

modality used by the technologist in mammography.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(C) Before a medical physicist may begin independently performing mammographic examinations using a new modality, that is, a modality other than one for which the physicist received training to qualify under paragraph (a)(3)(i) or (a)(3)(ii) of this

section, the physicist must receive at least 8 hours of training in surveying units with the new modality.

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

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

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

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

\* \* \* \* \*

Dated: March 22, 1996.

David A. Kessler,  
*Commissioner of Food and Drugs.*

Donna E. Shalala,  
*Secretary of Health and Human Services.*  
[FR Doc. 96-7832 Filed 3-29-96; 8:45 am]  
BILLING CODE 4160-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 900

[Docket No. 95N-0195]

RIN 0910-AA24

#### Proposed Quality Standards for Mammography Equipment and Quality Assurance

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is proposing to amend the regulations for facility standards established in the interim regulations implementing the Mammography Quality Standards Act of 1992 (the MQSA). This proposed rule will establish additional performance standards for mammography equipment and equipment-related quality assurance practices currently required of mammography facilities. FDA is proposing these amendments based on advice from the National Mammography Quality Assurance Advisory Committee (NMQAAC), mammography equipment manufacturers, and public comments received in response to the interim regulations. This proposed rule is intended to assure safe, accurate, and reliable mammography on a nationwide basis. This document is the fifth of five related proposed rules that FDA is publishing concurrently in this issue of the Federal Register.

**DATES:** Written comments by July 2, 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, except where otherwise indicated.

**ADDRESSES:** Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., 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.

**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 fifth 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* and § 900.2 *Definitions* (21 CFR 900.1 and 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**

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 obtained input through discussions with various professional and trade organizations and individuals with expertise related to mammography equipment, quality assurance, and infection control. Preliminary drafts of the proposed regulations were made generally available at the NMQAAC meetings and through notices of availability published in the Federal Register on December 30, 1994 (59 FR 67710) and January 26, 1995 (60 FR 5152).

Organizations participating in discussions of the regulations included the National Electrical Manufacturers Association (NEMA), the Conference of Radiation Control Program Directors (CRCPD), and four national medical physicist organizations: The American Association of Physicists in Medicine, the American Academy of Health Physics, the American College of Medical Physicists, and the Health Physics Society.

A discussion of the proposed amendments and a summary and analysis of NMQAAC input and public comments regarding the regulations is provided below.

###### **B. Equipment Regulations**

In § 900.12(b) of the interim regulations, performance standards were established for equipment used in the production of mammograms. These standards were substantially harmonized with existing standards, such as those established by the Health Care Financing Administration (HCFA), the American College of Radiology (ACR), and some States. This interim approach was consistent with the legislative intent of the MQSA (Ref. 1) and enabled FDA to certify the thousands of facilities that already met voluntary accreditation standards prior to publication of the interim regulations. This approach also allowed the agency to concentrate its initial resources on facilities with no such prior accreditation. Now that additional input regarding the equipment standards has been obtained from the NMQAAC, equipment manufacturers, and the public, FDA is proposing additional requirements in § 900.12(b) for radiographic, processing, and ancillary equipment used in mammography.

In developing the proposed equipment standards, FDA recognized the need to balance the economic impact of new standards against the associated gains to the public health. It was also necessary for FDA to consider the availability (initially, and over time) of mammography equipment meeting the new requirements. This was necessary because, for some requirements, considerable time might be needed to allow for redesign, production, purchase, and installation of new equipment, or for retrofitting of the installed equipment base. The amount of time needed would depend on the nature of the requirement, the capacity of manufacturers, and the number of facilities already meeting the requirement. In consideration of these factors, the agency is proposing to phase in the equipment standards in proposed § 900.12(b) over the next 1 to 10 years.

