

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.

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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

full, that permit a mammography facility to operate lawfully after October 1, 1994. This section states the length of time the certificates will be valid and the circumstances under which the certificates may be renewed or extended. In addition, proposed § 900.11(c) outlines reinstatement procedures for a facility that has allowed its certificate to expire, has been refused a renewal of its certificate, or has had its certificate revoked by FDA. It also states that the owner or operator of a facility that has had its certificate revoked by FDA may not apply for reinstatement until at least 2 years have passed from the time of the revocation. This additional restriction is required by the statute (42 U.S.C. 263b(i)(3)).

One comment on the interim regulations requested that FDA state clearly that a provisional certificate can only be issued once.

FDA reviewed this issue in connection with implementation of the interim regulations and concluded that the statute does not limit any particular facility to receiving a provisional certificate only once.

Situations in which a subsequent provisional certificate might be issued to a facility include cases where a facility was denied an initial full certificate or renewal of its full certificate or has had its certificate revoked by FDA but subsequently has made substantial progress in correcting the problems that led to denial or revocation of the certificate. In the case of a facility that failed to achieve accreditation and certification during its initial 6-month provisional time period, the regulations permit FDA to issue a second provisional certificate if the facility applies for one after a corrective action plan has been effectively implemented. At that point, a new 6-month provisional certificate may be provided to the facility while the accreditation process is underway. In the case of a revoked certificate, as described previously, at least 2 years must pass before the owner or operator of the facility can apply for a new provisional certificate. A subsequent provisional certificate also might be issued to a facility that allowed its previous certificate to expire but later wishes to resume providing mammography services.

However, the comment is correct to the extent that FDA may not issue two sequential, uninterrupted 6-month provisional certificates to the same facility. The agency invites comments on whether its policy of permitting a facility to obtain a subsequent 6-month provisional certificate once the facility

has effectively corrected its deficiencies should be included in the final regulations and, if so, what if any, conditions should be placed in the process.

The same comment expressed the opinion that provisional certificates were only intended to aid facilities in meeting the October 1, 1994, deadline.

Although it is true that the provisional certificates were valuable in helping existing facilities meet the October 1, 1994, deadline, they are also intended to provide a way for new facilities to commence operation after the date became effective. To become accredited and certified, a facility must pass clinical image review. However, without provisional certification, a new facility would be unable to perform the necessary mammographic examinations for presentation to the accreditation body for review after October 1, 1994. The provisional certificate allows such facilities lawfully to produce the images they need to achieve full accreditation and certification.

Two comments suggested that other justifications, in addition to avoiding an adverse impact on the availability of mammography, should be considered in making a determination to grant a 90-day extension of the provisional certificate.

Congress limited the possibility of a 90-day extension of a provisional certificate under the MQSA to cases in which there would be a significant reduction of access to mammography in the geographic area served by the facility (42 U.S.C. 263b(c)(2)). Provisionally certified facilities should make every effort to obtain full certification no later than 6 months from the date the provisional certificate is issued.

Other comments asked that the time periods for the provisional certificates and the 90-day extensions be increased, primarily because of the difficulty accreditation bodies experienced in meeting the timeframes.

Again, the agency notes that the MQSA established these timeframes and FDA cannot amend them. Although the number of applications for accreditation submitted to meet the October 1, 1994, deadline did cause some difficulties for accreditation bodies meeting the timeframes, the accreditation bodies have increased their staffs to match the workload. The agency believes that once the initial implementation period is over, the accreditation bodies will be fully staffed to meet these timeframes effectively and efficiently, provided that facilities promptly submit the required information for evaluation. In addition, accreditation bodies are taking steps to

adjust the timeframes for renewal of accreditation so that the workload is more evenly distributed.

One comment suggested that some additional time be allowed for FDA and facilities to gain experience with the interim standards before any major changes are proposed. The comment stated that experience could then serve as a guide in determining what revisions were needed.

When Congress gave FDA interim regulation authority, it intended that FDA take prompt action to promulgate final regulations through notice and comment rulemaking. Accordingly, FDA began work on the final standards almost immediately after the interim regulations were published. Because of the deliberative nature of the rulemaking process, however, the agency will have had some experience with the interim regulations before the final regulations are published. The lessons learned during this interim period have been and will continue to be applied in the development of the final regulations.

In addition, the passage of time has helped FDA identify concerns that were not immediately apparent when the interim regulations were drafted. For example, FDA has realized that there is a possibility that, at some future time, particular facilities may not have access to an accreditation body. If this event were to occur, FDA would have to provide an alternative for accreditation or the facilities could not lawfully operate. To be prepared for this possibility, the agency has added the words "or other entity as designated by FDA" at every point in § 900.11, and elsewhere in the regulations, where facilities are required to take some action with respect to their accreditation body.

D. Medical Records and Mammography Reports

Proposed § 900.12(c) establishes certain requirements for the content and terminology of the mammography examination report, the manner of communicating results of the mammography examination to the examinee and to health care providers, and the duties of the facility for maintaining records of examinees.

1. Mammography Reporting

The information and assessment categories listed in proposed § 900.12(c)(1) are intended to establish a minimum national standard that will permit the results of mammography examinations to be more easily compared. This standardized format for presenting the results of the

examination will assist in preparation of the medical outcomes audit that each facility is required to perform. The standard will also facilitate communication about the risk of breast cancer from the interpreting physician to the referring health care providers. The categories proposed in the regulation are recommended by the American College of Radiology and also recommended by the Agency for Health Care Policy and Research (AHCPR) mammography practice guidelines, "Quality Determinants of Mammography."

During discussions with NMQAAC, certain advisory committee members suggested that FDA establish standard operating procedures that facilities should follow for the production of mammography reports. FDA believes that regulating a facility's internal procedures for generating mammography reports would be overly intrusive. Interested parties can find suggested guidelines for optimal facility operating procedures for production and dissemination of mammography results in the AHCPR's "Quality Determinants of Mammography."

FDA and NMQAAC discussed the collection of racial and ethnic data as part of the recordkeeping requirements. Opinions of individual committee members varied with respect to collection of such data. FDA recognizes the value of these data in addressing such important issues as the utilization and efficacy of mammography, as well as other pertinent public health research questions. However, after consultation with other Public Health Service agencies that have experience in attempting to collect racial and ethnic data from mammography facilities, FDA determined that there is currently no effective established method for collecting this information. Therefore, FDA is not at this time proposing a requirement for facilities to collect racial and ethnic data. FDA does encourage facilities to collect all information, including racial and ethnic data, that will allow facilities to better understand and serve their particular communities.

The items listed in proposed § 900.12(c)(1) and (c)(2)(i) are minimum requirements and do not preclude the facility from including additional information in mammography reports or in notifications to examinees, including relevant public health messages to the health care provider or to the examinee.

2. Signatures

Proposed § 900.12(c)(1) would require the written mammography report to be signed by the interpreting physician.

FDA views the signature on the report as an attestation of the signatory as the individual who has read the mammogram and has rendered the interpretation in the report. Therefore, in addition to handwritten signatures on the mammography reports, FDA will accept other "signatures," including those that are generated from computer systems, typewritten, or name stamped, on the condition that these signatures were personally authorized by the interpreting physician.

NMQAAC advised FDA to adopt regulations to mandate that all facilities have a written policy that ensures the integrity of the signature on the mammography report as coming from the interpreting physician, or a designated interpreting physician, if the interpreting physician is unavailable. NMQAAC also encouraged FDA to mandate that facilities assure that all personnel signatures, and other legally binding equivalents in the medical record, include professional titles. FDA encourages these practices but believes that it is unnecessary to require them through regulation.

3. Communication With the Examinee and Health Care Providers

Communication responsibilities have long been a frustrating area in mammography practice. All women who have mammography need to know the results. Examinees without any health care providers need to have the actual reports to show to subsequent health care providers, especially in the case of abnormal findings. Many examinees believe no news is good news. This fallacy contributes to delays in treatment when, through communication problems, the significance of a finding is not properly communicated to the examinee.

