for mammography facilities.

Under the abbreviated process, Congress expected FDA to adopt existing standards to the maximum extent feasible, such as those established by the Health Care Financing Administration (HCFA), private voluntary accreditation bodies such as the American College of Radiology (ACR), and some States. The Secretary was not required to consult with the NMQAAC in developing the interim regulations. However, following issuance of the interim standards, Congress intended that FDA proceed with the more extensive rulemaking procedures envisioned under the MQSA, including consultation with the NMQAAC.

In the Federal Register of December 21, 1993 (58 FR 67558 and 58 FR 67565), FDA issued interim rules establishing requirements for entities applying to serve as accreditation bodies and for facilities applying to obtain FDA certification in order to continue legally providing mammography services after October 1, 1994. These interim rules became effective on February 22, 1994. They were amended by another interim rule published in the Federal Register on September 30, 1994 (59 FR 49808).

There are several reasons why it is important to replace the existing interim regulations on quality mammography standards with more comprehensive final regulations, apart from strong congressional encouragement for such action when the agency was granted interim regulation authority. In a 1995 report by the Physician Insurers Association of America, misdiagnosis of breast cancer remains the most common charge against radiologists in malpractice situations. In addition, there was considerable variation in clinical performance of mammography facilities in 1992 and 1993 despite compliance with existing voluntary accreditation standards that were similar to the interim regulations published by FDA (Ref. 4). FDA believes that more comprehensive final regulations would optimize facility performance.

The interim regulations, for reasons stated above, were based primarily upon the voluntary standards of the American College of Radiology (ACR) Mammography Accreditation Program (MAP). Applying these standards to all facilities has had a significant impact on mammography nationwide but evaluations of the ACR program (Ref. 5) have shown that further improvement is possible through more comprehensive standards than those of MAP.

This is especially true in the equipment area where the MAP standards were minimal and where the FDA's authority under the Medical Device Amendments to the Food, Drug, and Cosmetic Act is limited because presently used mammography systems are pre-amendment devices. To provide greater assurances of quality equipment performance (and to meet a priority identified in ''The National Strategic Plan for the Early Detection of Breast and Cervical Cancers'' (Ref. 7), the ACR, with the Centers for Disease Control and Prevention had convened expert committees to develop specifications for mammography equipment. The reports of these expert committees were an important basis for the equipment provisions in the proposed regulations.

Other portions of the proposed regulations, such as those providing standards for imaging patients with breast implants, are required by the MQSA. In addition, some of the details contained in the proposed regulations, such as requirements to ensure that personnel have practical training on equipment they use, reflect areas of concern that were inadvertently neglected in the interim regulations.

For all of these reasons, therefore, it is necessary to replace the interim regulations with more comprehensive final regulations if the highest quality mammography that is reasonably achievable is to be obtained.

In issuing the interim regulations, FDA attempted to balance the pressing need to put national mammography standards into effect with the agency's concern that facilities be provided a reasonable amount of time to comply with these standards. The interim regulations were drafted and implemented to maximize lawful operation by facilities under existing quality standards, and to ensure adequate examinee access to quality mammography during the transition to more comprehensive national standards.

For example, the ACR, a private, nonprofit association of radiologists, began a voluntary Mammography Accreditation Program (MAP) in 1987 to provide assurance of quality to examinees seeking services at ACR-accredited facilities. Many of the requirements under the interim rules were derived from the ACR's MAP program, as well as from HCFA regulations and some State programs. The MAP included a number of procedural and image quality requirements for facilities applying for ACR accreditation, including an evaluation of actual clinical images produced by each facility. In the absence of a national regulatory requirement, only those facilities that voluntarily sought accreditation pursued the ACR accreditation process. Nevertheless, many mammography facilities applied for and obtained ACR accreditation. Historically, approximately 30 percent of the facilities that applied for ACR

accreditation failed to become accredited on their first attempt, although many of these were subsequently able to improve their services and gain accreditation on a second attempt.

C. Accreditation and Certification

Before the October 1, 1994, statutory deadline, FDA approved the ACR and the State of Iowa as accreditation bodies and issued certificates to the more than 6,000 facilities (out of an estimated total of 10,666 facilities in the United States) accredited by these bodies. The States of Arkansas and California were also approved by FDA as accreditation bodies and began accrediting mammography facilities within their States after the statutory deadline. These facilities were subsequently certified by FDA.

In addition, the MQSA permitted FDA to issue 6-month provisional certificates to facilities whose applications for accreditation had not been approved by the statutory deadline but were sufficiently complete to be accepted for review by an FDA-approved accreditation body. The statute also allowed FDA to extend a facility's provisional certificate once, for up to 90 days, if: (1) The owner, lessor, or agent of the facility could demonstrate that, without such an extension, access to mammography in the geographic area served by the facility would be significantly reduced; and (2) the owner, lessor, or agent described in a report the steps that would be taken to qualify for full certification (42 U.S.C. 263b(c)(2)).

In recognition of the fact that a large number of facilities were working to meet accreditation standards at the same time, and cognizant of the increased demands placed on accreditation bodies during the initial implementation of the MQSA, FDA issued 6-month provisional certificates on October 1, 1994, to facilities whose applications for accreditation were sufficiently complete for review and which, on preliminary examination, appeared reasonably likely to receive accreditation. These 6-month provisional certificates were extendable for an additional 90 days for those facilities that satisfied the extension criteria under the statute (42 U.S.C. 263b(c)(2)) and had diligently pursued accreditation, but had not yet completed all aspects of the accreditation process before expiration of their provisional certificate.

Of the more than 10,000 facilities that provide mammography services in the United States, the vast majority have received full accreditation and certification. By October 1, 1994, FDA had issued approximately 6,000 certificates and 4,800 provisional certificates. Moreover, over 50 percent of those facilities issued provisional certificates on October 1, 1994, subsequently became accredited and FDA-certified by March 31, 1994, which was the closing date for the 6-month provisional period. The remainder of the provisionally certified facilities satisfied the extension criteria and were granted a 90-day extension to obtain accreditation and certification.

The agency estimates that 427 mammography facilities closed between October 1993 and October 1994. These closings were due to a number of reasons, including failure to apply for certification, voluntary closure, and failure to successfully complete the accreditation process. By April 26, 1995, 4 weeks after the end of the 6-month provisional period, 153 additional facilities had to close either because they did not pursue accreditation (57 facilities) or they failed accreditation (96 facilities). Sometime during the 6-month provisional certification period, 187 facilities voluntarily withdrew from the accreditation process.

D. Onsite Inspection of Facilities

In accordance with the MQSA, FDA established an annual onsite inspection program to monitor facility compliance with MQSA standards. FDA has trained and certified inspectors from most States, and inspection of mammography facilities began in January 1995. As of February 21, 1996, 7,265 inspections had been conducted and the results have been reported to the agency.

E. Role of the States

The MQSA explicitly states that nothing in the statute is intended to limit the authority of any State to enact State laws relating to mammography that are at least as stringent as the MQSA or regulations under the MQSA (42 U.S.C. 263b(m)). In addition to ensuring that States retain their authority to pass laws that raise mammography standards even higher, Congress provided a significant role for States to play in implementing the regulatory scheme and nationwide standards required by the MQSA.

