(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.12(b)(2) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies or revokes accreditation, or for which the accreditation body denies submission to FDA of information required from facilities for provisional certification or for extension of provisional certification, as described in paragraph (h)(3) of this section, and the reason(s) for such action;

(4) Provide to FDA other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body.

(i) *Fees.* Fees charged to facilities for accreditation shall be reasonable. Costs of accreditation body activities that are not related to accreditation functions under 42 U.S.C. 263b are not recoverable through fees established for accreditation.

(1) The accreditation body shall make public its fee structure, including those factors, if any, contributing to variations in fees for different facilities.

(2) At FDA's request, accreditation bodies shall provide financial records or other material to assist FDA in assessing the reasonableness of accreditation body fees. Such material shall be provided to FDA in a manner and time period specified by the agency.

§ 900.5 Evaluation.

FDA will evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives.

§ 900.6 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.5, or through other means, that an accreditation body is not in substantial compliance with this subpart, FDA shall initiate enforcement actions as follows:

(a) *Major deficiencies.* If FDA determines that an accreditation body has failed to perform a major accreditation function satisfactorily, has demonstrated willful disregard for public health, has violated the code of conduct, has committed fraud, or has submitted material false statements to the agency, FDA may withdraw its approval of that accreditation body.

(1) FDA will notify the accreditation body of the agency's action and the grounds on which the approval was withdrawn.

(2) An accreditation body that has lost its approval shall notify facilities accredited or seeking accreditation by it that its approval has been withdrawn. Such notification shall be made within a time period and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that an accreditation body has demonstrated deficiencies in performing accreditation functions and responsibilities that are less serious or more limited than the deficiencies in paragraph (a) of this section, FDA shall notify the body that it has a specified period of time to take particular corrective measures directed by FDA or to submit to FDA for approval the body's own plan of corrective action addressing the minor deficiencies. FDA may place the body on probationary status for a period of time determined by FDA, or may withdraw approval of the body as an accreditation body if corrective action is not taken.

(1) If FDA places an accreditation body on probationary status, the body shall notify all facilities accredited or seeking accreditation by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status will remain in effect until such time as the body can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems.

(3) If FDA determines that an accreditation body that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the accreditation body. The accreditation body shall notify all facilities accredited or seeking accreditation by it of its loss of approval authority, within a time period and in a manner approved by FDA.

(c) *Reapplication by accreditation bodies that have had their approval withdrawn.* (1) A former accreditation body that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

(2) If FDA determines that the new application demonstrates that the body satisfactorily has addressed the causes of its previous unacceptable performance, FDA may reinstate approval of the accreditation body.

(3) FDA may request additional information or establish additional conditions that must be met by a former accreditation body before FDA approves the reapplication.

(4) FDA will not accept an application from a former accreditation body whose approval was withdrawn because of fraud or willful disregard of public health.

§ 900.7 Hearings.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval or reapproval of accreditation bodies, withdrawal of approval of accreditation bodies, or rejection of a proposed fee shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body. The appeals process shall be specified in writing by the accreditation body and shall have been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(c) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeals process may appeal to FDA for reconsideration in accordance with § 900.15.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96–7831 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. 95N–0215]

RIN 0910–AA24

Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing 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. In addition to the statutory framework and the expertise and research of FDA personnel, the agency is proposing this rule based on advice provided by 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 that all personnel involved in mammography meet at least the minimum requirements for providing safe, accurate, and reliable mammography. This is the fourth of five 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 fourth 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 Mammography Quality Standards Act of 1992 (the MQSA). The first proposed rule entitled ''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 quality standards and a request for comments on the proposed alternatives.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

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 MQSA. As in the development of the interim regulations, FDA has been guided by the requirements of this statute 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 three 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.

Drafts of this proposed rule were also discussed with the NMQAAC, particularly at the February 1994 and January 1995 public meetings with the agency. The members of the NMQAAC include interpreting physicians, medical physicists, radiologic technologists, representatives of State agencies, and consumer representatives. Consultants to the Committee and guests invited to attend the meetings in recognition of their expertise in mammography also participated in these discussions. In the Federal Register of January 26, 1995 (60 FR 5152), the agency published a notice of availability of the draft of the proposed rule that was discussed with the NMQAAC.

Finally, the problems with the interim regulation were discussed with many of the individuals who currently perform annual inspections of mammography facilities under the MQSA to determine whether minimum quality standards are being achieved. Most of these inspectors have extensive prior experience in the inspection of radiology facilities. After the MQSA inspections began in January 1995, the agency closely monitored the process and gathered information that was valuable for developing the proposed final regulations.

B. Interpreting Physicians

The proposed regulation for interpreting physicians generally clarifies the requirements issued under the interim regulations and adds some new requirements. Although neither a national standard nor a continuing competency test for mammography interpretation currently exists, the proposed training and experience requirements for interpreting physicians will provide minimum standards to help ensure the reliability and accuracy of interpretation of mammograms for women throughout the country.

As discussed below, the quality standards proposed by FDA for interpreting physicians are divided into four general sections: Initial qualifications; continuing experience and education; exceptions; and reestablishing qualifications.

1. General Comments

Two comments expressed concern that providers in rural areas would have difficulty meeting the requirements of the interim regulations. They suggested that allowance should be made for such facilities, either through lowering the standards for rural facilities or establishing a longer phase-in period. One of these comments also stated that it would be helpful if the Department of Health and Human Services monitored the effect of the rules on rural providers.

Both FDA and NMQAAC are concerned about the impact of the MQSA on access to mammography in rural areas. However, both the agency and NMQAAC believe that the standards should not be lower for certain facilities. One of the primary goals of the MQSA is to ensure that all women receive at least the same minimum standard of care, no matter which facility they use. However, one of the specific duties that the MQSA requires of NMQAAC is to determine whether there exists a shortage of mammography facilities or health professionals in any areas and to determine the effects of the quality standards on access to mammography

services in such areas. This study already has begun and the results will be published upon completion.

2. Initial Qualifications

The first qualification for an interpreting physician under the MQSA is a State license to practice medicine (proposed § 900.12(a)(1)(i)(A)).