Currently, interim regulations provide that only women who have no health care provider receive the actual medical report and a summary of the mammography results in lay language. Two comments on the interim regulations recommended that the final regulations be amended to ensure that every examinee receives a written report signed by the interpreting physician and presented in lay language. One comment on the interim regulations suggested requiring the report to include all elements previously required by the Health Care Financing Administration's (HCFA's) screening mammography program.

Proposed § 900.12(c)(2) would require that all examinees receive notification of results expressed in lay terms. Examinees without health care providers would receive the actual

mammography report along with the lay notification. If there is a health care provider, the lay notification would go to the examinee and the actual report would go to the health care provider, who, in turn, could communicate with the examinee again or in greater detail, if necessary.

This proposal is in response to consumer complaints of failure to communicate abnormal and normal results to examinees. The proposed standard intends to maintain the examinee-provider relationship while ensuring that results get communicated to the examinee. The lay notification of results and recommendations vary in length and detail, but may be as simple as "Your mammogram reveals you need further tests. Please contact your physician." FDA also believes that notifications to examinees should be written in a way that is not overly alarming. In addition, FDA believes that in those cases in which an examination reveals the need for followup, notification directly to the examinee is essential.

FDA recognizes there are some referring health care providers who feel that they may be placed in an uncomfortable position if an examinee is notified of results before the health care provider is notified. There is also a concern that the examinee may be unduly alarmed by the facility's notification.

In response to these concerns, the agency notes that the main purposes of the lay notification requirements are to provide another safety mechanism to help to ensure that abnormal results are followed up and to ensure that all examinees know their mammography results. If facilities notify physicians and examinees simultaneously, the referring doctor will have access to the results of the mammogram at the time an examinee calls for clarification or followup. Those physicians who prefer to handle all communication with their examinees may continue that practice if procedures are properly coordinated with the facility generating the reports. The proposed requirements would not prohibit the mammography facility from providing standard lay notifications, along with the mammography report, to a referring health care provider who has agreed to issue these notices to his or her examinees. This agreement should be documented by attestation statements from the referring provider and should be on file at the mammography facility for inspection purposes.

During discussions with NMQAAC, FDA heard diverse opinions concerning the form and content of the notification that all examinees will receive.

However, NMQAAC did favor some form of written notification to all examinees, and that recommendation has been incorporated into the proposal.

Section 900.12(e)(2)(ii)(A) of the interim regulations establishes that the written report of any mammography examination shall be sent directly to the patient if the patient's physician is not "available" or if the patient does not have a physician. Two comments stated that the word "available" in this provision is ambiguous and could be interpreted to mean that the physician will not be notified if he or she is on vacation, at a meeting, or absent. One comment suggested deleting this word. Another comment asked how one is to ascertain the availability of the examinee's physician at the time a report is generated.

FDA advises that, in the proposed regulation, communication of mammography results to examinees and communication of results to health care providers are addressed in separate sections. As with the interim regulations, the proposed regulations require a facility to provide the mammography report directly to the examinee if she does not have a health care provider (§ 900.12(c)(2)(ii)). The issue of the "availability" of a physician is addressed in the section of the proposed regulation that covers communications of results to health care providers, § 900.12(c)(3).

Proposed § 900.12(c)(3)(ii) is intended to address the specific concern that arises when a mammography report reveals possible malignancy. The proposed regulations would require the mammography facility immediately to make reasonable attempts to communicate a finding of possible malignancy directly to the health care provider or a responsible designee, if the health care provider is not available. "Not available" is intended to mean "not on call," "not able to be reached at this time," or other similar situations. Health care providers normally have means of handling unexpected important health matters concerning their examinees through coverage systems and the proposed regulation recognizes this practice. The regulations are intended to require reasonable attempts to notify the health care provider or the entity designated by the referring health care provider as responsible for patient care while the referring health care provider is not available.

Questions were raised by the NMQAAC about retention of lay notifications. Although the regulations do not require a facility to keep a copy of the notification in the medical record,

each facility should have a system to monitor and verify that such a notice was sent out for each examinee. In addition, samples of the lay notifications which go to all examinees must be available for inspectors during annual the MQSA inspections.

The results given in the lay notification are purposely labeled as "results" and not as "assessment" to avoid facilities having to use one of the six assessment categories in proposed § 900.12(c)(1)(iii) and (c)(1)(iv). FDA encourages facilities to tailor these lay notification letters of results to their clientele's literacy level, and ethnic, cultural, and social sensibilities in order to maximize the likelihood that these examinees will understand and appropriately followup results.

Proposed § 900.12(c)(2) recognizes that assessments indicating a high probability of cancer need to be communicated with special care to examinees, especially to those examinees without health care providers. Examinees without a health care provider should receive person-to-person communication, such as a telephone call, if it is at all possible, when immediate followup is needed. In addition, in these and other circumstances, such as when there are physical findings in the absence of mammographic findings, when there are symptoms of breast disease, or when a mammography report recommends further testing, the proposed regulation requires each facility to have a formal system that can refer an examinee who is without a health care provider. FDA believes this proposed regulation codifies the role many radiologists now assume with self-referred examinees.

The interim regulations require each facility to prepare a written report of the results of each mammographic examination as soon as possible. Two comments on the interim regulations stated that it is not clear how a time limit of "as soon as reasonably possible" for completing a report can be enforced. The comments suggested inclusion of an actual time limit or replacing the word "shall" with "should."

FDA agrees that a timeframe should be specified. Proposed § 900.12(c)(3)(i) requires every mammography report to be prepared and communicated to the health care provider as soon as possible, but no later than 30 days from the date of the examination. Proposed § 900.12(c)(2) establishes the same timeframe for communication of results to examinees. If the facility is gathering comparison films, an initial report or notification can be sent to the examinee or health care provider indicating

preliminary results with an addendum to follow.

4. Recordkeeping

One comment stated that the mammograms should be kept indefinitely, noting particularly the need for retention of baseline mammograms.

FDA believes that the 10-year time period, which is set forth in the statute itself, 42 U.S.C. 263b(f)(1)(G)(i), allows for adequate prior information to be stored and used. The proposed regulations thus adopt, in § 900.12(c)(4)(i), the same retention periods required by the interim regulations, which establish a minimum of 10 years in situations where no additional mammography examinations are done for an examinee. The time period may be longer, if required by State law.

One comment stated that the retention requirement in § 900.12(e) of the interim regulations requires facilities to retain all mammograms for 10 years, because costs of determining after 5 years whether an examinee has had additional mammograms will exceed storage costs.

FDA does not agree with this comment. One way to determine if mammograms can be discarded is during filing of each new mammogram. At that time, prior mammograms over 5 years old can be discarded if clinically appropriate and if permitted by State law. This policy allows for a case by case determination of record retention for individual examinees. A facility can keep images longer than the minimum set forth in the proposed regulations.

The same comment further requested that FDA revise the interim regulations to require that mammography records be retained for the same time periods that are otherwise required by State law, or if any State lacks such a requirement, for a period of 7 years, which is the time period specified by California.

Because the MQSA specifies minimum retention periods, the proposed change would be inconsistent with the statute. The MQSA permits States to have more stringent regulations, including requirements relating to record retention. However, the 7-year California requirement for retention of a single mammography examination would not be a more stringent requirement, because it is less than the 10 years required by the MQSA.

One comment noted that two mammography studies taken on consecutive days would allow a facility to circumvent the requirement for 10-year record retention.

FDA does not believe this comment raises a valid concern. Although the first mammograms would be exempt from the 10-year retention period, the second study would not be. It is doubtful that a facility would discard the first study while maintaining the second and highly improbable that any facility would do double studies simply to avoid retaining a set of images.

One comment suggested that examinees should only have a right to copies of mammograms, not to the originals, because of the increased risk of loss or misplacement associated with examinees permanently taking possession of their original films and reports. Another comment from an interpreting physician noted great difficulty in obtaining original mammograms for comparison purposes. This comment stated that copied films are of inadequate quality when assessing the need for surgery.