In accordance with guidance from the NMQAAC, three effective dates are being proposed for different phases of implementation. Requirements to be implemented during the first phase would have an effective date of 1 year after the date of publication of the final rule. Such requirements would cover aspects of equipment performance that the NMQAAC considered fundamental to the delivery of quality mammography. Requirements to be

implemented during the second and third phases would have effective dates of 5 and 10 years after the date of publication of the final rule, which FDA estimates would correspond to approximately October 1, 2000, and October 1, 2005, respectively. Although these dates have been used for the purpose of this proposal, the final effective dates will be modified to correspond to the dates 5 and 10 years after the publication date of the final rule. The agency believes that this advance guidance to the industry regarding upcoming changes in requirements and the phasing in of such requirements will minimize the economic impact of implementing improvements in mammography.

Several comments received on the interim regulations indicated a lack of awareness of agency plans for notice-and-comment rulemaking in promulgating final regulations, or listed specific recommendations for changes or additions. Most of the recommendations for specific equipment requirements have been incorporated into the proposed standards. A summary of these comments and the FDA responses follow:

#### 1. General

One comment disagreed with the prohibition in the interim regulations against performance of mammography using a conventional x-ray system with device modifications or options specifically designed to enable use of the system for mammography. The comment stated that allowing use of such systems for mammography would represent an economical source of equipment that should not be problematic as long as the systems can produce quality images without compromising examinee safety or dosage considerations.

In response to this comment, FDA notes that the MQSA expressly states that equipment standards must "require use of radiological equipment specifically designed for mammography" (42 U.S.C. 263b(f)(1)(B)). Therefore, FDA is continuing the prohibition against use of nonmammography x-ray equipment for the production of mammograms.

One comment supported the interim requirements in § 900.12 (b)(2)(i) to (b)(2)(iii) but requested the addition of two subsections requiring: (1) Cassettes of appropriate size, to allow the technologist to obtain a complete breast image on a single film, and (2) grids specifically designed for mammography for each size of cassette.

FDA agrees with these comments and has included such requirements in proposed § 900.12(b)(4).

Three comments suggested that the provision in § 900.12(b)(2)(iii), requiring mammography equipment to have a removable grid, be expanded to require a reciprocating removable grid. A reciprocating (moving) grid would avoid grid lines often seen with a stationary grid. One comment did not understand the requirement in § 900.12(b)(2)(iv), and in particular the phrase "removable grid." The comment stated that, if the intent is not to reduce radiation dose, the appropriate word would be "moving," rather than "removable," because moving the grid improves image quality. Also, the comment questioned whether this standard refers to regular view or magnification mode.

FDA believes that all equipment should be provided with reciprocating (moving) grids and that these grids should be removable for all systems providing magnification capability. These grid requirements have been proposed in § 900.12 (b)(4)(ii) and (b)(4)(iii). The intent is that the grid be removable so that magnification procedures can be completed properly without increasing the radiation dose to the examinee.

Discussions with the NMQAAC indicated considerable concern that radiographic equipment be equipped to enable a number of routine views for all examinees. Of specific concern were the mediolateral oblique, caudo-cranial, and cranio-caudal views, and the need to ensure that each facility has equipment that allows for variation in individual body habitus.

Under § 900.12(b)(3) (ii) and (iii), FDA has proposed specific requirements related to the motion capability of the gantry assembly that the NMQAAC believes will achieve this goal.

The NMQAAC also strongly recommended that all mammography systems be required to have a light field that approximates the x-ray field and passes through the collimation system. This configuration would assist in positioning and allow visual verification that the radiographic view of the breast remains unobstructed. In response to this NMQAAC recommendation, FDA received comments from a major trade association representing manufacturers of mammography x-ray equipment indicating that a significant portion of the installed equipment base would not meet these requirements. This association further indicated that there may be significant costs associated with retrofitting existing equipment to comply with this recommendation.

FDA is proposing to require in § 900.12(b)(5) that all mammography systems have the light field recommended by the NMQAAC, effective October 1, 2000. FDA is requesting public comment on this proposed requirement and its likely impact on the cost and availability of mammography services.

Proposed § 900.12(b)(11)(i) references the requirements in § 1020.30(m)(l) (21 CFR 1020.30(m)(1)) for minimum beam quality (half-value layer (HVL)) for mammography x-ray systems. FDA realizes that this reference is redundant with proposed § 900.12(b)(2), but believes that it is necessary to clarify the requirements stated in proposed § 900.12(b)(11)(i).