One comment stated that § 900.12(a)(1)(i)(A) in the interim regulations was confusing and would appear to allow a facility to license a physician. Similarly, another comment stated that the licensing requirements of physicians practicing in Federal facilities are unclear.

In response, FDA notes that a facility cannot license a physician to practice medicine. Licensing of physicians is a State function. Proposed § 900.12(a)(1)(i) simply requires the interpreting physician to have a State license to practice medicine. However, if the State in which the mammography facility is located is different from the State that issued the license, a physician may have to meet additional State requirements in order to practice medicine lawfully at that facility. With respect to physicians practicing in Federal facilities, a valid State license from any State is sufficient. However, the Federal employee would be unable to practice outside the Federal facility unless the physician also fulfilled the requirements of that State for the practice of medicine.

Proposed § 900.12(a)(1)(i)(B) provides two pathways to establish the second initial qualification: Board certification or documented training in interpreting mammograms. The training shall include radiation physics (including radiation physics specific to mammography), radiation effects, and radiation protection.

One comment recommended that FDA accept both American and Canadian boards as certifying bodies.

FDA does accept certification from both American and Canadian boards. Currently, FDA recognizes certification in Diagnostic Radiology and Radiology by the American Board of Radiology (ABR), the American Osteopathic Board of Radiology (AOBR), and the Royal College of Physicians and Surgeons of Canada.

Another comment asked that two British radiology boards be added to the list of bodies designated by FDA as eligible to certify interpreting physicians: Fellow of the Royal College of Radiologists (FRCR) and, Diploma in Medical Radiodiagnosis (DMRD) from the Royal College of Physicians and Surgeons of England.

NMQAAC discussed but did not recommend including other bodies to certify interpreting physicians at this time because there was insufficient information about the procedures and requirements for obtaining board certification from other bodies. FDA has not added additional bodies to its list of certifying bodies because FDA agrees that it has insufficient information at this time.

One comment stated that certifying bodies for interpreting physicians should be listed in the regulations. Another comment noted that the interim regulations do not indicate the particular bodies that have or will be designated by FDA as eligible to certify interpreting physicians and noted that approval of inappropriate certifying bodies could result in poorly qualified physicians reading and interpreting mammograms. The comment suggested that guidelines are needed regarding the certification of interpreting physicians.

FDA believes that it is best not to codify the list of eligible certifying bodies in the regulation in order to be able to make changes to the list of certifying bodies in a timely manner each time a body must be added to or deleted from the list. FDA will add or delete names based upon the agency's determination that the body has in place and implements procedures and requirements that are adequate to ensure that interpreting physicians certified by the body are capable of satisfying the MQSA needs. Whenever possible, FDA intends to consult with the NMQAAC before making a determination about adding or removing a body from the list of those eligible to certify physicians. The list of currently eligible certifying boards is based upon FDA evaluation and consultation with NMQAAC, as described above. FDA will follow a similar policy with respect to its determination of eligibility for boards or organizations that certify radiologic technologists and medical physicists.

One comment noted that his State's requirements for interpreting physicians are more stringent than the interim requirements and suggested that FDA may want to include the following language in the regulation (sic): ''require A.B.R. or A.O.B.R. certification or has successfully completed and graduated from an accredited radiology residency within the past 24 months.'' Another comment stated that FDA should give careful consideration before approving either the ABR or the AOBR to certify interpreting physicians. The comment further explained that if the ABR or AOBR certifies physicians based on ''board certification,'' many physicians who are not adequately trained in mammography automatically would be allowed to interpret mammograms.

FDA recognizes that some earlier board examinations may not have included testing in mammography. FDA also recognizes that board certification that includes mammography cannot by itself ensure the accuracy of outcomes in clinical mammography practices. However, board certification is evidence that the physician is knowledgeable in the basics of diagnostic radiology and board certification serves as a foundation for the additional requirements specific to mammography that interpreting physicians must meet under FDA's interim and proposed regulations.

Alternatively, proposed § 900.12(a)(1)(i)(B) would permit 3 months of documented formal training in mammography, including the interpretation of mammograms and other topics related to mammography, in place of board certification in diagnostic radiology. The other topics related to mammography include, but are not limited to: Radiation physics, including radiation physics specific to mammography; radiation effects; and radiation protection. The interim regulations require 2 months of documented full-time training. The agency is proposing an additional month of required training to reflect the increased emphasis that has been placed on mammography in residency programs.

During discussions at an NMQAAC meeting, it was recommended that FDA require training in radiation physics specific to mammography instead of training in general radiation physics as the training required by the alternative pathway in proposed § 900.12(a)(1)(i)(B). FDA agrees that mammography specific training is necessary, but also believes that general training in radiation physics is important for basic principles and should be retained as part of the requirements for the alternative pathway provided by proposed § 900.12(a)(1)(i)(B). NMQAAC also suggested that all required training in physics be obtained from a physicist. However, the agency believes that this suggestion is too restrictive and would limit the availability of adequate training opportunities.

The agency is proposing that the training in interpretation required for the alternative pathway be performed under the direct supervision of an interpreting physician who meets the MQSA requirements for an interpreting physician. It was recommended during NMQAAC discussions that there be additional qualifications for the

supervising physician beyond those required of an interpreting physician. For example, FDA could require supervising physicians to be qualified to offer continuing medical education (CME) credits. Again, the agency believes that this suggestion would be too restrictive and reduce the availability of effective training opportunities.

One comment suggested having an alternative method for allowing a physician who is not a radiologist but who is experienced in interpreting film mammography to be certified and allowed to continue to interpret mammograms.

The agency agrees and has proposed § 900.12(a)(1)(i)(B) in order to provide an alternative to board certification for radiologists and physicians who are not radiologists, but who otherwise qualify.

One comment stated that the alternate pathway to board certification in the interim regulations, requiring 2 months of training in the interpretation of mammograms, is not adequate. The comment stated that some type of board certification is necessary to ensure that women are receiving high quality interpretation of mammograms. Another comment advocated the addition of a proficiency examination, which would require a physician to demonstrate his or her ability to interpret mammograms, both at the point of the physician's initial certification and at periodic intervals to maintain that certification. The latter comment noted that academic achievement, although important, is not sufficient to ensure high quality mammography.