The issue of whether to require copies or originals to be sent to facilities for clinical use or for comparison studies was discussed with NMQAAC. Although NMQAAC members did acknowledge problems with loss or misplacement of original films, there was general concern that many copies were of such poor quality that they did not provide adequate information. Sometimes only original films can provide the information that will prevent a woman from undergoing unnecessary invasive procedures, or confirm the need for such procedures. Thus, the NMQAAC agreed that FDA should require that originals be sent for comparison studies, as proposed in § 900.12(c)(4)(ii). Under the proposed regulations, examinees would need to request any transfer of their films. Facilities could ask examinees to sign releases as part of the request for the transfer of originals. A copy of the film could be kept at the original facility until the original films are returned.

FDA and NMQAAC discussed the issue of facility closure and disposition of the films and mammography reports. Members of the NMQAAC advised FDA to require that facilities give the public notice of their impending closure to allow a reasonable opportunity for examinees to obtain or transfer films and reports; that facilities be required to make financial plans to fulfill this notification requirement and to transfer medical records in the event of cessation of mammography activities; that facilities be required to notify the accreditation bodies and FDA of the disposition of films and records; and that facilities establish contingency locations for the transfer of examinees' films and records.

The issue of medical record and film disposition in the event of a closure is generic to the health care system. Facilities are required under the interim and proposed regulations to report all changes in status to their accreditation bodies, including plans to close. FDA would encourage facilities to plan for an orderly transfer of records in case of closure and to comply with applicable State laws concerning record retention. However, FDA believes that additional Federal regulations on this issue would be problematic with respect to compliance and enforcement.

E. Quality Assurance—General

The MQSA requires each facility to establish and maintain a quality assurance and quality control program to ensure the reliability, clarity, and accuracy of interpretation of mammograms.

Proposed § 900.12(d) establishes general requirements for quality assurance (QA) programs.

Proposed § 900.12(d)(1) requires the facility to assign responsibility for various components of its QA program to individuals who are qualified for their assignments and who shall be given adequate time to perform their duties. Proposed § 900.12(d)(1) also establishes QA responsibilities for the lead interpreting physician, interpreting physician, medical physicist, and quality control technologist.

The agency developed these regulations in response to several comments that objected to the medical physicist having primary responsibility for the QA program under the interim regulations. The comments noted that, especially if the medical physicist is a contract employee, he or she may not have the authority to ensure that all the actions necessary for proper implementation of the QA program are carried out. In addition, NMQAAC members advised FDA that some aspects of the QA program fall outside the medical physicist's area of expertise.

The agency believes that the division of responsibility under the proposed regulations addresses these concerns and satisfies the requirements under the MQSA that certain responsibilities be assigned to the physicist.

Proposed § 900.12(d)(1)(i) states that the lead interpreting physician shall have general responsibility for assuring that all of the QA requirements are met. The regulation is intended to recognize that, in order to carry out this responsibility effectively, the lead interpreting physician must have authority to ensure that the individuals involved with the QA program are

qualified for their duties and that they perform them properly.

The proposed regulation requires each facility to designate a qualified individual as lead interpreting physician for purposes of the QA program. However, the actual administrative title of the individual is left to the facility. Decisions to assign other supervisory duties, unrelated to the QA program, to the lead interpreting physician are left to the discretion of each facility.

NMQAAC felt strongly that the individual assigned overall responsibility for the QA program should be an interpreting physician. NMQAAC recognized that this may cause some difficulty for a facility whose interpreting physician is not normally at the facility. However, the committee believed, and FDA agrees, that the benefits to be gained when the individual overseeing the QA program has the skills of an interpreting physician outweighed the difficulties.

Proposed § 900.12(d)(1)(ii) establishes that all interpreting physicians have a responsibility to assist and participate in the QA program.

Proposed § 900.12(d)(1)(iii) establishes that the primary responsibility of the medical physicist in the QA program is related to mammography equipment.

Proposed § 900.12(d)(1)(iv) is intended to recognize that many aspects of the QA program should be assigned to quality control technologists. NMQAAC believed that it was essential that quality control technologists be qualified to perform diagnostic radiology examinations in order to be able to carry out adequately the responsibilities normally assigned to them, including, for example, responsibility for darkroom cleanliness, darkroom fog tests, processor quality control, analysis of fixer retention in film, and retake analysis. After some discussion, NMQAAC also concluded that the quality control technologists need not be qualified to perform mammography examinations specifically.

NMQAAC's position is reflected in the definition of quality control technologist in proposed § 900.2, published elsewhere in this issue of the Federal Register. The definition would bar biomedical engineers, manufacturer's service personnel, darkroom personnel, or individuals in other positions from serving as quality control technologists unless they were also qualified to perform diagnostic radiology examinations.

NMQAAC discussed the advisability of limiting performance of certain QA

tasks exclusively to quality control technologists. NMQAAC concluded that there might be certain situations where the absence of the technologist might require a medical physicist or interpreting physician to step in and perform these tasks in order to avoid the temporary closure of a facility. The proposed regulations, therefore, do not assign specific QA duties to particular individuals, as do the ACR manuals.

Proposed § 900.12(d)(2) outlines the necessary QA records the facility will be required to keep. These records include: A QA manual; a list assigning responsibility for the various aspects of the QA program; records to show the qualifications of the individuals involved in the program; and records that monitor the facility's implementation of its QA program and resolution of any problems that occur. FDA believes that such records are necessary to ensure that all employees are aware of their QA responsibilities and trained to perform them and that appropriate actions are taken to meet the goal of providing high quality mammography.

F. Medical Outcomes Audit

Proposed § 900.12(f) requires a mammography medical outcomes audit program to be part of each facility's QA program. A mammography medical outcomes audit is a systematic collection and analysis of mammography results and the comparison of those results with data from biopsy results.

The intent of the mammography medical audit is to provide an objective measure of the interpretive ability of the interpreting physician. This information can be useful for determining how the interpreting physician performs from year to year and in comparison with other interpreting physicians in the same facility and serving the same examinee population.

As the medical outcomes audit data are collected and analyzed, a facility should acquire information that can improve the interpretive skills of the physicians. Some examples of this type of information include: positive predictive value (PPV), cancer detection rate, and percent of minimal cancers found. The medical literature describes these and other outcome data that may prove useful in assisting the interpreting physician in assessing and continuing to develop and improve his or her interpretive skills. If one interpreting physician is not "doing as well" as his/her colleagues in the same practice, he/she may obtain additional training.

Although audits can be as detailed as necessary, the proposed requirements in

§ 900.12(f) for the medical outcomes audit program are general in nature. There are several reasons for this. In drafting the MQSA, Congress recognized that there is not consensus on the most desirable methodologies for such audit programs and provided authorization in 42 U.S.C. 263b(p) for research grants to study the most desirable methods for the collection and use of outcomes data. These research grants are administered by the National Cancer Institute (NCI). FDA believes it would be premature to require specific methodologies in the regulations before these studies are complete. In addition, some facilities may not be able to collect data that are meaningful if specific methodologies are mandated. The agency also believes that each facility should have flexibility to design an audit program that best serves its needs.

There was also concern expressed during discussion with NMQAAC that facilities may be reluctant to collect medical audit data because of concerns relating to legal liability and malpractice litigation.

In response to these concerns, FDA advises that the MQSA requires the agency to establish standards for a quality assurance and quality control program at each facility (42 U.S.C. 263b(f)(1)(A)). The agency believes that data generated and reviewed for mammography audits are to be used internally by each facility to improve individual and group performance and should not necessarily be viewed as information that is accessible to third parties.

The MQSA inspectors are trained to verify that a facility has a medical audits system that tracks positive mammograms, seeks followup results of surgical procedures, correlates those results with the mammogram, and interprets and evaluates the resulting data at least yearly for both the facility as a whole and for individual interpreting physicians. Inspectors ordinarily will not copy the data as part of the inspection and FDA has no current plans to ask facilities to provide the agency with the results of their medical audits. Accordingly, it is unlikely that the agency will have records in its possession that would be responsive to requests from the public for medical audit data.

If it does become necessary for an MQSA inspector to collect specific medical audit data, or if FDA should wish to obtain such data in the future, the agency would protect audit results from public disclosure in accordance with the Freedom of Information Act, the Trade Secrets Act, and the agency's implementing public information

regulations. Aggregate data that does not identify the medical audit outcomes of any particular facility would be available to the public.