A State may apply to FDA to become an accreditation body to accredit mammography facilities operating within the State. As earlier described, three States—Iowa, California, and Arkansas—have been approved to accredit the facilities operating within their respective jurisdictions. A State also may apply to the agency to become the certifying authority for mammography facilities operating within its borders (42 U.S.C 263b(q)). The agency currently is conducting research into various alternatives that would allow States to fulfill this role.

The statute also permits States to perform annual onsite facility inspections to ensure that facilities operating within the State are performing quality mammography (42 U.S.C 263b(g)). To date, the District of Columbia, Puerto Rico, New York City, and all of the States, except New Mexico, have negotiated contracts with the agency to perform these annual inspections.

Facilities located in States that elect to serve as accreditation bodies may elect to be accredited either by the State or the ACR, a private national approved accreditation body. Both types of accreditation bodies are audited by FDA to ensure that MQSA standards are being satisfied.

As mentioned above, most States contract with FDA to perform the annual inspection required under MQSA. These inspections are subject to audit by FDA. In those cases where States do not do the inspection, Federal personnel conduct the required annual inspection.

States' participation and implementation of MQSA is funded in a variety of ways. Because the MQSA provides for but does not mandate a particular level of State involvement in the mammography program, a State can choose to participate at a level that does not require the appropriation or expenditure of State funds. States acting as accreditation bodies may charge and collect a reasonable fee from the facilities which seek the States' accreditation. States that currently participate in the annual onsite inspection of facilities are paid by FDA through contract. The agency charges the facilities a reasonable inspection fee for this service in accordance with 42 U.S.C 263b(r). Once the agency issues provisions to permit States to serve as certifiers of mammography facilities, MQSA requires States that elect voluntarily to serve in this capacity to devote adequate funds to the administration and enforcement of MQSA requirements.

F. Development of Proposed Regulations

Coincident with the implementation of the interim rules, work was proceeding on the development of proposed regulations to replace the interim rules. As discussed previously, the MQSA established an advisory committee (NMQAAC) to advise FDA in this effort. By statute, the NMQAAC is to consist of 13 to 19 members, including health professionals whose work focused significantly on

mammography, as well as representatives of consumer groups. The NMQAAC was chartered on July 7, 1993. Nominations for members were accepted until September 7, 1993. The first meeting of the NMQAAC was held February 17 through 18, 1994. At that meeting, and in subsequent meetings in April, July, and September 1994, the NMQAAC reviewed and commented on drafts of portions of the proposed regulations developed by FDA. At its January, 1995 meeting, the NMQAAC reviewed the entire body of proposed regulations as then drafted. Many of the requirements in the proposed regulations are based on advice obtained from the NMQAAC during these meetings.

G. Framework of Proposed Regulations

FDA is issuing five separate proposed rules to amend the interim regulations. All of these proposals are published in this issue of the Federal Register. The first proposed rule as set forth below, contains background information (given above), a summary of the preliminary analysis of the costs and benefits of the proposed amendments to 21 CFR part 900, a description of the information collection requirements, proposed revisions to §§ 900.1 *Scope* (21 CFR 900.1) and 900.2 *Definitions* (21 CFR 900.2), and proposed alternative approaches to mammography quality standards and a request for comments on the proposed alternatives. The other four proposals set forth requirements related to: (1) Accreditation bodies; (2) general facility requirements, including requirements for a medical reporting and recordkeeping program, a medical outcomes audit program, special methods for examining individuals with breast implants, a consumer complaint mechanism, and a variance procedure for requesting FDA approval of alternative standards; (3) personnel requirements for interpreting physicians, radiologic technologists, and medical physicists; and (4) definitions, mammography equipment standards, and quality assurance requirements for mammography equipment.

The agency believes that the proposed amendments, when implemented, will increase the quality of mammography nationwide and facilitate the early diagnosis and treatment of breast cancer or other diseases of the breast.

In drafting the proposed regulations, and in consultation with the NMQAAC, FDA has established specific requirements for those areas that the agency believes are essential to the practice of quality mammography. Conversely, in those areas where the agency is aware of multiple methods or procedures for effectively accomplishing the same task, the proposed requirements have been drafted in more general terms, to give facilities more flexibility to accomplish a particular quality practice. In some cases, FDA will provide guidance documents that explain methods and practices that the agency recommends, based on its current thinking, but does not require by regulation.

The rules that are developed and finalized as a result of this rulemaking will replace the interim rules issued on December 21, 1993. The interim rules will continue to apply until final rules become effective.

II. Alternative Approaches for Quality Mammography

Executive Order 12866 requires Federal agencies to identify and assess alternative forms of regulation and, where feasible, specify performance objectives, rather than specifying the behavior and manner of compliance that regulated entities must adopt (E.O. 12866, Section 1(b)(8)). In addition, Executive Order 12866 (Section 1(b)(10)) requires each agency to avoid regulations that duplicate other regulations. In proposing final standards, FDA is aware that there can be alternative means for ensuring quality mammography other than through those presented in these proposals. FDA notes that the MQSA itself establishes many overlapping requirements relating to quality mammography which are reflected in the proposed final regulations. FDA also recognizes that many of the proposed final regulations contain design specifications, training and educational requirements, and process requirements, rather than performance or outcomes standards. In order to meet objectives established by the Executive Order 12866, FDA is soliciting comments on the following alternative approaches to achieve quality mammography under the MQSA. FDA encourages comments on these alternative approaches to be as detailed as possible. Comments that address and describe the application of specific performance or outcomes standards will be most useful in the event the agency is persuaded that this alternative is the more desirable approach.

Overlapping functions for facilities, accreditation bodies, and FDA have advantages and disadvantages. As an example, under section 354(e)(1)(B)(v) of the Public Health Service Act (PHS Act) (42 U.S.C. 263b(e)(1)(B)(v)), as amended by the MQSA, the accreditation body is required to perform monitoring and evaluation of medical physicists' annual surveys. At the same time, under section 354(g)(1)(B)(v) of the PHS Act, the MQSA requires FDA to annually inspect facility compliance with quality standards, including compliance with the section of the MQSA that requires each facility to have a qualified medical physicist annually survey mammography equipment (42 U.S.C. 263b(f)(1)(F)). In this instance, therefore, annual physicist surveys are being reviewed by both the accreditation body and the inspector. FDA's experience under the interim final regulations is that of 7,431 MQSA inspections in 1995, only 5 accredited facilities were without annual physicist surveys. This suggests that duplicative review serves a compliance purpose. However, it may be possible under a different approach for the accreditation body to accept inspection reviews of surveys, or, for inspectors to accept an accreditation body's review of a facility's survey. While there are strengths in a program that has multiple checks and overlapping areas of responsibility to ensure compliance, there are also cost and resource considerations that may favor alternative approaches to satisfy statutory mandates. Such alternative approaches will need to adequately ensure integrity of the evaluation if oversight mechanisms are decreased. FDA is soliciting comments on approaches that would reduce the overlapping nature of many quality assurance provisions proposed, while maintaining assurances for integrity of the evaluation.