One comment stated that, in addition to requiring the incorporation of a breast compression device, the regulation should mandate use of this device (at least for screening mammography), because compression enables better visualization of the breast and permits lower radiation dose to be used.

FDA recognizes that use of a breast compression device is considered by professionals to be essential for proper imaging of the breast. By requiring that each system be equipped with a breast compression device, FDA has attempted to ensure that this feature is always available to the technologist. However, because the requirement that the compression device always be used would be extremely difficult to enforce, such a requirement has not been proposed.

In § 900.12(b)(12), FDA is proposing that all mammography systems be equipped with both foot-controlled power driven and fine adjustment controls (either manual or power driven). The intent of this requirement is to allow the technologist to use both hands to position the examinee under foot regulated power control, and to make final adjustments to the compression under the increased control provided by the fine adjustment mechanism. FDA is specifically requesting additional comments on this proposed requirement. For example, would a power-only system that provided a slower, more controlled, final application of power driven compression be as useful as a combination of power and manual compression?

One comment suggested requiring that all compression equipment allow for automatic release of compression in case of power or mechanical failure.

FDA recognizes that some facilities consider an automatic compression release desirable, and the proposed regulations permit this. However, under

some conditions, an automatic release may represent a physical hazard to the examinee. Therefore, under § 900.12(b)(12)(ii), FDA is proposing certain restrictions on systems that provide an automatic decompression feature.

Two comments noted that the interim regulations do not require that the breast compression device be parallel to the imaging plane, thus potentially allowing unequal compression to occur.

FDA agrees and the proposed regulations contain a requirement under § 900.12(b)(12)(iii)(B) to address this concern. FDA notes, however, that there is one manufacturer that does not meet this proposed requirement because it claims that the nonparallel design of its device provides uniform compression. FDA requests comments (and supporting data) regarding whether the agency should: (1) Modify the proposed regulations to accommodate this alternative design, or (2) retain the requirement as proposed and allow manufacturers to obtain variances to market alternative devices, in accordance with the alternative equipment provision in proposed § 900.18 (published elsewhere in this issue of the Federal Register).

Seven comments recommended that FDA require automatic exposure control (AEC) capability on all systems. One comment suggested that the equipment requirements should be more specific to address phototimers, acceptable operating energies, radiation output, and milliamperage (mA) requirements.

FDA agrees and has included requirements for each of these areas in proposed § 900.12 (b)(13), (b)(14), and (b)(15). These requirements were supported by the NMQAAC.

One comment suggested that all mammography systems installed or transferred following implementation of the interim regulations should provide for milliamperage second (mAs) readout following each exposure.

FDA agrees that mAs readout is important and under proposed § 900.12(b)(13)(iv), all equipment that automatically selects the mAs will be required to indicate the mAs value used following the exposure.

Two comments suggested a number of technical requirements that all mammography equipment should be required to meet.

The recommended requirements are supported by FDA and the NMQAAC and have been included in proposed § 900.12 (b)(4), (b)(5), (b)(8), (b)(11), (b)(14), and (b)(15), or were already covered under the diagnostic x-ray system performance standard in §§ 1020.30 and 1020.31 (21 CFR

1020.31), with the exception of the following:

(1) One comment suggested that a tungsten target tube should never be used for screen-film mammography.

FDA disagrees with this comment. The agency believes there is no evidence to support prohibiting the use of tungsten target tubes and has not included this limitation in the proposed regulations.

(2) One comment stated that the nominal focal spot size should be regulated in conjunction with the system source-image receptor distance (SID).

FDA is proposing to address the issue of focal spot size through the proposed requirement for system resolution in § 900.12(b)(8). The intent of this requirement (which has been adopted by the ACR), is to provide a test for system resolution that is easier to perform than a focal spot size determination.

(3) One comment stated that the SID should not be less than 50 centimeters (cm).

FDA is proposing to adopt the ACR's minimum requirement for SID, which is 55 cm.

## 2. Xeromammography

Three comments requested FDA to prohibit use of xeromammography, which the comments believed produces lower quality mammograms at a higher dose of radiation than screen-film modalities.