The agency recognizes that State laws with respect to medical audit information vary considerably. The 1993 ACHPR guidelines on "Quality Determinants of Mammography" noted that very few broadly drawn statutes protecting audit information from discovery are in place at this time. Accordingly, the agency's commitment to protect such data may not prevent disclosure in state courts through discovery or other procedures established by State law. The agency believes, however, that the medical audit requirements that are proposed in this rule are general requirements that will not increase third-party requests for medical audit data.

Proposed § 900.12(f) requires each facility to establish and maintain a mammography medical outcomes audit program that correlates the results of biopsy and cytology examinations with the interpreting physician's recommendations. A facility must correlate the biopsy or cytology results of its positive mammograms with the interpreting physician's recommendations and mammographic report. A positive mammogram includes one that has an overall assessment of findings that are suspicious or highly suggestive of malignancy, as set forth in proposed § 900.12(c)(1)(iii). The pathologist examines the tissue sample and its cellular structure to determine whether or not the tissue is cancerous.

Proposed § 900.12(f)(4) requires each facility to designate at least one interpreting physician to review the audit data at least annually. This individual shall record the dates of the audit period(s) and be responsible for identifying issues and analyzing results based on this audit. This physician will notify other interpreting physicians of these issues and results, and ensure that necessary corrective actions are taken and documented. The proposal requires evaluations to be made individually and collectively for all interpreting physicians at the facility.

One comment noted that the preamble to the interim regulations discussed preventing false negative results, but the only quality assurance issue actually addressed in the interim regulations was the tracking of positive readings.

FDA believes that it would be too burdensome to require facilities to identify all false negative exams because, at the current time, adequate methods are not available to track all negative readings. The research studies funded by NCI grants may prove helpful

in future development of adequate methods for tracking false negative results.

A related comment expressed the belief that it was imperative that FDA spell out specific audit standards in the regulations. Another comment suggested that the final regulations should include a requirement for keeping statistics on additional procedures ordered by each radiologist.

Again, NCI's research program may aid in determining whether the collection and analysis of specific statistics should be mandated. However, FDA believes that currently there is inadequate data to justify making these suggestions regulatory requirements. NMQAAC supported the agency's position at its January 1995 meeting.

One comment suggested that, instead of correlating surgical biopsy results with mammography reports, a similar result can be achieved by requiring documentation of all erroneous or indistinguishable mammography results through a complaint program.

FDA believes the complaint mechanism and audit are substantially different in intent; therefore, one cannot replace the other.

One comment did not understand how the radiology department could use outcomes data, such as pathology reports, to improve the quality of mammography or the performance of technologists.

FDA believes that an audit program helps to provide quality assurance for the interpretation component of mammography by reviewing outcome data for each interpreting physician and monitoring how that physician is performing over time with respect to other interpreting physicians in the same facility and serving the same patient population. This review and analysis provides physicians with an opportunity to evaluate and improve performance. As mentioned previously, a physician may learn from an audit that he or she needs additional training in particular skills. Technologists' performance may be better evaluated through the repeat analysis process.

One comment mistakenly perceived a deficiency in the interim audit regulations because the comment believed that the interim regulations did not require followup of positive screening examinations. In fact, the interim regulations do require the facility's medical audit to track all positive mammograms and this requirement has been maintained in the proposed regulations at § 900.12(f)(1).

One comment suggested that all mammograms should be read a second time by a second qualified physician to

avoid unnecessary surgery and emotional distress that can be associated with a false positive reading, and to avoid lack of appropriate followup and treatment in the case of a false negative reading.

Although the proposed regulations do not preclude this practice, FDA has not required it due to a lack of consensus within the medical community as to whether the benefits of double reading outweigh the costs. FDA solicits further comments on this issue.

G. Mammography of Examinees With Breast Implants

The MQSA specifically requires that standards be established relating to special techniques for mammography of examinees with breast implants (42 U.S.C. 263b(f)(1)(H)). FDA interprets this requirement to mean mammography of the breast for the early detection of breast cancer, and not for imaging of the implant for rupture, leakage, or other problems. The agency recommends that women who have had breast surgery for cancer, including reconstruction with breast implants, consult with their physician as to the appropriateness of mammography for their particular situation.

Proposed § 900.12(g) requires facilities to establish procedure(s) to identify examinees with breast implants. The regulation also sets forth general techniques facilities should follow for mammographic examinations of women with breast implants. The proposed requirements are flexible enough to allow efficient adoption of newer imaging techniques as they become available.

One comment suggested that facilities should simply establish an intake procedure to identify examinees with implants and to indicate that special techniques are necessary. Another comment expressed concern that, if an examinee does not notify the technician that she has an implant, the mammogram may have to be redone.

FDA agrees with these comments and has proposed in § 900.12(g)(1) that facilities have a procedure to inquire if an examinee has a breast implant at the time of mammogram scheduling.

Another comment suggested that there be a requirement for "Eklund" views (four views per breast). A similar comment stated that, in order to obtain an adequate image of a breast with an implant, both the breast and implant should be carefully manipulated so that the maximum amount of breast tissue is imaged. A third comment, however, stated that FDA should not mandate medical procedures in regulations.

FDA and NMQAAC agree that currently the Eklund procedures, including appropriate individualized views, provide the best mammographic means to visualize breast tissue for most women with implants. There was also recognition, however, that other methods may exist that would be preferable in particular cases.

In addition, breast implant imaging is evolving, and the agency believes that it would be premature to limit this imaging by regulation to only one technique.

However, in response to the comment that stated FDA should not require medical procedures in regulations, the agency notes that the MQSA does require FDA to establish standards and that the codification of certain procedures in regulations may be appropriate when there is consensus that such procedures are necessary to protect women and assure accurate and safe mammography.

Another comment suggested that mammography facilities provide an excellent opportunity for further data collection and health assessment of examinees with implants.

In response to this comment, FDA notes that proposed § 900.12(f) requires mammography facilities to perform mammography medical outcomes audits, and that these audits would include examinees with breast implants.

Two comments were concerned about possible harm from the compression of the implant.

To minimize this possibility, FDA has proposed in § 900.12(a)(2)(ii)(C) (published elsewhere in this issue of the Federal Register) that the technologist have at least 5 hours of training in imaging examinees with breast implants and in § 900.12(g)(3) that the supervising interpreting physician be required to have training in mammography of examinees with breast implants, including specialized mammographic techniques.

H. Facility Complaint Mechanism

In accordance with section 354(n)(3)(E) of the Public Health Service Act (the PHS Act) as amended by the MQSA (42 U.S.C. 263b(n)(3)(E)), FDA has worked with the NMQAAC to develop mechanisms to investigate consumer complaints about mammography services provided by facilities. The preamble for proposed § 900.4(g), published elsewhere in this issue of the Federal Register, provides a thorough discussion of the complaint mechanism, including the role of the accreditation body in the process. In addition, FDA received a number of written comments on the complaint

mechanism following the publication of the interim rules (58 FR 67558 and 58 FR 67565). These comments are also addressed in the preamble to proposed § 900.4(g).

While proposed § 900.4(g) focuses on the responsibility of accreditation bodies for consumer complaint processes, proposed § 900.12(h) establishes corresponding requirements for facilities to develop a system to evaluate and resolve consumer complaints about the mammography services that they provide. FDA believes that consumer complaints can be resolved most easily at the individual facilities providing the mammography services. Therefore, FDA encourages the facilities to work diligently to resolve these complaints. However, in the event that a facility is unable to resolve a complaint to the consumer's satisfaction, proposed § 900.12(h) requires the facility to provide the consumer with adequate directions to file the complaint with the facility's accreditation body.

Some members of the NMQAAC suggested that FDA require facilities to post a sign that explains how to file consumer complaints or provide a toll free telephone number for making such reports to the accreditation body.

At this time, FDA is proposing not to mandate such requirements. Instead, FDA believes facilities should have the flexibility to promote their own consumer complaint mechanism to their clientele in a manner that is most appropriate. The agency notes that the name of the accreditation body is listed on the facility certificate, which the facility is required by statute to post prominently within view of the examinees.