Advantages and disadvantages exist in adopting an approach that utilizes detailed design and qualification-based standards versus an approach based on performance standards and outcomes measures. For example, detailed design and behavior-based standards may be clear and precise; they can provide an objective evaluation of compliance during an inspection and make clear to facilities what is expected of them. However, these standards can limit flexibility and innovation and do not ensure that everyone who meets the established criteria is indeed competent. On the other hand, performance standards and outcome measures may allow greater variability in behavior and methods of compliance. However, while outcome measures may reflect the true nature of performance in a population and be an incentive to good performance, they may also be subject to adjustments to circumvent low performance. FDA is soliciting comments on the possibility of pursuing

quality mammography through more performance and outcome-based standards. FDA would also like comments on the anticipated economic consequences of this approach compared to the approach of the proposed regulations. FDA hopes the comments will provide more information regarding the short and long-term viability of this alternative approach for purposes of mammography regulation.

The following sections discuss ideas for the application of performance and outcome-based standards to mammography facility operations:

A. Mammography Equipment and Quality Control

Under current proposals, FDA has specified mammography equipment performance and design requirements. While design specifications are clear, they may inadvertently impede technical innovation. An alternative proposal would be to use phantom image testing as a complete equipment system test, thereby eliminating the need for other specific quality control tests, or, permitting those other tests to be conducted less frequently. The phantom image test is currently being proposed to be done weekly as a part of the facility's ongoing quality assurance program. The current phantom used, however, is not the optimal design if phantom image testing were to serve as a single system performance evaluation criterion. A recent article (Ref. 8) suggested that the current phantom has limitations in simulating the average breast. Research may be necessary to design a phantom whose image will be significantly affected by enough characteristics of the system so that other tests could be eliminated.

Another issue associated with the use of phantom image testing as a single system evaluation test is that there is inadequate information available on how phantom images correlate with actual clinical images. There is concern that no phantom image evaluation will adequately predict the clarity and characteristics of the entire biologic spectrum of breast tissue.

FDA believes it is theoretically possible to substitute phantom image testing for some equipment requirements and some quality control tests if some other standards were made more stringent and the phantom were suitable. For example, the frequency of phantom image testing might be increased to daily if the backing material could be changed to be more tissue equivalent, if different thicknesses could be developed to represent the range of actual breast thicknesses encountered in daily practice, and if research established appropriate performance parameters based on these changes. A step wedge might be included in the design of the phantom so that, after a trial period, daily sensitometry could be eliminated. It may be necessary to record the mAs value daily, so that when deviations occur, it would be possible to determine if it was an x-ray machine variation or film processor variation. Ideally, this image test would be combined with a dose measurement, at least periodically, so that an even more complete system test would be conducted.

Another possible performance measure for equipment and substitute for equipment specifications and quality control tests is an ongoing analysis of a facility's repeat rate. Under both the interim final regulations and the proposed final regulations set forth elsewhere in this issue of the Federal Register, the repeat rate is to be analyzed every 3 months, and up to 250 exams are used. Ongoing repeat analysis might substitute for some quality control tests, equipment requirements, and technologist requirements. Using the repeat rate as a performance outcome might be appropriate if repeat analysis were conducted continuously, rather than periodically, if personnel were trained to evaluate the films according to the criteria currently used by accreditation bodies for clinical image review, and if trends or problems were identified and corrected immediately. One potential problem with this approach is that the repeat rate is easily altered by a facility through the acceptance of all examinations of any quality performed. Thus, a facility could conceivably have a zero repeat rate, but many problems. Adopting use of repeat rates as a performance measure would require the development of mechanisms to minimize this type of manipulation.

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

Under the current proposal for final standards, interpreting physicians would be required to meet initial qualifications through board certification or training, mammography-specific training and experience, and continuing education and experience requirements. While these requirements for training and experience guarantee familiarity with mammography and interpretation issues, it is possible that interpretation performance can be less than optimal despite meeting these requirements. An alternative means to ensuring the MQSA's mandate of ''* * * quality assurance * * * at each facility that is adequate and appropriate to ensure the reliability, clarity, and accuracy of interpretation of mammograms * * *'' (42 U.S.C. 263b(A)(1)(A)) may be to use performance-based standards.

The use of specific medical outcomes measures is discussed in the proposal entitled ''Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements'', published elsewhere in this issue of the Federal Register. FDA recognizes the significant cost and effort associated with tracking examinations interpreted as nonmalignant. While the absence of cancer registries in many locales limits the feasibility of collecting many outcomes measures, those locales with cancer registries may be able to collect data on sensitivity and specificity. These locales might be able to forego compliance with all or some of the proposed personnel qualifications so long as sensitivity and specificity for screening mammography, or other measures such as minimal cancer detection rates, were within an acceptable range, e.g., the Agency for Health Care and Policy Research guidelines. These ranges may have to be refined using other data from recently published practice patterns, clinical trials, and information from the National Cancer Institute's Breast Cancer Consortium studies. In order to be valid, facilities would have to track other variables of the screening clientele that could affect sensitivity and specificity such as age and other parameters that are currently being identified through research. This data collection, while time-consuming, would enhance the validity of calculated statistics.

In areas without cancer registries, positive predictive value may be calculated to assist in ensuring appropriateness and accuracy of physician recommendations. FDA notes that there is not yet a consensus on what ranges of the positive predictive value are acceptable, and that this value is subject to intentional adjustment by practices in the facility. However, use of the positive predictive value coupled with indices of early detection, such as sizes of cancers detected, could reduce concerns about intentional manipulation of data and provide a useful measure of an individual physician's comparative performance from year to year.

FDA recognizes concerns raised by the NMQAAC about public disclosure of statistics, including issues of legal liability and public confusion over the meaning and limitations of statistics.

The agency believes that data generated and reviewed for mammography audits should be used internally by each facility to improve individual and group performance. The agency further recognizes that State laws with respect to medical audit information vary and may not prevent disclosure in State courts through discovery or other procedures established by State law. However, concerns raised about public disclosure of statistics and consumers not understanding their limitations could be addressed through active consumer education to assist consumers in analyzing information and making health care decisions. A recent summary of the New York State experience with public reporting of cardiovascular surgery mortality outcomes showed improved risk-adjusted operative mortality beyond what was expected using nationwide trends for adjustment. The summary states that the collection data on mortality and reporting risk-adjusted mortality rates to hospitals and physicians contributed to improved outcomes (Ref. 9).

Finally, FDA is aware that substantial differences in statistics can arise from differences in definitions of screening mammography. Under an outcomes measurement approach, it might be necessary for the agency to define the precise situations that would constitute screening. For example, a woman with implants might have a diagnostic mammogram, meaning the procedure was under the direct supervision of an interpreting physician and consisted of more than standard mediolateral oblique/craniocaudal views. However, this woman's mammogram interpretation and her medical outcome might be classified by FDA as screening for statistical calculations if she was asymptomatic at the time of the examination. Thus, choosing to use outcomes measures could require the agency to establish certain definitions of medical practice.

Another alternative to proposed training and experience regulations is to have interpreting physicians undergo proficiency testing on mammogram interpretation. While the establishment of such tests and their periodic administration would be challenging, this testing, perhaps administered through the accreditation bodies, would allow for direct assessment of mammography interpretive skills. Remedial programs and reassessments would have to be established as well. FDA is aware of the ACR's Committee on Mammography Interpretive Skills Assessment (COMISA), created in 1992. COMISA is charged with development of an educational examination tool. Experiences gained through this project could be used for development of a proficiency test.