The NMQAAC discussed the possibility of requiring that interpreting physicians undergo proficiency testing in mammography, but did not recommend such testing at this time. To date, sufficient data have not been compiled on existing levels of interpretive skills for interpreting physicians to determine whether there is a general need for proficiency testing. With respect to the adequacy of the training required under the alternate pathway, FDA is proposing to increase that requirement from 2 to 3 months of documented training in the interpretation of mammograms.

Proposed § 900.12(a)(1)(i)(C) requires 60 hours of documented continuing medical education credits in mammography for all interpreting physicians, including instruction in the interpretation of mammograms and training appropriate to each mammographic modality used in the interpreting physician's practice. At least 40 of these hours must be Category I CME credits and, to ensure that the physician has recent mammography education, at least 15 of these 40 Category I CME hours must have been acquired within the 3 years immediately preceding qualifying as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I CME and will be accepted if documented in writing by the appropriate representative of the training institution.

One comment stated that the interim regulations, which require 40 hours of documented CME in mammography, are quite adequate to ensure that interpreting physicians have the training, expertise, and experience necessary to do mammographic interpretations.

The agency believes that an increase to 60 hours is in keeping with current training trends and the emergence of new technologies.

Proposed § 900.12(a)(1)(i)(C) requires training in each mammographic modality employed in the interpreting physician's practice. FDA added this requirement because of the differences among imaging modalities (e.g., film screen and xeromammography) currently in use and emerging technologies, such as digital mammography. The agency believes that, before a physician begins to interpret images produced by a particular modality, he or she should have specific training in the interpretation of such images. FDA is proposing that at least 8 hours of Category I CME credit be related to each mammographic modality used by the interpreting physician.

FDA has also proposed, with the concurrence of NMQAAC, that the interpreting physician must have education in each of the following: basic breast anatomy; breast pathology and physiology; technical aspects of mammography (e.g., exposure factors, compression, positioning); quality assurance and quality control in mammography.

One comment questioned whether ABR certified physicians are required to document 40 hours of initial education under the interim regulations.

The interim regulations require this documentation from physicians using either of the two pathways and proposed § 900.12(a)(1)(i)(C) would continue this requirement for the 60 hours of required initial training.

Two comments asked what FDA will consider to be adequate documentation of the radiologist's training.

A variety of documentation has and will be accepted (e.g., copy(s) of the license(s) to practice medicine, copy(s) of the certificate issued by certifying board(s), CME credit certificates). The agency previously issued guidance on adequate documentation under the interim regulations that will be revised, as needed, and made available when the final regulations are published. Such guidance does not bind the agency or the facility and facilities may choose to accept documentation that is not discussed in FDA guidance. However, FDA encourages facilities that plan to accept alternate documentation to discuss the matter in advance with FDA in order to avoid potential loss of time and resources. Upon inspection of the facility, in any situation in which documentation appears inadequate, the burden will be upon the employee and the facility to provide additional evidence to demonstrate the qualifications of personnel employed by the facility.

One comment suggested that time spent in a residency program devoted to mammography should be documented by the residency program.

FDA agrees and is proposing that the resident's training be documented in writing by the appropriate representative of the training institution.

Proposed § 900.12(a)(1)(i)(D) requires the qualifying physician to interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within the 6 months immediately prior to fulfilling the initial qualifications as an interpreting physician. The intent of this requirement is to demonstrate recent supervised experience before the physician begins to interpret mammograms independently. Proposed § 900.12(a)(1)(iii)(B) provides an exception from this prior 6-month timeframe for diagnostic radiology residents who become board certified at the first allowable time, as defined by the eligible certifying body of their choice. Such residents must still interpret at least 240 mammographic examinations in the last 2 years of residency under the direct supervision of a qualified interpreting physician.

One comment expressed concern that the volume of films that must be read to achieve and maintain certification may have an unintended, negative impact on a physician working on a locum tenens basis, that is, a physician serving as a temporary replacement for another physician.

In response, FDA notes that proposed § 900.12(a)(1)(i)(D) is an initial requirement that need only be met once if the interpreting physician maintains his or her continuing experience requirements under proposed § 900.12(a)(1)(ii).

3. Continuing Qualifications

Proposed § 900.12(a)(1)(ii)(A) is the first of the requirements established to ensure that interpreting physicians maintain their qualifications. Under this requirement, in order to continue to qualify under the MQSA, interpreting physicians must have read an average of at least 40 mammographic examinations a month during the previous 24 months. Although the wording has changed somewhat from the interim rule, the proposed regulation is not substantially different from the interim requirement.

There were numerous comments on this requirement in the interim regulations. Comments expressed concern about the difficulty in meeting this requirement in rural areas due to lack of volume at the facility. One comment expressed concern that the requirement may have a negative impact on physicians serving as temporary replacements for other physicians (i.e., on a locum tenens basis). Two comments suggested allowing the substitution of continuing education for this experience requirement, and one of these comments suggested that the physician be allowed to submit interpretations on a specified number of test mammograms in lieu of the 40 per month average and that the requirements could also be modified slightly to focus on the number of mammograms read per year, instead of per month. Another comment requested that rural x-ray departments be exempted from this requirement.

As previously stated, FDA believes that all women, including those in rural areas, are entitled to the same quality of care, and the agency cannot support lower standards for particular facilities. The agency also believes, as discussed below, that it will not be difficult for most physicians to meet this continuing qualification, even for those in rural areas.

The monthly average is to be maintained over a 24-month period. FDA selected 24 months to allow interpreting physicians a reasonable chance to maintain the required average. Physicians who are absent for a period of time, due to sabbaticals or other reasons, or who only read mammographic images during selected periods, because of their facility rotation schedule or employment on a locum tenens basis, will have the opportunity to read enough images during some portions of the 24-month period to maintain the required average. The agency also wants to clarify that this is a physician requirement, not a facility requirement. Interpreting physicians who provide services to low workload facilities can read films at more than one facility to attain the required average. Double reading of images (2 or more physicians interpreting the same mammogram) is also accepted as a way of meeting this requirement. However, the agency excludes from its definition of double reading the interpretation of the same mammogram more than once by a same physician. For all of these reasons, the agency believes there will not be widespread difficulty in meeting this requirement.