Proposed § 900.12(h) is intended to ensure that "serious" complaints within the purview of the MQSA are adequately addressed. "Serious" complaints are defined in proposed § 900.2. FDA has worked extensively with the NMQAAC in developing the proposed consumer complaint mechanism and believes the proposed requirements meet important consumer needs without imposing an undue burden on facilities. Proposed § 900.12(h) establishes minimum requirements for facilities and provides them with the flexibility to institute their own complaint mechanism procedures. FDA encourages facilities to design their complaint mechanism procedures to be responsive to the language, ethnic, and literacy differences among consumers served by the facility.

I. Additional Clinical Image Review and Examinee Notification

Proposed § 900.12(i) requires a facility to cooperate with FDA in the investigation of concerns about the quality of the images produced by that facility and in notification of examinees or the public, should the investigation justify such notification.

Proposed § 900.12(i)(1) complements the requirements in proposed § 900.4(f) of the accreditation body regulations, which are published elsewhere in this issue of the Federal Register. Proposed § 900.4(f), among other things, would require accreditation bodies, or other entities as specified by FDA, to perform additional clinical image reviews when there are concerns or complaints about the quality of images produced at a facility. Proposed § 900.12(i)(1) requires the facility to provide the clinical images for this review.

If FDA determines that any activity related to the provision of mammography at a facility presents a serious risk to human health, proposed § 900.12(i)(2) would require a facility to notify examinees, their designees, or the public of actions that may be necessary to minimize the risk. Such notification may be used in cases where diagnoses of possible malignancy may have been missed due to the grossly inadequate performance of the facility. Examinees, their designees, health professionals, or the public may have to be notified so that they may take appropriate remedial action. For example, affected examinees may wish to repeat examinations at another facility or a member of the public may be able to contact an otherwise unreachable examinee.

J. Revocation of a Facility's Accreditation and Revocation of FDA Approval of a Facility's Accreditation Body

Proposed § 900.13 establishes procedures for revocation of facility accreditation and accreditation body approval. No comments were received on these requirements as promulgated under the interim regulations. The agency is proposing to retain these procedures with the exception of the following changes and additions:

Proposed § 900.13(a) gives FDA the discretion to revoke or suspend the certificate of a facility whose accreditation has been revoked by its accreditation body while the agency investigates what actions to take with respect to the facility as a result of the revocation.

Proposed § 900.13(b)(1) gives the agency greater flexibility with respect to facilities when FDA has revoked

approval of the accreditation body that accredited the facilities. Under the proposed regulation, the certificates of the facilities would normally remain in effect for up to 1 year after the accreditation body approval was revoked. The change from the interim regulations, however, would allow the agency to shorten this period if FDA determined that a facility had been accredited fraudulently or posed a serious threat to public health or safety.

Proposed § 900.13(b)(2) incorporates the additional language the agency has proposed in § 900.11 in order to provide alternative means of accreditation if the accreditation body cannot or will not perform this function at some future date.

K. Suspension and Revocation of Certificates

FDA has revised § 900.14 to set forth the bases for agency action to suspend or revoke certificates and the procedural rights available to facilities in these circumstances.

Proposed § 900.14 tracks 42 U.S.C. 263b(i), the section of the PHS Act that establishes provisions for suspension and revocation of certificates. Proposed § 900.14(a) provides that the agency may suspend or revoke a certificate, following notice and opportunity for a hearing in accordance with part 16 (21 CFR part 16), if FDA finds that the owner, operator, or any employee of the facility: (1) Has been guilty of misrepresentation in obtaining the certificate; (2) has failed to comply with standards under § 900.12; (3) has failed to comply with reasonable requests for records or information; (4) has refused to permit duly authorized inspections; (5) has violated or aided and abetted violations of the MQSA or implementing regulations; or (6) has failed to comply with prior sanctions imposed under 42 U.S.C. 263b(h).

Proposed § 900.14(b) sets forth the bases for FDA to suspend a certificate prior to holding a hearing. Here, too, the regulation tracks the statutory provision. FDA may dispense with a hearing if, in addition to making one of the findings listed above, the agency also determines that: (1) Failure to comply with the required standards presents a serious risk to human health; (2) the refusal to permit inspection makes immediate suspension necessary; or (3) there is reason to believe that the violative acts were intentional or otherwise rise to a level that presents a threat to the public. These three aggravating factors create circumstances in which the need to protect the public health outweighs the harm to the affected facility, which will have to wait a period of time for an

opportunity to demonstrate that the agency's determinations are erroneous.

As set forth in the statute and in the proposed regulation at § 900.14(b)(1), FDA may take action before a hearing if the agency determines that a facility's failure to comply with promulgated standards presents a serious risk to human health.

FDA may also take such action following a determination that a facility has refused reasonable requests for inspection. The agency believes this provision is intended to provide discretion for the agency to suspend a certificate in circumstances where recalcitrant actions by a facility make it impossible for the agency to inspect and investigate violations in order to determine whether the public is at risk if the facility continues operation. Proposed § 900.14(b)(2) sets forth this basis for suspension prior to hearing.

The agency may also take action prior to hearing upon a determination that a facility has violated or aided and abetted in the violation of any provision of the statute or an implementing regulation. FDA has interpreted this statutory provision to mean that the agency may suspend prior to hearing when the compliance record of the facility or other evidence demonstrates that responsible persons at that facility are not disposed to comply with established standards or with representations that were made during the certifying process. Proposed § 900.14(b)(3) states that the agency may suspend a certificate prior to hearing when the agency determines that there is reason to believe that the violation, or aiding and abetting of the violation, was intentional or associated with fraud. Such behavior cannot be tolerated without undermining the entire regulatory system and is sufficiently egregious to warrant immediate action by the agency.

As required by the MQSA and proposed in § 900.14(c)(1), facilities whose certificates are suspended prior to hearing will have an opportunity for a hearing within 60 days of the suspension.

As a matter of general policy, FDA will not suspend certificates without a hearing unless the agency believes that violations at the facility or misconduct by responsible persons present a serious risk to human health. Furthermore, suspension of a certificate, with or without a hearing, is not a regulatory action FDA intends to initiate as a matter of course. The MQSA favors voluntary compliance over regulatory sanctions, and FDA is committed to working with facilities to correct deficiencies rather than eliminating

services. Suspension will be necessary only in those cases where voluntary action or lesser sanctions have proven ineffective.

L. Appeals of Adverse Accreditation Decisions

The MQSA includes a provision that requires the Secretary of DHHS (the Secretary) to provide particular appeal procedures to a facility that has been denied certification. Section 263b(d)(2) of the PHS Act requires the Secretary (FDA, by delegation) to provide the facility with a statement of the grounds upon which the denial is based, and "an opportunity for an appeal in accordance with procedures set forth in regulations published at 42 CFR 498 and in effect on the date of the enactment of [the MQSA]." (42 U.S.C. 263b(d)(2).)

Because FDA may not certify a facility that has failed to become accredited, appeal of an FDA decision not to certify a facility will become, in actuality, a review of the accreditation body's determination that the facility did not meet necessary standards. For this reason, FDA believes that the procedural rights that are referenced in the statute should be available to the facility at the time it receives an adverse accreditation decision from the accreditation body to which it has applied.

FDA also believes that accreditation bodies should establish and implement impartial procedures for review and reconsideration of adverse accreditation decisions. As discussed elsewhere in this issue of the Federal Register, FDA is requiring each accreditation body to establish such reconsideration procedures and to inform any facility that receives an adverse accreditation decision of the opportunity to seek reconsideration by the accreditation body. Because it is the accreditation body that has the most detailed knowledge of the facts and alleged deficiencies of the facility's mammography practice, it is the accreditation body that is in the best position to make suggestions or review additional information that may result in accreditation.

FDA is proposing to require mammography facilities to seek reconsideration by the accreditation body before appealing the adverse decision to FDA. The agency believes this practice is in the best interest of the facility, the agency, and the public. As discussed above, the accreditation body will be in the best position to evaluate any additional information the facility presents for reconsideration. In addition, in order to perform an adequate evaluation of the adverse

accreditation decision, FDA will request and review materials provided by the accreditation body as well as the facility. The internal reconsideration process at the accreditation body level will permit the areas of dispute to be clarified for FDA review and conserve the limited resources of agency personnel.