It is possible that regulations for interpreting physician qualifications could include all three options: Training and experience requirements, medical outcomes audit statistics and acceptable ranges, and an option for periodic proficiency testing, or some combination allowing for choice of compliance option. Again, FDA solicits comments on the utility and advisability of this approach.

C. Mammography Personnel: The Radiologic Technologist

Under the current proposal for final standards, radiologic technologists would be required to meet initial qualifications through board certification or training, mammography-specific training and experience, and continuing education and experience requirements. While these requirements for training and experience guarantee familiarity with the performance of mammograms and mammography issues, it is possible that the technologist's own performance can be less than optimal despite meeting these requirements. An alternative means to ensure proper mammography performance is to consider using clinical image review as a performance assessment tool. Clinical image review of a sufficient number of mammograms performed by the radiologic technologist would provide information on compression, positioning, selection of adequate technique factors, and production of clear and reliable mammograms. This assessment would have to control for equipment performance and processing in order for it to be a true measure of technologist performance. This could perhaps be accomplished through appropriate daily phantom imaging as discussed above. In addition, the method for selection of mammograms would have to be carefully defined to allow for representative sampling of technologist performance given differences in patients' habitus, breast morphology, and cooperativeness with the procedure. The assessment would also have to be correlated with repeat rate. It would be undesirable for the technologist to achieve a high level of clinical image quality at the cost of a high repeat rate.

As with interpreting physicians, the development of a technologist proficiency test that would include a practical examination could also be viewed as a performance-based measure. Currently, the ARRT's certification in mammography only includes a written examination. Expansion of this to include a practical examination along with periodic recertification examinations would increase the viability of ensuring competency in mammographic procedures.

D. Mammography Personnel: The Mammography Medical Physicist

Under the current proposal for final standards, medical physicists must be either board certified in an appropriate specialty or State approved, and, in addition, meet education and experience requirements. While these requirements are meant to ensure knowledge and experience in surveying and overseeing mammography machines and quality control, they do not necessarily ensure good performance. Alternative performance measures would include the development of a written examination along with a practical survey test. The survey test, while most reflective of actual practice, still could not test for all possible situations a medical physicist is called upon to deal with at facilities. It would be necessary to have this proficiency test repeated periodically, requiring the development of new logistic and administrative procedures. If this approach were adopted, the practicing medical physicist's actual performance outside of the testing environment still must be correlated to test performance. Development of an accurate and predictive tool would require adequate resources.

E. Request for Comments

FDA is interested in comments on the desirability of any of the approaches described above, and on any other possible approaches that would address the issue of performance-based standards. If performance-based standards are considered desirable, there may be need for additional research to provide information to make scientifically sound and cost effective performance based standards. There are several options as to how the agency could proceed while such research is being performed. The agency could leave the interim final standards in place, or, the agency could make minor amendments to the interim final standards to clarify points but not add any new requirements, or, the agency could proceed with final implementation of the set of standards contained in this proposal as modified after consideration of the comments. FDA invites comment on the pursuit of any of these or other options.

III. Scope and Definitions

A. Scope

Proposed § 900.1 summarizes the scope of part 900 (21 CFR part 900), which contains two subparts implementing different sections of 42 U.S.C. 263b. Subpart A of part 900 establishes application procedures and requirements for accreditation bodies. Subpart B of part 900 establishes procedures for mammography facility certification and quality standards for mammography facilities. The proposed requirements for subpart B of part 900 are published elsewhere in this issue of the Federal Register.

B. Definitions

FDA is proposing amendments and additions to the definitions established in § 900.2 of the interim regulations. These proposed definitions apply to the regulations in this proposal and in the other MQSA proposals published elsewhere in this issue of the Federal Register.

1. Amendments

a. *Mammography.* The amendments to the interim regulations published in the Federal Register of September 30, 1994 (59 FR 49808), added definitions of ''screening mammography'' and ''diagnostic mammography'' to clarify the applicability of the interim regulations to various types of facilities. However, differences of opinion within the professional community regarding the distinction between these two types of mammography became apparent in discussions between NMQAAC members and consultants at the January 1995 NMQAAC meeting. In addition, proposed changes to the interim regulations have made it unnecessary to define screening and diagnostic mammography for the purpose of these regulations. Therefore, FDA is proposing to delete these two definitions. The reference to screening and diagnostic mammography previously included in the interim definition of ''interpreting physician'' also would be deleted.

The definitions of screening and diagnostic mammography were intended to clarify which breast cancer screening or diagnostic mammography activities conducted by a facility were exempt from the MQSA regulations. Such exempted activities included any breast imaging conducted in a research setting as part of a scientific study to evaluate experimental mammography devices, in accordance with FDA's investigational device exemption regulations (21 CFR part 812). This exclusion did not apply to mammography conducted using any conventional mammography device as part of the scientific study to provide baseline data for evaluating the safety and efficacy of the experimental device. An exemption was also made for interventional mammography, which involves the use of breast radiography devices to produce radiographic images of the breast in association with localization or biopsy procedures.

These exemptions were based on FDA's belief that science had not advanced to the point where effective national quality standards could be developed for these devices. Because FDA still believes this to be the case, the agency is proposing to retain these exemptions, but to incorporate them into the proposed definition of ''mammography.'' Eventually, FDA does expect to develop standards for interventional mammography devices and for research devices that come into standard use.

b. *Interpreting physician.* Throughout the MQSA regulations, FDA is proposing to use only the term ''interpreting physician'' to refer to persons who interpret mammograms or perform clinical image reviews. Therefore, the agency is deleting the interim definition for ''qualified practicing physician.'' Also, as discussed previously, the term ''interpreting physician'' would be modified to refer to mammography, rather than screening and diagnostic mammography.

c. *Patient.* In the interim regulations, the term ''patient'' is used to mean any individual who undergoes clinical evaluation in a mammography facility, regardless of whether the person is referred by a physician or self-referred. However, most individuals who undergo mammography are not ill and do not have a condition requiring medical care. Therefore, FDA is proposing to substitute the term ''examinee'' for the term ''patient.''

2. New Definitions

a. *Personnel qualifications.* During implementation of the interim regulations, questions were raised concerning how physicians, technologists, or physicists in training, who had not satisfied the personnel requirements by October 1, 1994, or who failed to maintain them after October 1, 1994, might establish or reestablish their credentials. In response to these concerns, FDA is proposing amendments (published elsewhere in this issue of the Federal Register) to the personnel requirements in § 900.12(a) (21 CFR 900.12(a)). For the purpose of implementing these provisions, FDA is proposing to add definitions of ''contact hour,'' ''direct instruction,'' and ''direct supervision.'' The intent of these definitions is to clarify that: (1) The individuals providing training to mammography personnel must be in contact with the trainees, at least to the extent of evaluating their work; and (2) those who are supervising the trainees must be available to review, and, if necessary, correct the trainees' work.

The proposed revisions to § 900.12(a) also would ensure that individuals trained in the use, survey, or interpretation of images produced using one modality do not begin work using another modality without first receiving training related to that modality. The addition of this requirement made it necessary to define the term ''modality.'' FDA is proposing to define this as a form of technology, within the scope of the MQSA, for performing radiography of the breast. The technologies considered to be modalities under this proposed definition would include existing technologies, such as screen-film systems and xeromammography, and any future technologies within the scope of the MQSA. Technologies such as ultrasound that are used to image breast tissue but do not fall within the scope of the MQSA would not be considered modalities for the purpose of this proposed rule.