FDA is aware of the controversy regarding use of xeromammography, but the agency believes that, with respect to certain diagnostic applications, the modality may still be equal to screen-film systems. At the same time, the virtual disappearance of xeromammography units from the marketplace indicates that the mammography community itself is discontinuing the general use of this modality. Both the interim and proposed regulations place a maximum limit on the dose that can be delivered to an examinee using xeromammography. In proposed § 900.12(c), published elsewhere in this issue of the Federal Register, the dose that may be delivered by xeromammography has been reduced from the interim requirement of 4.0 milliGray (mGy) to 3.0 mGy. This decision was based on communication from the manufacturer of xeromammography systems informing FDA that properly adjusted and maintained xeromammography systems could meet such a requirement. Under the proposed regulations, therefore, the

dose limits for screen-film and xeromammography would be the same.

One comment questioned whether xeromammography will continue to be considered inadequate for screening purposes, in accordance with HCFA regulations.

FDA regulations replace those issued by HCFA concerning mammography facilities and FDA regulations do not prohibit the use of xeromammography for screening.

## 3. Operator Protection

Two comments expressed concern that no regulations addressed the protection of the operator by requiring radiation protective barriers or anchored exposure switches.

FDA believes that specific operator safety requirements remain the responsibility of State and local authorities regulating the use of diagnostic x-ray equipment. Therefore, FDA has not proposed any requirements relating to this aspect of the facility operation.

## 4. Examinees With Disabilities

In addition to meeting the specific requirements listed in this regulation, it was the opinion of the NMQAAC that each facility has the responsibility to accommodate examinees with physical disabilities and to provide such examinees with access to the same quality mammography provided to other examinees. The NMQAAC further believed that facilities that could not provide such special services should be required to screen prospective examinees during the appointment scheduling process and refrain from scheduling disabled examinees who cannot be accommodated.

FDA has included a requirement in proposed § 900.12(b)(16) reflecting this recommendation. The agency also encourages facilities that cannot accommodate disabled individuals to refer these individuals to a facility that is equipped to provide mammography services for them. FDA encourages comments regarding the necessity and appropriateness of this section in light of the requirements currently imposed by the Americans with Disabilities Act of 1990.

## 5. Interventional Mammography

Five comments indicated that standards and test methods are needed for stereotactic units and dedicated biopsy-type machines.

FDA agrees with these comments. However, the agency believes that no consensus exists in the mammography community regarding appropriate standards for such equipment and

procedures. Various public and private organizations are working to develop such standards and FDA will propose requirements some time in the future.

#### 6. International Harmonization

In the Federal Register of November 28, 1994 (59 FR 60870), FDA published an agency policy on international harmonization of regulatory requirements. In accordance with that policy, the agency requests comments regarding the implications of the proposed equipment standards on any related international harmonization efforts for mammography equipment.

#### C. Quality Assurance (QA)—Equipment

The primary purpose of the equipment aspects of the quality assurance program is to prevent problems with equipment or detect and correct problems before they can have a significant effect on clinical image quality. To achieve this, the performance parameters of the equipment must be tested at appropriate frequencies, the test results must be promptly analyzed to determine if the performance of the equipment is satisfactory, and any identified problems must be corrected as soon as possible. In addition, followup tests must be conducted to determine whether the corrective actions were effective. Requirements for these types of tests are proposed in § 900.12(e).

#### 1. Testing of Screen-Film Systems

Proposed § 900.12 (e)(1) through (e)(5) establish the minimum performance tests to be conducted on screen-film systems. The agency has decided not to propose extensive detailed requirements in order to provide facilities with the flexibility to use alternative methods that might be equally satisfactory or to add other tests. Under the interim regulations, FDA adopted the ACR's relatively detailed QA requirements (Ref. 2). However, the NMQAAC has advised FDA that these ACR requirements were intended to be used as guidelines, not in a prescriptive manner.

Therefore, the agency is proposing to limit the quality assurance requirements for equipment to a more general listing of the required tests, establishment of the required test frequencies, definition of action limits, and, in some cases, specification of critical test conditions.