A facility that is not satisfied with the result of the accreditation body's reconsideration may appeal that determination to the government. The regulations set forth at 42 CFR part 498, which are referenced in the MQSA, are Health Care Financing Administration (HCFA) regulations that were promulgated for appeals of decisions that among other things deny providers of medical services the opportunity to participate in Medicare. In order to implement a certification appeals process that is in accordance with those provisions and appropriate to the review of mammography accreditation decisions, FDA has consulted with other agencies of the Department of Health and Human Services (DHHS) that utilize and apply those procedures on a regular basis. As a result of those cooperative efforts, FDA and other agencies of DHHS have agreed that FDA's Division of Mammography Quality and Radiation Programs (DMQRP) will handle all appeals for reconsideration of an accreditation body's decision to deny accreditation. Hearing officers of the DHHS' Departmental Appeals Board (DAB) will conduct formal hearings for facilities that wish to appeal the FDA's reconsideration decision, and the DAB itself will hear appeals of the hearing officer's decision.

The procedures to be followed for these various appeals are detailed in 42 CFR part 498. However, as discussed above, because those are HCFA regulations, references to HCFA should be read as FDA for purposes of the MQSA program. In addition, references to the Social Security Appeals Council in 42 CFR part 498 should be read as the DAB; although 42 CFR part 498 has not been amended to reflect the delegation of authority, administrative law judges of the DAB have been handling adversarial HCFA hearings since 1992 and the DAB itself has been handling appeals of those hearing decisions.

Although 42 CFR part 498 is referenced in the MQSA and in FDA's implementing regulations, FDA is also proposing that its MQSA regulations broadly summarize the way these HCFA regulations will be applied by FDA. The agency believes that summary of the various appeal levels will make the procedures more accessible to facilities that wish to challenge adverse

decisions. Applicable details about the various appeal procedures that are not codified in FDA's proposed regulations can be found at 42 CFR part 498.

A facility that is appealing an adverse accreditation decision, regardless of the level of appeal, may not perform mammography services until the decision has been reversed and the facility has been certified by FDA.

M. Alternative Requirements

In the interim rule published in the Federal Register of September 30, 1994 (59 FR 49808), FDA established procedures for approval of alternatives to the quality standards of § 900.12. Such alternatives can be approved if, among other things, the alternatives provide at least as great an assurance of quality mammography as the original standards. These procedures were developed to permit flexibility in appropriate individual circumstances and to encourage further improvement in the practice of mammography. The alternative requirement procedures will allow the agency to permit the practice of mammography to benefit rapidly from improvements and advancements without the need first to amend regulations, which is often a lengthy process. Approved alternative requirements will be made available for review in the public docket file in FDA's Dockets Management Branch (address above). In addition, notices of approved alternative requirements with wide applicability will be published in the Federal Register.

The comment period on the interim regulations ended on December 29, 1994. No comments were received on the alternative requirements or, for that matter, on any of the amendments. The agency has interpreted this lack of response to indicate that members of the public did not object to the content of the amendments.

NMQAAC discussed the alternative requirement regulation (§ 900.18) at its February 1994 meeting. The regulation was discussed again at NMQAAC's January 1995 meeting. The only suggestion for change at the latter meeting came from a Federal liaison to NMQAAC who recommended that Federal agencies be given the same opportunity as State Governments to apply for approval of alternative requirements. NMQAAC endorsed this suggestion and FDA has revised § 900.18(b)(2) accordingly.

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, personnel 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 are contained in the proposed rule "Quality Mammography Standards; General Preamble and Alternative Approaches" published elsewhere in this issue of the Federal Register with an estimate of the annual reporting and recordkeeping burden.

The agency has submitted a copy of this proposed rule to OMB for its review and approval 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 proposal. 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, 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. Section 900.10 is revised to read as follows:

§ 900.10 Applicability.

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide screening or diagnostic mammography services, with the exception of the facilities of the Department of Veterans Affairs.

3. Section 900.11 is revised to read as follows:

§ 900.11 Requirements for certification.

- (a) *General.* After October 1, 1994, a certificate issued by FDA is required for

lawful operation of all mammography facilities subject to the provisions of subpart B of this part. To obtain a certificate from FDA, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity as designated by FDA.

(b) *Application*—(1) Certificates. (i) In order to qualify for a certificate, a facility must apply to an FDA-approved accreditation body, or to another entity as designated by FDA. The facility shall submit to such body or entity the information required in 42 U.S.C. 263b(d)(1).

(ii) Following the agency's receipt of the accreditation body's decision to accredit a facility, or an equivalent decision by another entity as designated by FDA, the agency will issue a certificate to the facility, or renew an existing certificate, if the agency determines that the facility has satisfied the requirements for certification or recertification.

(2) Provisional certificates. (i) New facilities beginning operation after October 1, 1994, are eligible to apply for provisional certificates. The provisional certificate will enable the facility to perform mammography and to obtain the clinical images needed to complete the accreditation process. To apply for and receive a provisional certificate, a facility must meet the requirements of 42 U.S.C. 263b(c)(2) and submit the necessary information to an approved accreditation body or other entity designated by FDA.

(ii) FDA will issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of paragraph (b)(2)(i) of this section. A provisional certificate shall be effective for up to 6 months from the date of issuance. A provisional certificate cannot be renewed, but a facility may apply for a 90-day extension of the provisional certificate.

(3) Extension of provisional certificate. (i) To apply for a 90-day extension to a provisional certificate, a facility shall submit to its accreditation body, or other entity as designated by FDA, a statement of what the facility is doing to obtain certification and evidence that there would be a significant adverse impact on access to mammography in the geographic area served if such facility did not obtain an extension.

(ii) FDA will issue a 90-day extension for a provisional certificate upon determination that the extension meets the criteria set forth in 42 U.S.C. 263b(c)(2).

(iii) There can be no renewal of a provisional certificate beyond the 90-day extension.

(c) *Reinstatement policy*. A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate revoked by FDA, may apply to have the certificate reinstated.

(1) Unless prohibited from reinstatement under paragraph (c)(4) of this section, a facility applying for reinstatement shall:

(i) Contact an FDA-approved accreditation body or other entity as designated by FDA to determine the requirements for reapplication for accreditation;

(ii) Fully document its history as a previously provisionally or fully certified mammography facility, including the following information:

(A) Name and address of the facility under which it was previously provisionally or fully certified;

(B) Name of previous owner/lessor;

(C) FDA facility identification number assigned the facility under its previous certification; and

(D) Expiration date of the most recent FDA provisional or full certificate; and

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity as designated by FDA, a corrective action plan that details how the facility has corrected deficiencies that contributed to the lapse of, denial of renewal, or revocation of its certificate.

(2) FDA will issue a provisional certificate to the facility if:

(i) The accreditation body or other entity as designated by FDA notifies the agency that the facility has adequately corrected, or is in the process of correcting, pertinent deficiencies; and

(ii) FDA determines that the facility has taken sufficient corrective action since the lapse of, denial of renewal, or revocation of its previous certificate.

(3) After receiving the provisional certificate, the facility may lawfully resume performing mammography services while completing the requirements for full certification.

(4) If a facility's certificate was revoked, that facility is not eligible for reinstatement until at least 2 years from the date the certificate was revoked if the facility is owned or operated by any person who owned or operated the facility at the time of revocation.

4. Section 900.12 is amended by revising paragraphs (c) and (d) and by adding new paragraphs (f), (g), (h), and (i) to read as follows:

§ 900.12 Quality standards.