Under the interim regulations, interpreting physicians are allowed to use double reading to meet the initial and continuing experience requirements for physicians. The proposed requirements would permit this practice to continue. However, because there was some confusion over the meaning of the term, FDA is proposing to add a definition of ''double reading.''

A major concern of the NMQAAC was to make sure that the initial experience requirement for interpreting physicians did not cause problems for diagnostic residency programs that schedule the mammography rotations in the first 6 months of the final year. At the same time, it was considered important that interpreting physicians meet this requirement in a relatively short time before beginning to interpret mammograms independently. To meet both goals, FDA is proposing (elsewhere in this issue of the Federal Register) to require residents to become certified at the ''first allowable time'' if they want to use residency training to meet the initial experience requirement. Therefore, a definition of the term ''first allowable time'' has been added to the proposed regulations.

The interim requirements in § 900.12(a)(3) deal specifically with the qualifications of the medical physicist.

The interim regulation refers to requirements for degree programs in ''physical science.'' This term can cover a broad spectrum of scientific disciplines, some of which are unrelated to the knowledge and skills needed for mammography. For this reason, a narrower definition of physical science is needed (with respect to both bachelor's and advanced degrees). FDA is proposing that only physics, chemistry, radiation science (including medical physics and health physics), and engineering be considered as physical sciences for the purpose of this regulation.

b. *Equipment.* Standards for equipment used in mammography were established in § 900.12(b) of the interim regulations. Because of additional proposed equipment requirements, FDA is adding a definition for the term ''mean optical density,'' defined as the average of optical densities measured for specified phantom thicknesses at clinically appropriate peak kilovoltage (kVp) levels. A definition of the term ''mammography unit'' is being added to clarify that when this term is used, the reference is to the x-ray generator and associated components.

c. *Quality assurance.* Proposed § 900.12(d) would specify new requirements for the individuals responsible for various aspects of the facility quality assurance program. These proposed changes have made it necessary to define the terms ''lead interpreting physician'' and ''quality control technologist.'' The lead interpreting physician would be the interpreting physician with primary responsibility for ensuring that the facility quality assurance program meets the requirements of paragraphs (d) through (f) of § 900.12. It would be left to the discretion of the facility whether this individual would also have other supervisory duties. The quality control technologist(s) would be responsible for those aspects of the quality assurance program not carried out by the lead interpreting physician or medical physicist.

Several definitions are being added to proposed § 900.2 on quality assurance requirements for equipment. These include a definition for ''time cycle,'' which means the film development time, and for ''traceability,'' which relates to calibration of radiation measuring instruments.

d. *Mammography medical outcomes audit.* Discussions with the NMQAAC regarding the medical auditing requirements in proposed § 900.12(f) indicated a need to define medical audit. Therefore, FDA is proposing to define the ''mammography medical outcomes audit'' as a systematic collection of mammography results and the comparison of these results with outcome data (e.g., results of subsequent biopsy followup procedures).

For use with the mammography medical outcomes audit, FDA is also defining a ''positive mammogram'' as one with an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.'' This definition incorporates two of the assessment categories described in § 900.12(c)(1)(iii) (published elsewhere in this issue of the Federal Register) for use in mammography records and reports.

e. *Breast implant.* Proposed § 900.12(g), published elsewhere in this issue of the Federal Register, contains new standards for mammography of examinees with breast implants. Establishment of such standards is required by the MQSA. FDA is proposing to define a ''breast implant'' as a prosthetic device implanted in the breast.

f. *Consumer complaint mechanism.* FDA is proposing new requirements in §§ 900.4(g) and 900.12(h), published elsewhere in this issue of this Federal Register, for consumer complaint mechanisms to be established by facilities and accreditation bodies. The purpose of these new requirements is to ensure that serious complaints about the quality of the MQSA-related mammography services are adequately addressed without unduly burdening facilities and accreditation bodies with Federal regulations requiring extensive consideration of relatively minor complaints (e.g., complaints about facility air temperature). Therefore, FDA is proposing to add definitions of ''adverse event,'' ''serious adverse event,'' and ''serious complaint'' to clarify the kinds of situations that would require full investigation and correction under the statute. These definitions also would clarify that any substantive complaints that warrant attention, but are not within the scope of the MQSA (e.g., discrimination or harassment), must be handled through other mechanisms.

FDA is proposing to add a definition of ''consumer'' to clarify that the consumer complaint process also can be used by interested parties other than the examinee (e.g., family members or referring physicians).

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

This proposed rule sets forth preliminary ideas for the application of alternative performance and outcome-based standards to ensure quality mammography. FDA requests that comments submitted on this proposal also address the estimated costs and benefits of such alternatives.

FDA has examined together the impacts of the remaining four proposed rules to implement the MQSA requirements, published concurrently in this issue of the Federal Register, under Executive Order 12866, under the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an annual expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The agency has conducted preliminary analyses of the proposed rules, and has determined that the proposed rules are consistent with the principles set forth in the Executive Order and in these two statutes. The Regulatory Impact Study that details the agency's calculation of these economic impacts is available at the Dockets Management Branch for review. A brief summary of the cost and benefit determination follows.

Incremental annual costs were estimated for each section of the proposed regulations. Actions expected to be taken by mammography facilities to come into compliance with the proposal were identified and current compliance levels were estimated in conjunction with agency experts and industry consultants. Costs were determined for a 10-year analysis period. Yearly costs of compliance for mammography facilities were estimated to range from a high of $203.2 million during the first year of implementation

to $25.2 million during the 10th year (2005). These yearly costs differed due to the phased implementation dates for some of the proposed requirements. Overall, average annualized costs of this proposal (at a 7-percent discount rate) are preliminarily estimated to equal $61.4 million.

Over the full 10-year analysis period, expenditures for the largest cost element (replacement of mammography units and film processors with units meeting standards required in proposed § 900.12(b)) could total more than $270 million and contribute approximately $35 million in average annual costs (57 percent of total average annual costs). Other major cost components include proposed § 900.12(c)(2)(i) (written notification of patient) which accounts for average annual costs of $14 million (23 percent of total average annual costs), proposed § 900.12(c)(3)(ii) (telephone contact with referring physicians) which accounts for over $4 million in annual costs (7 percent of total average annual costs), and proposed § 900.12(e)(2) (requiring weekly image quality tests) which accounts for average annual costs of almost $2 million (3 percent of total average annual costs).

The benefits of the proposed rule were estimated as illustrations of the expected health outcomes for given levels of quality improvement. FDA believes that the proposed rules are complementary, and that quality improvements are limited by the ''weakest link'' in the process of conducting or interpreting a mammographic examination. Thus, benefits were estimated assuming compliance with all of the proposed requirements at the same level of overall quality.

Benefit scenarios were based on an outcome prediction model that forecast breast cancer survival based on stage-determination at the time of identification. In addition, FDA estimated the reduction in costs attributable to the avoidance of followup procedures for those patients correctly diagnosed as not having cancer due to a range of quality gains that may occur as a result of the proposed rule. The calculated benefits are illustrative of the magnitude of health gains that would be expected to follow heightened quality levels of sensitivity and specificity. For example, a 5-percent gain in a sensitivity measurement of 80 percent would indicate a revised sensitivity level of 81 percent (a reduction of the rate of false positives from 20 percent to 19 percent).