One comment suggested that the agency develop something besides an artificial number to tell whether or not a radiologist is able to do a good job.

FDA recognizes that numbers alone cannot guarantee competency, but believes that the experience a radiologist accumulates through interpreting a certain minimum number of films is a necessary aspect of the qualification process. Elsewhere in this issue of the Federal Register, FDA is proposing requirements for the establishment and implementation of a medical outcomes' audit for individual physicians. This type of monitoring can further improve the reliability, clarity, and accuracy of interpretation of mammograms.

One comment suggested that FDA establish a maximum number of images that the interpreting physician would be allowed to read in a given period of time.

FDA does not believe there is any evidence to support a need to establish such a limit.

Proposed § 900.12(a)(1)(ii)(B) requires interpreting physicians to further maintain their skills by teaching or completing at least 15 Category I CME credits in mammography in the previous 3 years. Category I CME credits are generally those that offer more formal training and provide a solid basis for the ongoing maintenance and growth of the interpretive skills of the physician.

The interim regulations require interpreting physicians to participate in education programs, either by teaching or completing an average of at least five CME credits in mammography per year. There were numerous comments on this requirement in the interim regulations, most of which focused on the lack of a specified average period. Some comments suggested that it should be 15 hours over a 3-year period.

Proposed § 900.12(a)(1)(ii)(B) addresses these concerns by establishing a 3-year period of time for determining the yearly average. FDA has proposed that the credits be in category I CME in order to ensure that continuing education is more formal and contributes to the development of the physician. The section also requires that at least 6 of the CME hours be in each mammographic modality used in the interpreting physician's practice. Therefore, the CME hours required for an interpreting physician who practices in a facility that employs more than 2 modalities will be in excess of the minimum requirement of 15 hours of category I CME.

Proposed § 900.12(a)(1)(ii)(C) requires that, before using a new mammographic modality in his or her practice, the interpreting physician must have at least 8 hours of training with that modality. This education requirement is a logical parallel to the requirement in proposed § 900.12(a)(1)(i)(C) that the physician must have at least 8 hours of training in each modality used in his or her practice when the initial qualifications are first met.

4. Exceptions

Proposed § 900.12(a)(1)(iii) would allow exceptions to some of these requirements in certain specific cases. In order to ensure continuing and uninterrupted availability of mammography services, FDA is proposing to permit those interpreting physicians who have qualified under the interim regulations to continue to interpret mammograms, provided that they maintain the continuing experience and education requirements in proposed § 900.12(a)(1)(ii)(A) through (a)(1)(ii)(C). Proposed § 900.12(a)(1)(iii)(A) would exempt these physicians from the new and additional initial requirements proposed in § 900.12(a)(1)(i). The additional month of training in proposed § 900.12(a)(1)(i)(B) for physicians using the alternative pathway, the additional 20 hours of CME in proposed § 900.12(a)(1)(i)(C), the 8 Category I CME credits in new modalities in proposed § 900.12(a)(1)(i)(C), and the requirement that 15 Category I CME credits must have been acquired in the 3 years immediately before qualifying as an interpreting physician in proposed § 900.12(a)(1)(i)(C).

Proposed § 900.12(a)(1)(iii)(B) allows another exception in response to NMQAAC's concern that the initial experience requirement in proposed § 900.12(a)(1)(i)(D) may pose a problem in some diagnostic residency programs that schedule mammography rotations in the first 6 months of the last year. This exception permits a resident to satisfy the requirement of proposed § 900.12(a)(1)(i)(D) by having interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting

physician during the last 2 years of the residency. FDA has included this exception only for the diagnostic radiology resident who successfully becomes board certified at the earliest opportunity provided by an eligible certifying board (''first allowable time'').

For the physician who qualifies for the exception under proposed § 900.12(a)(1)(iii)(B), the continuing education and experience requirements of proposed § 900.12(a)(1)(ii)(A) through (a)(1)(ii)(C) would begin from the date of that physician's board certification in diagnostic radiology, provided the other initial requirements are satisfied. If the physician does not become board certified at the first allowable time by the certifying board, then this physician must interpret 240 mammographic examinations under the direct supervision of a qualified interpreting physician within a period of 6 months immediately prior to initial qualification as an interpreting physician. The ''first allowable time'' means the earliest time a physician is eligible to take the diagnostic radiology boards of an eligible certifying body. Because the ''first allowable time'' a resident becomes eligible to take the boards may vary with the certifying body, that term is not defined further in the regulations. If the physician wishes to use this exemption, it is the physician's responsibility to ascertain the requirements of the body by which he or she wishes to become certified and to seek that certification as soon as he or she becomes eligible to do so.

5. Reestablishment of Qualifications

Proposed § 900.12(a)(1)(iv) provides a method for physicians to reestablish their qualifications as interpreting physicians in the event they do not maintain the continuing experience or education requirements. Proposed § 900.12(a)(1)(iv)(A) requires the physician who fails to meet the continuing experience requirements to interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within a period of 6 months immediately before reestablishing qualifications and resuming independent interpretation.

Proposed § 900.12(a)(1)(iv)(B) requires physicians who do not maintain the continuing education requirements to obtain a sufficient number of Category I CME credits in mammography to bring their total up to the required 15 credits in the previous 3 years. A physician who fails to maintain continuing experience or education requirements may not serve as an interpreting physician until he or she reestablishes those qualifications.

C. Radiologic Technologists

FDA's interim regulations for radiologic technologists performing mammography sought to ensure that: (1) The technologists possessed adequate general qualifications for performing radiologic examinations; (2) the technologists possessed adequate specific qualifications for performing mammography examinations; and (3) the technologists maintained these qualifications over time. The proposed regulations are intended to achieve the same goals. They are primarily clarifications of the interim regulations with some added requirements to address concerns that developed as the interim regulations were implemented.

The first clarification is in response to a number of comments received by FDA asking whether all of the radiologic technologists who perform mammography at the facility had to meet the requirements or if it would be sufficient if only some of them did. These questions may have been generated from experience with a previous voluntary system for accreditation.