At the July 1994 NMQAAC meeting, an additional daily total system test was discussed, which read as follows:

##### Total System Test:

(A) The optical density (OD) of the film at the center of an image of a uniform phantom when exposed in AEC

mode shall not change by more than  $\pm 0.20$  from the established operating level. The OD of the established operating level shall be above 1.20. The mAs shall not change by more than 10 percent from the established value corresponding to the operating level OD.

(B) The film shall be examined for system artifacts.

The agency believes that this total system test, in conjunction with the processor performance test set forth in proposed § 900.12(e)(1), should be performed daily before the first examinee is examined. The performance of these two tests will assure the overall quality of the x-ray machine, processor, and films. The records of the tests will also enable a medical physicist to quickly detect the source of a problem when it occurs. The above described system test takes only a few minutes to perform and can be performed by a quality control technologist.

The NMQAAC suggested that more data about the usefulness of the total system test should be gathered before this test is introduced as a required daily test. The NMQAAC also agreed that the image quality evaluations described in proposed § 900.12(e)(2) should be performed weekly if the total system test is not required.

The agency is proposing system testing requirements in accordance with the NMQAAC's advice. Although FDA is not proposing to require the daily total system test at this time, the agency requests comments regarding the utility of this test. If the total system test were introduced, FDA would revise the regulations to require monthly, rather than weekly, performance of the image quality evaluations in proposed § 900.12(e)(2).

Several comments on the interim regulations raised concern about basing the quality control requirements on a single manual, such as the ACR manual (Refs. 2 and 3).

In the proposed regulations, no manual has been referenced. A facility may consult any appropriate manual or rely on agency guidance to meet the requirements in proposed § 900.12(e)(1) through (e)(5).

One comment requested that any standard that is developed be achievable with current technology. As an example of a test that the comment believed could not be achieved using current technology, the comment cited ACR's criteria for passing the screen-film contact test, as described in the 1992 ACR manual (Ref. 2).

The agency is convinced, based on the expertise of its staff and experience with the interim regulations, that the requirements and action limits proposed

in this regulation can be met with current technology.

One comment suggested that a minimum allowable dose should be specified for a 4.5-cm compressed breast composed of 50 percent glandular tissue and 50 percent adipose tissue. Also, one comment suggested that the mean glandular dose should not exceed 1.0 mGy for screen-film systems without grids.

FDA believes that placing a lower limit on dose may hamper further technological advancement of systems that may reduce the dose without compromising image quality. In addition, the agency has decided to use only one upper dose limit for all systems.

Several comments stated that FDA's data indicate that an accepted phantom simulates a 4.2-cm thick compressed breast, not 4.5 cm. Therefore, the regulations should use a 4.2-cm thickness. One comment stated that the dose should be determined using clinically employed technique factors for a 4.5-cm thick compressed breast composed of 50 percent glandular tissue and 50 percent adipose tissue, instead of using the phantom technique factors promulgated in the interim regulations. Two comments noted that, in many cases, the technique factors used by a facility to produce phantom images do not reflect the technique factors actually used on examinees. This could result in examinees receiving doses exceeding the limits specified in the regulations, even though the facility technically passed the compliance test by using their phantom image technique factors. One comment stated that the dose should be determined under the facility's proposed technique factors for a 4.2-cm thick compressed 50 percent glandular/50 percent adipose breast.

After review of these comments, FDA is proposing to require clinical technique factors and a phantom simulating a 4.2-cm thick compressed 50 per cent glandular/50 per cent adipose tissue breast to be used during dose measurements. Although FDA has data to show that an accepted phantom simulates the attenuation properties of 4.2 cm of 50/50 compressed breast tissue, the agency recently has developed additional data indicating that the phantom may be equivalent in attenuation properties to approximately 4.0-cm of 50/50 compressed breast tissue, as per the dose model used to convert skin exposure to dose. The agency, therefore, is soliciting more information and comments on the appropriate equivalent thickness of the phantom for dose calculation.

One comment requested an explanation of the methods for obtaining FDA certification of QA phantoms. Another comment suggested that the regulations should specify one, and only one phantom, and should specify the minimum acceptable performance, rather than leaving this to the discretion of accreditation bodies.