Overall, the agency could not predict precise quality improvement gains. FDA estimates, however, those 5-year survival rates of all patients identified with breast cancer would increase by 0.006 percent if quality improves by 1 percent, 0.028 percent if the proposed rules result in a 5-percent gain in quality, and 0.084 percent if the quality improvements induce a 20-percent gain in sensitivity. (These are equal to increased survival rates of 0.02, 0.1, and 0.3 percent for all screened patients at the estimated levels of improvement.) Based on current disease prevalence rates, these results project that a 1-percent quality improvement would avert 10 breast cancer fatalities annually (based on 5-year survival rates), whereas quality improvement levels of 5 and 20 percent, respectively, would prevent 50 and 150 cancer fatalities.

Several analyses have estimated that society has indicated a willingness to pay to avoid a statistical death of approximately $5 million. Therefore, a 1-percent improvement in sensitivity as a result of this proposal would have monetized benefits of $50 million. Likewise, 5 and 20 percent improvements would bring annual benefits of $250 million and $750 million, respectively.

In addition, the proposed rules are anticipated to result in corresponding percent improvements in specificity, which would reduce the number of followup procedures in nondiseased patients. An improvement of 1 percent would reduce current annual medical expenditures by approximately $14 million. If the improvement in specificity were as high as 5 percent, the annual reduction in medical costs would equal $72 million. A 20-percent improvement in quality would reduce current annual medical costs by $287 million.

FDA recognizes that the nature of these proposed regulations may have a disproportionate effect on small volume mammography facilities as fixed costs of compliance for equipment improvements are likely to increase the cost per mammogram for low-volume facilities relatively more than for high-volume facilities. FDA is currently collecting additional information on the potential impact on this industry sector, and requests comments that will assist it in accounting for this impact.

The agency also notes that average annual compliance costs of $61.4 million could increase the cost per screening mammogram at certain clinics by from 2 to 6 percent. FDA has estimated that if these costs are passed on to consumers, the demand for mammograms could be reduced by approximately 200,000 per year (or 0.9 percent of current demand). However, the agency believes that quality improvement savings may more than balance these expected price effects.

FDA also examined the effect of alternative implementation schedules for this proposal. An alternative requiring even more elaborate equipment upgrade immediately upon issuance of the regulations was rejected as putting an unnecessary burden on the industry, with estimated average annual costs of more than $120 million. By eliminating some specifications that were considered marginal to ensuring mammography quality, and phasing in some requirements to allow for normal replacement of current equipment, the agency reduced the cost of compliance. FDA also found that delaying the implementation of the proposed equipment requirements by an additional year, while reducing the average annual compliance costs by $7.1 million, would mitigate the expected impact of the proposed rule on quality improvements. Therefore, the proposed implementation schedule was selected as a reasonable balance between compliance costs and quality improvements.

MQSA includes a separate reimbursement mechanism to repay State, local, or tribal governments for the costs of inspections required by these proposed regulations. Consequently, no unfunded mandate is placed on local governments as a result of these proposals.

In summary, FDA expects that the proposal would lead to mammography quality increases. Average annual costs of compliance with this proposal are estimated to be $61.4 million. The estimated benefits accrue as a result of fewer breast cancer mortalities as well as the avoidance of unnecessary surgery. While the magnitude of the expected quality increases are currently under investigation, an improvement of only 1 percent would result in monetized annual benefits of $64 million including 10 fewer cancer mortalities, which slightly exceed the estimated compliance costs. If the quality improvements range to 5 or 20 percent, the benefits would increase proportionately. A 5-percent improvement projects average annual monetized benefits of $322 million. At this level of quality improvement, the cost savings of avoiding surgery are, by themselves, greater than compliance costs. This would occur in addition to 50 fewer breast cancer mortalities per year. A 20-percent quality improvement would result in average annual monetized benefits of $1,037 million, with 150 fewer annual breast cancer deaths due to earlier detection.

Because of the preliminary nature of these estimates, FDA requests comments on all of the methodology and projections included in this analysis. Comments may be submitted to the Dockets Management Branch (address above).

IV. Paperwork Reduction Act of 1995

The information collections contained in the December 21, 1993, interim regulations implementing the MQSA were approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13) under control number 0910–0309, which includes OMB approval for Form FD–3422. The approval will expire July 31, 1998. Three of the five proposed rules to amend 21 CFR part 900, published together in this issue of the Federal Register, contain amendments to the approved information collections, and these revisions are subject to review by OMB under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the revised information collections to 21 CFR part 900 are shown below with an estimate for any annual reporting and recordkeeping burdens which will be changed by these proposed rules. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Title: Mammography Facilities.

Description: These information collection requirements apply to accreditation bodies and to mammography facilities. In order to be an approved accreditation body, private nonprofit organizations or State agencies must submit an application to FDA and establish procedures and a quality assurance program. Mammography facilities must obtain and prominently display an FDA-issued certificate or provisional certificate; have a medical reporting and recordkeeping program, a medical outcomes audit program, a consumer complaint mechanism; and maintain records documenting personnel qualifications. These actions are being taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

Respondent Description: Businesses and other for-profit organizations, nonprofit organizations, Federal, State, and local governments.

Therefore, the agency solicits public comments on the revised information collection requirements in order to: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (2) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) enhance the quality, utility, and clarity of the information to be collected; and (4) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

PROPOSED REQUIREMENTS FOR ACCREDITATION BODIES OF MAMMOGRAPHY FACILITIES

[Table 1a.—Estimated Annual Reporting Burden]

CFR Section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours	Total capital costs	Total operating and maintenance costs
900.3(b)(3)	10.0	1.0	10.0	60	600	$50	
900.4(a)(7) [1].							
900.4(b)(2) [1].							
900.4(c) [1].							
900.4(d) [1].							
900.4(e)(1) [1].							
900.4(e)(2) [1].							
900.4(h)(1) [1].							
900.4(h)(3) [1].							
900.4(i)(1)[1].							
900.4(i)(2)[1].							
Total					600	$50	0

[1] There is no additional burden.

PROPOSED REQUIREMENTS FOR ACCREDITATION BODIES OF MAMMOGRAPHY FACILITIES

[Table 1b.—Estimated Annual Recordkeeping Burden]

CFR section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.3(f)(1)	10	130	1,300	200	2,000		
900.4(c) [1].							
900.4(c)(2)(viii) [1].							
900.4(c)(5)(iii) [1].							
900.4(d) [1].							
900.4(d)(5)(iii) [1].							
900.4(e)(1) [1].							
900.4(e)(2) [1].							
900.4(f)(2) [1].							
900.4(g) [1].							
900.4(h)(1) [1].							
Total					2,000	0	0

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; GENERAL FACILITY REQUIREMENTS

[Table 2a.—Estimated Annual Reporting Burden]

CFR section	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours	Total capital costs	Total operating and maintenance costs
900.11(b)(1) [1]	.....	.....	.....	.....	.....	.....	.....
900.11(b)(2) [1]	.....	.....	.....	.....	.....	.....	.....
900.11(b)(3) [1]	.....	.....	.....	.....	.....	.....	.....
900.11(c)	10,000	0.005	50	20	1,000	.....	$1,000
900.12(c)(1) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(c)(2)(i) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(c)(3)(i) [1]	.....	.....	.....	.....	.....	.....	.....
900.15(d)(3)(ii)	10,000	0.002	20	2	40	.....	100
900.18(c)	10,000	0.0005	6	2	12	.....	60
900.18(e) [1]	10	0.1	1	1	1	.....	10
Total	.....	.....	.....	.....	1,053	0	$1,170

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; GENERAL FACILITY REQUIREMENTS

[Table 2b.—Estimated Annual Recordkeeping Burden]

CFR section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.12(c)(4) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(d)(2)(i) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(d)(2)(ii)	10,000	1	10,000	0.25	2,500		
900.12(d)(2)(iii)	10,000	1	10,000	1	10,000		
900.12(d)(2)(iv) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(f)(2) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(f)(4) [1]	.....	.....	.....	.....	.....	.....	.....
900.12(h)(2)	10,000	2	20,000	0.5	10,000	.....	$20,000
Total	.....	.....	.....	.....	22,500	0	$20,000

[1] There is no additional burden.