All radiologic technologists who perform mammography must meet the requirements. The plain language of the statute clearly states that personnel who perform mammography must meet the minimum training and experience requirements and either be licensed by a State or certified to perform radiological procedures by an organization designated by the Secretary of HHS (42 U.S.C. 263b(f)(1)(C)). The statute does not provide, nor does the legislative history indicate, that Congress intended any of the individuals who perform mammography to be exempt from minimum quality standards. Exempting some radiologic technologists from compliance with the personnel standards required under the act would increase, not diminish, the possibility that an incipient cancer might be misdiagnosed because of a poorly produced mammogram. FDA has revised § 900.12(a)(2) to read ''All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements.'' Similar revisions were included in other paragraphs of § 900.12(a) to clarify the requirement that all physicians and medical physicists must also meet the personnel qualifications specific to their areas of practice.

Several comments expressed concern that the interim regulations would allow technologists with ''partial'' or ''special'' licenses to perform mammography. States that issue such licenses usually limit their holders to the performance of certain narrow types of examinations (e.g., extremities or dental x-rays) or particular medical practices (e.g., podiatry).

The intent of the licensure requirement under the MQSA is to ensure that the radiologic technologist has a broad background in radiologic technology as a basis for his or her specific work in mammography. FDA does not believe that partial or special licenses demonstrate this necessary background. The provisions set forth in proposed § 900.12(a)(2)(i)(A) require the State license to be a general license to perform radiologic procedures. As an alternative to obtaining such a State license, proposed § 900.12(a)(2)(i)(B) would recognize a general certification by one of the bodies designated by FDA to certify radiologic technologists as adequate evidence that a technologist satisfies the general radiologic technology requirements.

The license required by proposed § 900.12(a)(2)(i)(A) must be a State license but need not be from the State in which the technologist currently practices, as some States do not have a licensing requirement. For States that do have their own licensing requirements, the technologists practicing in these States are responsible for meeting those licensing requirements as well as the requirements under the MQSA.

One comment suggested that FDA amend the language of the interim regulations at § 900.12(a)(2)(i)(B) to indicate that certification by an eligible body is an alternative that is available only when the State in which the radiologic technologist is practicing has no licensure procedures or requirements.

Proposed § 900.12(a)(2)(i) requires the technologist to become licensed or certified to perform general radiological procedures. The license may be obtained from a State under § 900.12(a)(2)(i)(A) or the certificate can be obtained from an eligible certification body under § 900.12(a)(2)(i)(B). If the technologist is certified by an eligible certifying body and practices in a State that has its own licensing requirement, the technologist must still become licensed under State law, unless otherwise exempted by the State.

Although such individuals would be in compliance with Federal requirements under the MQSA, a technologist that is not licensed in accordance with the requirements of the

State in which he or she practices will be in violation of the State law.

Several comments on the interim regulations stated that FDA should clarify the initial requirements that a radiological technologist must satisfy to demonstrate specific mammography training.

After seeking and obtaining the advice of the NMQAAC, the agency has proposed more specific requirements for this training in § 900.12(a)(2)(ii). Under the proposed regulation, training specific to mammography includes the performance of a minimum of 50 examinations under the direct instruction of a qualified individual. After the effective date of these regulations, only individuals meeting the requirements of § 900.12(a)(2) for radiologic technologists will be considered qualified to provide this supervision.

The NMQAAC has discussed the option of recognizing the American Registry of Radiologic Technologists' (ARRT) special certification in mammography as fulfilling, at least in part, the training requirement under § 900.12(a)(2)(ii). At its February 1994 meeting, the NMQAAC advised against reducing the training required based on the ARRT special certification. However, at its subsequent meeting in May 1994, members reconsidered this possibility and discussed how much credit might reasonably be allocated for an ARRT special certification and for which aspects of the training requirements. Suggestions were made by some NMQAAC committee members that this special certificate be accepted in lieu of 20 of the required 40 contact hours, but that the certificate not be a substitute for any part of the required performance of 50 examinations under the direct supervision of a qualified radiologic technologist.

After further consideration, FDA has decided not to propose recognition of the special certificate as a partial fulfillment of the training requirement. FDA does not want to incorporate into its regulations a training requirement that specifically relies on a particular certification program by a private group. If, in the agency's view, subsequent changes in the certification program diminished the certificate's value in assuring properly trained radiologic technologists, the agency might, nevertheless, be bound to continue to accept the certificate until the regulations could be amended through notice and comment rulemaking to remove the recognition of the certificate as a substitute for training. On the other hand, the agency believes that the training that is required to earn the certificate can fulfill part of the proposed training requirements, even if the program is not mentioned explicitly in the regulations. In fact, when evaluating technologists' training under the interim regulations, the agency has recognized the value of training hours required for AART special certification as well as training hours required by other programs. The agency intends to continue to do so, as long as it believes such recognition is warranted. Agency guidance on this subject is available for review. As mentioned earlier, guidance represents the agency's best thinking at the current time and does not bind either the facility or FDA.

The NMQAAC did recommend that there be a requirement that all technologists have the equivalent of at least five continuing education units (CEU) of initial training in imaging examinees with breast implants. NMQAAC recognized that many technologists rarely conduct examinations of individuals with breast implants. However, the committee recommended that this training be required of all technologists so that all examinees with breast implants can use any certified facility with assurance that there will be technologists trained to perform these examinations.

FDA agrees and has included this requirement in proposed § 900.12(a)(2)(ii)(C).

The interim regulations permit a technologist to have all of his or her training in mammography, both initial and continuing, related to one modality (e.g., film screen, xerography), even if the radiologic technologist uses other modalities to perform mammography. However, the agency and the NMQAAC believe that education and training should be required for each modality performed by the technologist. Proposed § 900.12(a)(2)(ii)(B) and (a)(2)(iii)(B) would correct this shortcoming in the interim regulations by requiring both the initial training and the continuing education requirements to include training in each modality used by the technologist.

Several comments on the interim regulations objected to the use of an undefined overall averaging period for the requirement that the radiologic technologist earn at least five CEU's per year in mammography.