* * * * *

(c) *Medical records and mammography reports*. (1) Contents and terminology. Each facility shall prepare a written report signed by the interpreting physician for each mammography examination performed under its certificate. The mammography report shall include the following information:

(i) The name of the examinee;

(ii) Date of examination;

(iii) Overall final assessment of findings, classified in one of the following categories:

(A) "Negative:" Nothing to comment upon. (If the interpreting physician is aware of clinical findings or symptoms, despite the negative assessment, these shall be explained);

(B) "Benign:" Also a negative assessment, but benign finding(s) can be described at the discretion of the interpreter;

(C) "Probably benign:" Finding(s) has a high probability of being benign;

(D) "Suspicious:" Finding(s) without all the characteristic morphology of breast cancer but indicating a definite probability of being malignant;

(E) "Highly suggestive of malignancy:" Finding(s) has a high probability of being malignant;

(iv) In cases where no final assessment category can be assigned due to incomplete work-up, "Needs additional imaging evaluation" shall be assigned as an assessment and reasons why no assessment can be made shall be stated by the interpreting physician; and

(v) Recommendations made to the health care provider about what additional actions, if any, should be taken. All clinical questions raised by the referring health care provider shall be addressed in the report to the extent possible.

(2) Communication of mammography results to the examinee. Each facility shall maintain a system for providing written notification of results of each mammographic examination to the examinee. The written notification issued by the facility or by its designee shall be communicated to the examinee as soon as possible, but no later than 30 days from the date of the mammography examination. If assessments are "Suspicious" or "Highly suggestive of malignancy" and if the examinee has not named a referring health care provider, the facility shall make reasonable attempts to communicate results to the examinee immediately.

(i) The written notification of results provided to the examinee shall include:

(A) The date of the examination;

(B) The results of the examination in lay terms; and

(C) A recommendation to the examinee on followup actions.

(ii) Examinees who do not name a health care provider to receive the mammography report shall be sent the report described in paragraph (c)(1) of this section, in addition to the written notification described in paragraph (c)(2)(i) of this section.

(iii) Each facility that accepts examinees who do not have a primary care provider shall maintain a system for referring such examinees to a health care provider when clinically indicated.

(3) Communication of mammography results to health care providers. When the examinee has a referring health care provider or the examinee has named a health care provider, the facility shall:

(i) Provide a written report of the mammography examination, including the items listed in paragraph (c)(1) of this section, to that health care provider as soon as possible, but no later than 30 days from the date of the mammography examination; and

(ii) If the assessment is "Suspicious" or "Highly suggestive of malignancy," make reasonable attempts to communicate with the health care provider immediately, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) Recordkeeping. Each facility shall maintain mammography films and reports in a permanent medical record of the examinee as follows:

(i) For a period of not less than 5 years, or of not less than 10 years if no additional mammograms of the examinee are performed at the facility, or a longer period if mandated by State or local law; or

(ii) Until requested by an examinee to transfer the original mammograms and copies of the examinee's reports to a medical institution, or to a physician or health care provider designated by the examinee, or to the examinee directly, and the records are so transferred.

(iii) Any fee charged to examinees for providing the services in paragraphs (c)(4)(ii) of this section shall not exceed the actual documented costs associated with this service.

(d) *Quality assurance—general.* Each facility shall establish and maintain a quality assurance program to ensure the safety, reliability, clarity, and accuracy of mammography services performed at the facility.

(1) Responsible individuals. Responsibility for the quality assurance program and for each of its elements shall be assigned to individuals who are qualified for their assignments and who

shall be given adequate time to perform these duties.

(i) Lead interpreting physician. The facility shall identify a lead interpreting physician who shall have the general responsibility of ensuring that the quality assurance program meets all requirements of paragraphs (d) through (f) of this section. No other individual shall be assigned or shall retain responsibility for quality assurance tasks unless the lead interpreting physician has determined that the individual's qualifications for, and performance of, the assignment are adequate.

(ii) Interpreting physicians. All interpreting physicians interpreting mammograms for the facility shall provide feedback on the quality of the mammograms they interpret to the radiologic technologists producing those mammograms and shall participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have available the services of an individual or individuals, who meet the qualifications of paragraph (a)(3) of this section, to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility.

(iv) Quality control technologist. Responsibility for all individual tasks within the quality assurance program not assigned to the lead interpreting physician or the medical physicist shall be assigned to quality control technologists.

(2) Quality assurance records. The facility shall maintain the following documents related to its quality assurance program:

(i) A quality assurance manual describing the procedures that are to be followed in meeting the requirements of paragraphs (e) and (f) of this section, including "action levels" for corrective actions, as defined in § 900.2. The manual shall be readily available to all staff members. It shall contain a sign-off page documenting that it has been read and approved by the lead interpreting physician and the medical physicist.

(ii) A current list of the individuals to whom quality assurance responsibilities have been assigned and the duties assigned to them. This list shall be readily available to all staff members.

(iii) Records to show that all staff members assigned responsibilities in the quality assurance program are qualified to conduct their assigned duties.

(iv) Records to show the data obtained during monitoring of the facility's performance, the analysis of the monitoring data, the problems detected and corrective actions carried out, and

the effectiveness of the corrective actions in resolving the problems. These records shall be kept for each test specified in paragraphs (e) and (f) of this section for a minimum of 1 year or until the test has been performed two additional times at the required frequency, whichever is longer.

* * * * *

(f) *Quality assurance—mammography medical outcomes audit.* Each facility shall establish and maintain a mammography medical outcomes audit program for followup based on mammographic assessments and to correlate biopsy or cytology results with interpreting physicians' recommendations. This program shall be designed to ensure the reliability, clarity, and accuracy of the interpretation of mammograms.

(1) General requirements. Each facility shall establish a system for reviewing outcome data from all mammography performed, in order to followup on the disposition of positive mammograms and to correlate biopsy or cytology results with interpreting physician's mammography report.

(2) Data collection. Data shall be collected on an ongoing basis for all examinees with positive mammograms.

(3) Frequency of audit analysis. An initial audit analysis shall be conducted no later than 12 months after the date the facility became fully certified. Subsequent audit analyses shall be conducted at least once every 12 months from the date of the initial analysis.

(4) Reviewing interpreting physician. The facility shall designate at least one interpreting physician to review the audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for identifying issues and analyzing results based on this audit, notifying the other interpreting physicians of these issues and results, and ensuring that necessary corrective actions are taken and documented. Evaluations shall be made individually and collectively for all interpreting physicians at the facility.

(g) *Mammographic procedure and techniques for mammography of examinees with breast implants.* (1) Each facility shall have a procedure to inquire whether an examinee has a breast implant at the time of mammogram scheduling.

(2) Except where contraindicated, or unless modified by a physician's directions, examinees with breast implants undergoing mammography shall have mammographic views to maximize the visualization of breast tissue and optimize breast cancer detection.

(3) These mammographic examinations shall be supervised by an onsite interpreting physician who is trained in mammography of examinees with breast implants, including training in specialized mammographic techniques of these examinees and training in interpreting the mammograms of these examinees.

(h) *Consumer complaint mechanism.* Each facility shall:

(1) Establish a written and documented system for collecting and resolving consumer complaints;

(2) Maintain a record of each serious complaint received by the facility for at least 3 years from the date the complaint was received;

(3) Provide the consumer with adequate directions for filing the complaint with the facility's accreditation body, if the facility is unable to resolve a serious complaint to the consumer's satisfaction;

(4) Report unresolved serious complaints to the accreditation body in a manner and timeframe specified by the accreditation body.

(i) *Additional clinical image review and examinee notification.*

(1) If FDA believes that image quality at a facility has been severely compromised and presents a serious risk to human health, the facility shall provide clinical images, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional clinical image review will help the agency to determine whether there is a need to notify affected examinees and the public.

(2) If FDA determines that any activity related to the provision of mammography at a facility presents a serious risk to human health such that examinee notification is necessary, the facility shall notify examinees, their designees, or the public of action that may be taken to minimize the effects of the risk. Such notification shall occur within a timeframe specified by FDA.

5. Section 900.13 is revised to read as follows:

§ 900.13 Revocation of accreditation, and revocation of accreditation body approval.

(a) FDA action following revocation of accreditation. If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. If FDA determines that the revocation was justified, FDA may take action, revoke or suspend the facility's certificate, or require the submission and implementation of a corrective action plan, whichever action or combination of actions will best protect the public health.

(b) Revocation of FDA approval of an accreditation body.