QUALITY STANDARDS AND CERTIFICATION REQUIREMENTS FOR MAMMOGRAPHY FACILITIES; PERSONNEL REQUIREMENTS

[Table 3.—Estimated Annual Recordkeeping Burden]

CFR Section	Number of recordkeeepers	Annual frequency of recordkeeping	Total annual records	Hours per recordkeeper	Total hours	Total capital costs	Total operating and maintenance costs
900.12(a)(4)[1]	.....	.....	.....	.....	.....	.....	.....

[1] There is no additional burden.

Under OMB information collection no. 0910–0309, 82,810 burden hours were approved for information collection currently contained in 21 CFR part 900. The additional requirements contained in these proposed rules will add 26,153 burden hours to this estimate, resulting in a total annual burden of 108,963.

As required by section 3507(d) of the Paperwork Reduction Act of 1995, FDA has submitted a copy of the five proposed rules amending 21 CFR part 900 to OMB for its review of the revised information collection requirements; these five proposed rules are published together in this issue of the Federal Register. Other organizations and individuals interested in submitting comments regarding this burden estimate or any aspect of these information collection requirements, including suggestions for reducing the burden, should direct them to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, ATTN: Desk Officer for FDA. Written comments on the information collections should be submitted by May 3, 1996.

VII. Comments

The agency will consider any comments submitted in response to this proposed rule in its evaluation of the proposed alternative approaches for quality mammography and the four proposed amendments to the interim regulations published elsewhere in this issue of the Federal Register. FDA advises that, under 21 CFR 10.30(d), any comments submitted in response to this notice will be included under the docket number found in brackets in the heading of this document.

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this NPRM. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

VIII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Wingo, P. A., T. Tong, and S. Bolden, ''Cancer Statistics 1995,'' *CA: A Cancer Journal for Clinicians*, 45:8–30, 1995.

2. Feuer, E. J., L. M. Wun, and C. C. Boring, et al., ''The Lifetime Risk of Developing Breast Cancer,'' *Journal of the National Cancer Institute*, 85:892–897, 1993.

3. Ries, L. A. G., B. A. Miller, and B.F. Hankey, et al. (eds.), ''SEER Cancer Statistics Review, 1973–1991,'' National Cancer Institute, NIH Pub. No. 94–2789, Bethesda, MD, 1994.

4. Brown, M. L., F. Houn, E. A. Sickles, L.G. Kessler, ''Screening Mammography in Community Practice: Positive Predictive Value of Abnormal Findings and Yield of Follow-Up Diagnostic Procedures,'' *American Journal of Radiology*, 165:1373–1377; 1995.

5. Kuester, G. F., S. M. Wolfe, ''HRG Report on Screening Mammography, Public Citizen Health Research Group,'' July 1991.

6. Conway, B. J., O. H. Suleiman, F. G. Rueter, R. G. Antonsen, R. J. Slayton, J. L. McCrohan, ''Does Credentialing Make a Difference in Mammography?,'' U.S. Food and Drug Administration, Center for Devices and Radiological Health, Rockville, MD, Presented to the Radiological Society of North America, November 19, 1992.

7. ''The National Strategic Plan for the Early Detection and Control of Breast and Cervical Cancers,'' U.S. Department of Health and Human Services, Public Health Service.

8. Geise, R. A., A. Palchevsky. Composition of Mammographic Phantom Materials. *Radiology* 198:347–350, 1996.

9. Chassin, M. R., E. L. Hannan, B. A. DeBuono. Benefits and Hazards of Reporting Medical Outcomes Publicly. The New England Journal of Medicine, pp. 394–398 February 8, 1996.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, Mammography, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 900 be amended as follows:

PART 900—MAMMOGRAPHY

1. The authority citation for 21 CFR part 900 continues to read as follows:

Authority: Secs. 519, 537, and 704(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i, 360nn, and 374(e)); sec. 354 of the Public Health Service Act (42 U.S.C. 263b).

2. Sections 900.1 and 900.2 are revised to read as follows:

§ 900.1 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (42 U.S.C. 263b). The intent of subpart A of this part is to establish procedures whereby an entity can apply to become an FDA-approved accreditation body to accredit facilities to be eligible to perform screening or diagnostic mammography services. Subpart A further establishes requirements and standards for accreditation bodies to ensure that all mammography facilities under the jurisdiction of the United States are adequately and consistently evaluated for compliance with national quality standards for mammography. The intent of subpart B of this part is to establish minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. The regulations set forth in this part do not apply to facilities of the Department of Veterans Affairs.

§ 900.2 Definitions.

The following definitions apply to subparts A and B of this part:

(a) *Accreditation body* or *body* means an entity that has been approved by FDA under 42 U.S.C. 263b(e)(1)(A) to accredit mammography facilities.

(b) *Action limits* or *action levels* means the minimum and maximum values of a quality assurance measurement that can be interpreted as representing acceptable performance of the equipment being tested. Values less than the minimum or greater than the maximum action limit or level indicate that corrective action must be taken by the facility. Action limits or levels are also sometimes called control limits or levels.

(c) *Adverse event* means an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Adverse events include, but are not limited to:

(1) Poor image quality;

(2) Failure to send mammography reports within 30 days to the referring physician or the self-referred examinee (as specified in § 900.12(c)(2) and (c)(3)(i)); and

(3) Use of personnel that do not meet the applicable requirements of § 900.12(a).

(d) *Breast implant* means a prosthetic device implanted in the breast.

(e) *Certificate* means the certificate described in 42 U.S.C. 263b(b)(1).

(f) *Certification* means the process of approval of a facility by FDA to provide mammography services.

(g) *Clinical image* means a mammogram.

(h) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the examinee or representatives of the examinee (e.g., family members or referring physicians).

(i) *Contact hour* means an hour of training received through direct instruction.

(j) *Direct instruction* means:

(1) Face-to-face interaction between instructor(s) and student(s), as when the instructor provides a lecture, conducts demonstrations, or reviews student performance; or

(2) The administration and correction of student examinations by an instructor(s) with subsequent feedback to the student(s).