Although the use of an undefined time period has provided a flexibility that is advantageous under the interim regulations, FDA agrees that more specific requirements are desirable. Therefore, proposed § 900.12(a)(2)(iii) requires that, on any given date, each technologist must have earned at least 15 CEU's in mammography in the 3 years immediately preceding that date. To be fair to technologists who have just completed their initial training in mammography, proposed § 900.12(a)(2)(iii) would not apply this requirement immediately. Technologists will have up to 3 years after completing their initial training to earn at least 15 CEU's related to mammography. After the end of the initial 3-year period, all technologists would have to be able to demonstrate, on any subsequent date, that they had earned at least 15 CEU's in mammography in the 3 previous years.

Proposed § 900.12(a)(2)(iii)(C) describes the actions that must be taken by technologists who fail to meet the continuing education requirement in order to reestablish their qualifications. Until these actions are taken, such technologists cannot perform mammographic examinations without supervision.

In recognition of the fact that unused skills may deteriorate, proposed § 900.12(a)(2)(iv) establishes a continuing experience requirement corresponding to the continuing experience requirement for interpreting physicians found in both the interim and proposed regulations. This requirement is based upon the advice of NMQAAC that performance of 100 or more mammography examinations a year represents a reasonable level of experience. Proposed § 900.12(a)(2)(iv)(B) permits radiologic technologists who fail to meet this continuing requirement to reestablish their qualification through performance of 50 examinations (a number suggested by NMQAAC) under the direct supervision of a qualified radiologic technologist before resuming independent performance of mammography examinations.

One comment on the interim regulations questioned the use of October 1, 1996, for changing certain requirements for radiologic technologists while a date of October 27, 1997, was used for similar changes for medical physicists. The comment suggested that the dates should be the same.

FDA notes that the MQSA established these dates and FDA cannot modify them. It is likely that the differences in these provisions is the result of congressional concern about the availability of medical physicists.

Another comment suggested that a training and experience alternative to the licensure or certification requirement be made available to radiologic technologists similar to the alternative available to medical physicists.

FDA disagrees, Congress specified the alternative route for medical physicists in the statute. The MQSA did not provide a similar alternative for technologists.

D. Medical Physicists

Proposed requirements for medical physicists are set forth in § 900.12(a)(3). FDA recognizes that the medical physicist plays a pivotal role in assuring the overall quality of mammography and, therefore, seeks to emphasize, in the proposed regulations, the need for uniform national minimum requirements for medical physicists working in mammography facilities.

In developing the proposed qualifications for medical physicists, the agency has considered: (1) The requisite amount of prior knowledge and experience to evaluate mammography equipment; (2) the level of performance of individuals currently providing mammography physics support; (3) the concern over the supply of qualified medical physicists; and (4) the recommendations from members of the NMQAAC and comments from the Conference of Radiation Control Program Director's Task Force on Medical Physics Criteria. The issue of qualifications for medical physicists was discussed extensively at several NMQAAC meetings. Earlier draft regulations on this subject were shared with the NMQAAC and made available to the public.

The MQSA provides two alternative pathways for medical physicists to demonstrate minimum qualifications after October 27, 1997. These alternative pathways, set forth in the statute and codified in proposed § 900.12(a)(3)(i)(A), are: (1) State licensure or approval or (2) certification by a board approved by FDA. However, the NMQAAC expressed concern during the February 1994 meeting that not all States have adequate minimum qualification standards. Concern has also been expressed that some board certified physicists do not have adequate experience with mammography equipment. Therefore, FDA proposes to add additional requirements for all physicists, regardless of which initial route they follow to become qualified under the MQSA. After October 27, 1997, or the effective date of the regulation, whichever is later, only those medical physicists who meet the initial additional education and experience requirements proposed in § 900.12(a)(3)(i)(B) or (a)(3)(ii)(B) will be qualified to perform surveys under the MQSA.

FDA believes that ongoing developments in imaging technology, including the development of new technologies, such as digital mammography, will require medical physicists to have increased understanding of science and technology in order to apply these scientific advances to the practice of mammography. Proposed § 900.12(a)(3)(i)(B) addresses this need by requiring medical physicists who enter the field after October 27, 1997, to hold at least a master's degree in a physical science, including a minimum of 20 semester credit hours or equivalent of college level physics, to have specialized training in conducting mammography surveys, and to have actual experience conducting surveys of at least 5 mammography facilities and a total of at least 10 mammography units. The experience in conducting surveys must be acquired under the direct supervision of a medical physicist who has fulfilled all of the requirements of § 900.12(a)(3)(i) and (a)(3)(iii). This requirement is intended to ensure that medical physicists who serve as supervisors will have an adequate educational background to train new physicists in new imaging technologies.

The advisory committee recommended that FDA require the 20 semester credit hours of physics be specific to imaging physics.

FDA agrees that courses in imaging physics would be desirable. However, the agency does not have enough information about the number of imaging physics courses offered in different curricula to be certain that these courses would be available nationwide. Therefore, the agency has not proposed limiting the physics credit hours to imaging physics at this time. The agency is soliciting public comment on this issue.

Although FDA believes that future changes in technology will require an enhancement of the educational qualifications of medical physicists, the agency also recognizes that currently there are a number of medical physicists with bachelor's degrees and substantial experience who are performing medical physics surveys of mammography facilities with care and competence. These physicists provide valuable physics support to facilities. The agency believes that it would be unjust to these physicists and potentially detrimental to the facilities that they serve to bar them from continuing to provide this physics support to mammography facilities in the absence of any evidence to show that the services that they currently offer are inadequate. Accordingly, proposed § 900.12(a)(3)(ii) provides an opportunity for those individuals who are lawfully practicing medical physics under the interim regulations (21 CFR 900.12(a)(3)) to continue their practice after October 27, 1997.

Proposed § 900.12(a)(3)(ii) has been modified from the draft proposal discussed at the January 1995 meeting with the NMQAAC. During this meeting, the NMQAAC recommended that the opportunity to continue services as a mammography physicist because of prior experience should be open only to physicists with bachelor's degrees and 5 years of experience in conducting surveys of mammography facilities by October 27, 1997.

However, upon further consideration, FDA believes that the fundamental requirement of this alternative pathway is the quality and depth of the survey experience itself, and not the number of years it has taken the individual to acquire that experience. Therefore, proposed § 900.12(a)(3)(ii) requires those physicists who intend to qualify because of prior experience to have performed surveys of at least 10 facilities and a total of at least 20 units by October 27, 1997, or the effective date of these regulations, whichever date is later. This change has been made in order to give all medical physicists who are currently eligible to practice under the interim rules a reasonable opportunity to acquire the requisite experience before this alternative pathway closes.