(1) If FDA revokes approval of an accreditation body under § 900.6, the certificates of facilities previously accredited by such body shall remain in effect for up to 1 year from the date of revocation, unless FDA determines, in order to protect human health or because the accreditation body fraudulently accredited facilities, that the certificates of some or all of the facilities should be revoked or suspended or that a shorter time period should be established for the certificates to remain in effect.

(2) After 1 year from the date of revocation of approval of an accreditation body, or within any shorter period of time established by the agency, the affected facilities must obtain accreditation from another accreditation body, or from another entity designated by FDA.

6. Section 900.14 is revised to read as follows:

§ 900.14 Suspension or revocation of certificates.

(a) FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the owner, operator, or any employee of the facility:

(1) Has been guilty of misrepresentation in obtaining the certificate;

(2) Has failed to comply with the standards of § 900.12;

(3) Has failed to comply with reasonable requests of the agency for records, information, reports, or materials that FDA believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that:

(1) The failure to comply with required standards presents a serious risk to human health;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

(c) If FDA suspends a certificate in accordance with paragraph (b) of this section:

(1) The agency shall provide the facility with an opportunity for an informal hearing under part 16 of this chapter not later than 60 days from the effective date of the suspension;

(2) The suspension shall remain in effect until the agency determines that:

(i) Allegations of violations or misconduct were not substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The facility's certificate is revoked in accordance with § 900.14(d).

(d) After providing a hearing in accordance with paragraph (c)(1) of this section, the agency may revoke the facility's certificate if the agency determines that the facility:

(1) Is unwilling or unable to correct violations that were the basis for suspension; or

(2) Has engaged in fraudulent activity to obtain or continue certification.

7. New § 900.15 is added to subpart B to read as follows:

§ 900.15 Appeals of adverse accreditation and certification decisions.

(a) The appeals procedures described in this section are available only for adverse accreditation decisions that preclude certification or recertification by FDA. Agency decisions to suspend or revoke certificates that are already in effect will be handled in accordance with § 900.14.

(b) Upon learning that a facility has failed to become accredited, FDA will notify the facility that the agency is unable to certify that facility without proof of accreditation.

(c) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body, in accordance with § 900.7. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from FDA.

(d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published at 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42

CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must make its request for reconsideration to DMQRP, within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include 3 copies of the following records:

(A) The accreditation body's original denial of accreditation;

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the bases for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

8. Section 900.18 is revised to read as follows:

§ 900.18 Alternative requirements for 42 U.S.C. 263b quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined under

paragraph (b) of this section, the Director, Division of Mammography Quality and Radiation Programs (the Director), may approve an alternative to a quality standard under § 900.12, when the Director determines that:

(1) The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace, and

(2) The proposed alternative:

(i) Is too limited in its applicability to justify an amendment to the standard; or

(ii) Offers an expected benefit to human health that is so great that the time required for amending the standard would present an unjustifiable risk to the human health; and

(3) The granting of the alternative is in keeping with the purposes of 42 U.S.C. 263b.

(b) *Applicants for alternatives.* (1) Mammography facilities and accreditation bodies may apply for alternatives to the quality standards of § 900.12.

(2) Federal agencies and State governments that are not accreditation bodies may apply for alternatives to the standards of § 900.12(a).

(3) Manufacturers and assemblers of equipment used for mammography may apply for alternatives to the standards of § 900.12 (b) and (e).

(c) *Applications for approval of an alternative standard.* An application for approval of an alternative standard or for an amendment or extension of the alternative standard shall be submitted in an original and two copies to the Director, Division of Mammography Quality and Radiation Programs, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. The application for approval of an alternative standard shall include the following information:

(1) Identification of the original standard for which the alternative standard is being proposed and an explanation of why the applicant is proposing the alternative;

(2) A description of the manner in which the alternative is proposed to deviate from the original standard;

(3) A description, supported by data, of the advantages to be derived from such deviation.

(4) An explanation, supported by data, of how such a deviation would assure equal or greater quality of production, processing, or interpretation of mammograms than the original standard;

(5) The suggested period of time that the proposed alternative standard would be in effect; and

(6) Such other information required by the Director to evaluate and act on the application.

(d) *Ruling on applications.* (1) The Director may approve or deny, in whole or in part, a request for approval of an alternative standard or any amendment or extension thereof, and shall inform the applicant in writing of this action. The written notice will state the manner in which the requested alternative standard differs from the agency standard and a summary of the reasons for approval or denial of the request. If the request is approved, the written notice will also include the effective date and the termination date of the approval and a summary of the limitations and conditions attached to the approval and any other information that may be relevant to the approved request. Each approved alternative standard will be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof will be placed in the public docket file in the Dockets Management Branch and may also be in the form of a notice published in the Federal Register. The notice will state the name of the applicant, a description of the published agency standard, and a description of the approved alternative standard, including limitations and conditions attached to the approval of the alternative standard.

(3) Summaries of the approval of alternative standards, including information on their nature and number, will be provided to the National Mammography Quality Assurance Advisory Committee.

(4) All applications for approval of alternative standards and for amendments and extensions thereof and all correspondence (including written notices of approval) on these applications will be available for public disclosure in the Dockets Management Branch, excluding examinee identifiers and confidential commercial information.

(e) *Amendment or extension of an alternative standard.* An application for amending or extending approval of an alternative standard shall include the following information:

(1) The approval number and the expiration date of the alternative standard;

(2) The amendment or extension requested and the basis for the amendment or extension; and

(3) An explanation, supported by data, of how such an amendment or extension would assure equal or greater quality of production, processing, or

interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* Any approval of an alternative standard, amendment, or extension may be implemented only by the entity to which it was granted and under the terms under which it was granted, except that when an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(g) *Withdrawal of approval of alternative requirements.* The Director shall amend or withdraw approval of an alternative standard whenever the Director determines that this action is necessary to protect the human health or otherwise is justified by § 900.12. Such action will become effective on the date specified in the written notice of the action sent to the applicant, except that it will become effective immediately upon notification of the applicant when the Director determines that such action is necessary to prevent an imminent health hazard.

Dated: March 22, 1996.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

[FR Doc. 96-7830 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-0192]

RIN 0910-AA24

Proposed Requirements for Accreditation Bodies of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its interim regulations for application procedures for FDA approval as an accreditation body under the Mammography Quality Standards Act of 1992 (the MQSA). FDA is proposing these amendments based on experience gained in administering the interim regulations, advice from the National Mammography Quality

Assurance Advisory Committee (NMQAAC), and public comments received in response to the interim regulations. This proposal would also establish new requirements and responsibilities for accreditation bodies. This proposal is the second of five proposed rules published in this issue of the Federal Register regarding MQSA requirements applicable to mammography facilities. These proposed rules are being issued to ensure adequate and consistent evaluation of mammography facilities on a nationwide basis.

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, Office of Management and Budget, 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 second 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 the proposed rules, 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.

II. Provisions of the Proposed Rule

A. Development of the Proposed Regulation

This proposed rule covers procedures for application to FDA for approval as an accreditation body and the requirements and responsibilities of such bodies. As with the interim regulations, FDA was guided in the development of this proposed rule by the intent of the legislation to guarantee access to safe and effective mammography services for all women in the United States (Ref. 1). FDA also relied upon three major sources of information, in addition to the expertise and research of FDA personnel.

First, the agency considered public comments received on the interim regulations. The agency received 103 comments from individuals and organizations, including professional organizations, medical facilities, State agencies, consumer groups, manufacturers, and individual physicians, medical physicists, and radiologic technologists. The proposed regulations were also discussed in a series of quarterly meetings with the NMQAAC. 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 committee meetings in recognition of their expertise in mammography also participated in these discussions of the proposed regulations. Finally, the agency's experience over the last year with the four accreditation bodies approved under the interim regulations also influenced the development of the proposed regulations. A discussion of the proposed amendments and a summary and analysis of both NMQAAC input and public comments regarding the regulations are provided below.

B. Application for Approval as an Accreditation Body

In § 900.3 (21 CFR 900.3) of the interim regulations, FDA established standards for approving the applications of prospective accreditation bodies. These standards are expanded in proposed § 900.3 to provide FDA with more thorough criteria for assessing a