(k) *Direct supervision* means that:

(1) During joint interpretation of mammograms, the supervising physician reviews, discusses, and confirms the diagnosis of the physician being supervised and signs the resulting report before it is entered into the examinee's records; and

(2) During the performance of a mammography examination or survey of the facility's equipment and quality assurance program, the supervisor is present to observe and correct, as needed, the performance of the individual being supervised who is performing the examination or conducting the survey.

(l) *Double reading* means two or more interpreting physicians interpreting the same clinical image.

(m) *Examinee* means any individual who undergoes a mammography evaluation in a facility, regardless of whether the person is referred by a physician or is self-referred.

(n) *Facility* means a hospital, outpatient department, clinic, radiology practice, mobile unit, office of a physician, or other facility that conducts mammography activities, including the following: Operation of equipment to produce a mammogram, processing of the mammogram, initial interpretation of the mammogram, and maintaining viewing conditions for that interpretation. This term does not include a facility of the Department of Veterans Affairs.

(o) *First allowable time* means the earliest time a resident is eligible to take the diagnostic radiology boards from an FDA-approved certifying body. The ''first allowable time'' may vary with the certifying body.

(p) *Interpreting physician* means a physician who interprets mammograms and who meets the requirements set forth in § 900.12(a)(1).

(q) *Lead interpreting physician* means the interpreting physician assigned the general responsibility for ensuring that a facility's quality assurance program meets all of the requirements of § 900.12(d) through (f). The administrative title and other supervisory responsibilities of this individual, if any, are left to the discretion of the facility.

(r) *Mammogram* means a radiographic image produced through mammography.

(s) *Mammography* means radiography of the breast, but does not include:

(1) Radiography of the breast performed during invasive interventions for localization or biopsy procedures; or

(2) Radiography of the breast performed as part of a scientific study to evaluate an investigational mammography device conducted in accordance with FDA's investigational device exemption regulations in part 812 of this chapter.

(t) *Mammography equipment evaluation* means an onsite assessment of a mammography unit or image processor for the purpose of making a preliminary determination as to whether the equipment meets all of the applicable standards in § 900.12(b) and (e).

(u) *Mammography medical outcomes audit* means a systematic collection of mammography results and the comparison of those results with outcomes data.

(v) *Mammography unit* or *unit* means an assemblage of components for the production of x-rays for use during mammography, including, at a minimum: An x-ray generator, an x-ray control, a tube housing assembly, a beam limiting device, and the necessary supporting structures for these components.

(w) *Mean optical density* means the average of the optical densities measured for phantom thicknesses of 2 centimeters to 6 centimeters using values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

(x) *Medical physicist* means a person trained in evaluating the performance of mammography equipment and facility quality assurance programs and who meets the qualifications for a medical physicist set forth in § 900.12(a)(3).

(y) *Modality* means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Examples are screen-film mammography and xeromammography.

(z) *Phantom* means a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast disease and cancer.

(aa) *Phantom image* means a radiographic image of a phantom.

(bb) *Physical science* means physics, chemistry, radiation science (including medical physics and health physics), and engineering.

(cc) *Positive mammogram* means a mammogram that has an overall assessment of findings that are either ''suspicious'' or ''highly suggestive of malignancy.''

(dd) *Provisional certificate* means the provisional certificate described in 42 U.S.C. 263b(c)(2).

(ee) *Quality control technologist* means an individual meeting the requirements of § 900.12(a)(2)(i) who is responsible for those quality assurance responsibilities not assigned to the lead interpreting physician or to the medical physicist.

(ff) *Radiographic equipment* means x-ray equipment used for the production of static x-ray images.

(gg) *Radiologic technologist* means an individual specifically trained in the use of radiographic equipment and the positioning of examinees for radiographic examinations and who meets the requirements set forth in § 900.12(a)(2).

(hh) *Serious adverse event* means an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.

(ii) *Serious complaint* means a report of a serious adverse event.

(jj) *Survey* means an onsite physics consultation and evaluation of a facility performed by a medical physicist.

(kk) *Time cycle* means the film development time.

(ll) *Traceability* means the ability to show that an instrument has been

calibrated at least annually through an unbroken chain of comparisons starting with either an appropriate national standard established by the National Institute of Science and Technology (NIST), Gaithersburg, MD, or with a transfer standard calibrated by NIST.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7829 Filed 3–29–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 93N–0351]

RIN 0910–AA24

Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the facility standards established in the interim regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA). This proposed rule would modify and add to the general requirements for mammography facilities, including requirements for a medical reporting and recordkeeping program, a medical outcomes audit program, special methods for examining individuals with breast implants, a consumer complaint mechanism, and a variance procedure for requesting FDA approval of alternative standards. In addition to the statutory framework and the expertise and research of FDA personnel, the agency is proposing this rule based on advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC) and public comments received in response to the interim regulations. This action is being taken to ensure safe, accurate, and reliable mammography on a nationwide basis. This is the third of five related proposed rules being published concurrently.

DATES: Written comments on this proposed rule by July 2, 1996.

Written comments on the information collection requirements should be submitted by May 3, 1996. The agency is proposing that any final rule based on this proposed rule become effective 1 year after its date of publication in the Federal Register.

ADDRESSES: Submit written comments on this proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Regulatory Impact Study (RIS) is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857.

Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Charles K. Showalter, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This proposal is the third of five related proposed rules published in this issue of the Federal Register to amend interim regulations published on December 21, 1993 (58 FR 67558 and 58 FR 67565) implementing the MQSA (Pub. L. 102–539). The first proposed rule, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' contains background information and a summary of the preliminary analysis of the costs and benefits of all of these proposed rules, a description of the information collection requirements, proposed revisions to § 900.1 *Scope* and § 900.2 *Definitions*, and proposed alternative approaches to mammography standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulations

This proposed rule establishes mammography facility standards for recordkeeping and reporting, medical outcomes audit, quality assurance, imaging of examinees with breast implants, and addressing consumer complaints. The proposal also establishes general certification requirements, and a procedure for any entity regulated under this rule to request FDA approval of alternative standards. As in the development of the interim regulations, FDA has been guided by the requirements of the MQSA and its stated legislative intent to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1).

In addition to the statutory framework and the expertise and research of FDA personnel, the agency relied upon two major sources of information in developing this proposed rule. The first source was the written comments received on the interim regulations. FDA received 103 comments from individuals and organizations on the interim regulations. Included among the written comments were responses from professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists.

The second outside source of information used to develop the proposed regulations was the advice and recommendations of the NMQAAC. Sections of these proposed regulations were discussed at the NMQAAC meetings in February, May, July, and September 1994. All of these proposed regulations, as then drafted, were reviewed again at the January 1995 meeting of the NMQAAC. The members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the NMQAAC and guests invited to attend the meetings in recognition of their expertise in mammography also participated in the discussions.

B. Applicability

Proposed § 900.10 states that the provisions of subpart B apply to all facilities under the jurisdiction of the United States that provide mammography services, with the exception of the facilities of the Department of Veterans Affairs (DVA).

Several comments objected to the exemption of DVA facilities from the interim regulations. In response to these comments, the agency notes that the DVA facilities are excluded from the requirements of the MQSA by the statute itself (42 U.S.C. 263b(a)(3)(A)). However, since the publication of the interim regulations, DVA has voluntarily committed its facilities to a program consistent with the standards issued under the MQSA.

C. Certification Requirements

Proposed § 900.11 defines the two types of certificates, provisional and