Proposed § 900.12(a)(3)(ii) further requires that the bachelor's degree and specific training requirements be completed before any physics survey or unit evaluations may be counted toward satisfying the experience requirement under this provision. During a presentation at the January 1995 NMQAAC meeting, a representative of the medical physics community, speaking on behalf of the professional medical physicists who are members of the American College of Radiology, the American College of Medical Physics, and the North American Association of Physicists in Medicine, expressed the view that any mammography medical physics experience obtained prior to obtaining a basic understanding of fundamental principles through education is of little value. The NMQAAC also strongly recommended that the degree requirement must be a prerequisite to the experience requirement. The agency's proposal, therefore, establishes that the initial education and training qualifications must be met before any experience can be considered for purposes of satisfying the initial experience qualifications. The

agency is soliciting public comment on this requirement.

Under proposed § 900.12(a)(3)(iii), medical physicists will be required to maintain their education and experience qualifications, as are radiologic technologists and interpreting physicians.

Proposed § 900.12(3)(iv) establishes the requirements that medical physicists who fail to maintain their qualifications must meet to reestablish their eligibility to perform mammography facility surveys.

At its February 1994 meeting, the NMQAAC members raised the concern that medical physicists who meet the qualifications requirement may nevertheless delegate the onsite survey work to less qualified personnel.

FDA shares this concern and, therefore, is proposing in § 900.12(e)(9), published elsewhere in this issue of the Federal Register, that the medical physicist who signs the facility survey report must be present at the facility during the survey and must meet the requirements of proposed § 900.12(a)(3).

Physicists in training may perform surveys in order to meet the experience requirement described in these standards, but they must do so under the direct supervision of a qualified medical physicist. ''Direct supervision'' is defined in proposed § 900.2(k)(2), also published elsewhere in this issue of the Federal Register, to mean: ''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.''

E. Retention of Personnel Records

Under the interim regulations, FDA is often asked how long records demonstrating personnel qualifications must be kept after an individual is no longer employed by the facility.

Proposed § 900.12(a)(4) requires that records be retained for all individuals employed in mammography by the facility from: (1) The date of the last inspection or (2) the effective date of the final regulations, whichever is later. Because inspections are required annually under the MQSA, records of individuals no longer employed by the facility typically would be retained less than a year after the individual's employment ends. The agency believes that this requirement will allow FDA adequately to assess whether personnel requirements are being met without putting an undue paperwork burden on the facility. Facilities should also become familiar with any State regulations that are applicable to personnel records because these State laws may require retaining the records for a longer period of time.

III. 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.

IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on accreditation bodies, general facility requirements, and quality standards for mammography equipment and quality assurance, published elsewhere in this issue of the Federal Register, under Executive Order 12866, the Regulatory Flexibility Act (Pub. L. 96–354), and under the Unfunded Mandates Reform Act. The analysis has addressed the proposed requirements of these four rules as one unit for purposes of determining their economic impact. The preamble to the proposed rule ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'', published elsewhere in this issue of the Federal Register, contains a brief summary of the cost and benefit determination and the Regulatory Impact Study that details the agency's calculation of these economic impacts and is available at the Dockets Management Branch (address above) for review. FDA recognized that these proposed regulations may have a disproportionate effect on small volume mammography facilities and is currently collecting additional information on the potential impact on this industry sector. The agency requests comments that will assist it in accounting for this impact.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collections which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). The title, description, and respondent description of the information collection and an estimate of the annual reporting and recordkeeping burden are contained in the proposed rule entitled ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' published elsewhere in this issue of the Federal Register.

The agency has submitted a copy of this proposed rule to OMB for its review of these information collections. Other organizations and individuals desiring to submit 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 collection should be submitted by May 3, 1996.

VI. Request for Comments

Interested persons may, on or before July 2, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposed rule. 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.

VII. Reference

The following reference has 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. ''Report on the Mammography Quality Standards Act of 1992,'' S. Rept. 102–448, October 1, 1992.

List of Subjects in 21 CFR Part 900

Electronic products, Health facilities, 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. Section 900.12 is amended by revising paragraph (a) to read as follows:

§ 900.12 Quality standards.

* * * * *

(a) *Personnel.* The following requirements apply to all personnel involved in any aspect of mammography, including the production, processing, and interpretation of mammograms and related quality assurance activities.

(1) Interpreting physicians. All physicians interpreting mammograms shall meet the following qualifications:

(i) Initial qualifications. Before beginning to interpret mammograms independently, the interpreting physician shall:

(A) Be licensed to practice medicine in a State;

(B)(*1*) Be certified in an appropriate specialty area by a body determined by FDA to have procedures and requirements adequate to ensure that physicians certified by the body are competent to interpret radiological procedures, including mammography; or

(*2*) Have had at least 3 months of documented formal training in the interpretation of mammograms and in topics related to mammography. The training shall include instruction in radiation physics, including radiation physics specific to mammography, radiation effects, and radiation protection. The mammographic interpretation component shall be under the direct supervision of a physician who meets the requirements of paragraph (a)(1) of this section;

(C) Have a minimum of 60 hours of documented medical education in mammography, which must include: Instruction in the interpretation of mammograms; at least 8 hours of Category I continuing medical education credits in each mammographic modality used in the interpreting physician's practice; and education in basic breast anatomy, pathology, and physiology; technical aspects of mammography, and quality assurance and quality control in mammography. At least 40 of these hours must be Category I and at least 15 of the Category I hours must have been acquired within the 3 years immediately prior to the date that the physician qualifies as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I continuing medical education credits and will be accepted if documented in writing by the appropriate representative of the training institution; and

(D) Have interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician within the 6-month period immediately prior to fulfilling the requirements of paragraph(a)(1)(i) of this section.

(ii) Continuing experience and education. All interpreting physicians shall maintain their qualifications by meeting the following requirements:

(A) At all times following the second anniversary date of completion of the requirements of paragraph (a)(1)(i) of this section, the interpreting physician shall have interpreted an average of at least 40 mammographic examinations a month during the previous 24 months;

(B) At all times following the third anniversary date of completion of the requirements of paragraph (a)(1)(i) of this section, the interpreting physician shall have taught or completed at least 15 Category I continuing medical education credits in mammography in the previous 3 years. This training must include at least six Category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

(C) Before an interpreting physician may begin independently interpreting mammograms produced by a new mammographic modality, that is, a modality in which the physician has not previously been trained, the interpreting physician shall have at least 8 hours of training in the new modality.

(iii) Exceptions. (A) Those physicians who previously qualified as interpreting physicians under FDA's interim regulations at § 900.12(a)(1) are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

(B) Physicians who have interpreted at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

(iv) Reestablishing qualifications. Interpreting physicians who fail to maintain the required continuing experience or continuing education requirements shall reestablish their qualifications before resuming the independent interpretation of mammograms, as follows:

(A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall interpret at least 240 mammographic examinations under the direct supervision of a qualified interpreting physician, within a period of 6 months immediately prior to reestablishing their qualifications as an interpreting physician.

(B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional Category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 3 years before resuming independent reading.

(2) Radiologic technologists. All mammographic examinations shall be performed by radiologic technologists who meet the following general requirements, mammography requirements, and continuing education and experience requirements:

(i) General requirements. (A) Be licensed to perform general radiographic procedures in a State; or

(B) Have general certification from one of the bodies determined by FDA to have procedures and requirements adequate to ensure that radiologic technologists certified by the body are competent to perform radiologic examinations; and

(ii) Mammography requirements. Have undergone 40 contact hours of documented training specific to mammography under the supervision of a qualified individual. A qualified individual is one that has met all the requirements of paragraph (a)(2) of this section. The 40 hours of documented training shall include:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques;

(B) The performance of a minimum of 50 examinations under the direct supervision of a qualified individual; and

(C) At least 5 hours of training in imaging examinees with breast implants and at least 8 hours of training in each imaging modality to be used by the technologist in performing mammography exams.

(iii) Continuing education requirements. (A) At all times following the third anniversary date of completion of the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section or (insert effective date of the final regulation), whichever date is later, the radiologic technologist shall have taught or completed at least 15 continuing education units related to mammography in the previous 3 years.

(B) At least six of these continuing education units shall be related to each

modality used by the technologist in mammography.

(C) Requalification. Following any 3-year period in which a radiologic technologist fails to meet the continuing education requirements under paragraphs (a)(2)(iii)(A) through (a)(2)(iii)(B) of this section, that technologist shall obtain a sufficient number of continuing education units in mammography to bring the total up to at least 15 in the previous 3 years, at least 6 of which shall be related to each modality used by the technologist in mammography. The technologist may not resume performing unsupervised mammography examinations until the continuing education requirements are completed.

(D) Before a radiologic technologist may begin independently performing mammographic examinations using a modality other than one of those for which the technologist received training under paragraph (a)(2)(ii)(C) of this section, the technologist shall have at least 8 hours of continuing education units in the new modality.

(iv) Continuing experience requirements. (A) In each 12-month period after completion of the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section or (effective date of the final rule), whichever date is later, the radiologic technologist shall perform a minimum of 100 mammography examinations.

(B) Requalification. Following any 12-month period in which a radiologic technologist fails to perform at least 100 mammography examinations, that technologist shall perform a minimum of 50 mammography examinations under the direct supervision of a qualified radiologic technologist, before resuming the performance of unsupervised mammography examinations.

(3) Medical physicists. All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under 42 U.S.C. 263b shall meet the following:

(i) Initial qualifications. (A) Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics surveys; and

(B)(*1*) Have a master's degree or higher in a physical science from an accredited institution, including at least 20 semester hours or equivalent (e.g., 30 quarter hours) of college (graduate or undergraduate) level physics;

(*2*) Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities; and

(*3*) Have the experience of conducting surveys of at least 5 mammography facilities and a total of at least 10 mammography units. After the later date of October 27, 1997, or the effective date of these regulations, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section; or

(ii) Alternative initial qualifications. (A) Have qualified as a medical physicist under the interim regulations at § 900.12(a)(3) and maintained the active status of any qualifying licensure, approval, or certification required under the interim regulations; and

(B) By October 27, 1997, or [Date 1 year after date of publication of the final rule] regulations, whichever is later, have:

(*1*) A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college level physics,

(*2*) Forty contact hours of documented specialized training in conducting surveys of mammography facilities and,

(*3*) The experience of conducting surveys of at least 10 mammography facilities and a total of at least 20 mammography units. The training and experience requirements must be met after fulfilling the degree requirement.

(iii) Continuing qualifications. (A) Continuing education. At all times after the third anniversary of completion of the initial requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section, the medical physicist shall have taught or completed at least 15 continuing education units in mammography over the preceding 3 years. This continuing education shall include training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs.

(B) Continuing experience. At all times after the first anniversary of completion of the initial requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section, the medical physicist shall have surveyed at least three mammography facilities within the preceding 12 months.

(C) Before a medical physicist may begin independently performing mammographic examinations using a new modality, that is, a modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this section, the physicist must receive at least 8 hours of training in surveying units with the new modality.

(iv) Reestablishing qualifications. Medical physicists who fail to maintain the required continuing qualifications of paragraph (a)(3)(iii) of this section may not perform the MQSA surveys without the supervision of a qualified medical physicist. Before independently surveying another facility, medical physicists must reestablish their qualifications, as follows:

(A) Medical physicists who fail to meet the continuing educational requirements of paragraph (a)(3)(iii)(A) of this section shall obtain a sufficient number of continuing education units to bring their total units up to the required 15 in the previous 3 years.

(B) Medical physicists who fail to meet the continuing experience requirement of paragraph (a)(3)(iii)(B) of this section shall complete a satisfactory survey of three mammography facilities under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section.

(4) Retention of personnel records. Facilities shall maintain records to document the qualifications of all personnel employed by the facility in the production, processing, and interpretation of mammographic images. These records must be available for review by the MQSA inspectors and should not bediscarded until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the MQSA personnel requirements.

* * * * *

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 900

[Docket No. 95N–0195]

RIN 0910–AA24

Proposed Quality Standards for Mammography Equipment and Quality Assurance

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.