The agency continues to believe that accreditation bodies should establish phantom specifications and related performance criteria. However, as part of its responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specifications and performance requirements, which will have to be substantially the same among different accreditation bodies.

One comment recommended that FDA publish some type of voluntary form(s) for maintaining appropriate records.

FDA believes it is inadvisable for the agency to generate sample forms because such forms may be unnecessarily restrictive. Facilities that do not want to generate their own forms may adopt forms that are provided in various manuals, as appropriate.

## 2. Systems With Other Modalities

Proposed § 900.12(e)(6) would require that the facility quality assurance program for systems with image receptor modalities other than screen-film (e.g., xeromammography) be substantially the same as that recommended by the image receptor manufacturer. This section would also require that such systems meet the same dose limits as screen-film systems.

## 3. Mobile Units

Proposed § 900.12(e)(7) would establish additional quality assurance requirements for mobile mammography units. These mobile units are operated in a variety of environments and undergo the stress of frequent movements, often over rough surfaces. In view of this, a number of comments on the interim regulations urged FDA to require that a phantom image quality test be performed after every move, before any additional examinations are conducted at the new site. These comments stated that if a problem occurs after a move which could compromise the quality of clinical images, this problem should be detected and corrected before any further clinical use of the equipment. These comments believe this additional testing is necessary for mobile units in order to minimize the need for repeat examinations, which would result in additional radiation exposure and

expense and might result in some cancers going undetected if it is not possible to get examinees to return to the facility.

In contrast, other comments noted that a requirement for a post-move, pre-examination image quality test would pose great difficulties to mobile services that are some distance from their home base and do not have access to adequate processing at the test site. These comments expressed concern that such a requirement would cause some mobile services to cease operation and would significantly reduce access to mammography in rural and inner city areas. Several comments cited their own experience in stating that image quality tests conducted after moves rarely or never show that a problem has occurred because of the move. The preliminary results of a survey of mobile facilities conducted by the ACR found that nearly 90 percent of the facilities rarely found problems after a move. However, the remaining facilities found problems as often as daily or weekly.

The 1992 edition of the ACR QA manual (Ref. 2) recommended that an image quality test be conducted after every move, but was somewhat ambiguous regarding when the processing and analysis of the images should occur. However, the agency has been informed by members of the ACR committee who were responsible for the manual that they did not intend to require processing before further examinations were conducted. The 1994 edition of the ACR QA manual (Ref. 3) completely dropped the requirement for conducting image quality testing after every move. Under this revised ACR requirement, therefore, mobile units are required to undergo image quality testing at the same frequency as fixed units, which ordinarily is monthly.

At its September 1994 meeting, the NMQAAC discussed this issue and recommended that post-move, pre-examination testing of mobile units be required in the final regulations. FDA agreed with this recommendation and has incorporated it in proposed § 900.12(e)(7).

The NMQAAC further recommended allowing use of a method of testing based on post-exposure mAs readout values in place of phantom image testing. FDA has decided not to require a particular method of testing at this time. Instead, the agency is proposing to require each facility to adopt a test method that will verify the adequacy of image quality following a move, but to leave the choice of test method to the facility. The agency believes that this approach will give individual facilities maximum flexibility. FDA will issue

guidance documents that reflect the agency's current thinking about test methods that are appropriate. At this time, FDA expects those methods to include the method recommended by the NMQAAC as well as the traditional phantom image quality test.

Including these methods of testing in guidance rather than in regulations has the advantage of increased speed and flexibility. As the agency becomes aware of new test methods of proven value, the agency's evaluation of such methods can be publicized through modification of guidance materials much more rapidly than through amendment of regulations. In addition, mobile units will have the option of using post-move pre-examination image quality test methods that are different from those described in guidance. Testing methods described in these materials will guide inspectors as they evaluate the adequacy of an individual facility's testing methods. Although the methods described in guidance will represent the agency's most current thinking about appropriate testing for this purpose, such guidance will not bind the facility or the agency. If a facility chooses alternative procedures, FDA encourages the facility to discuss the choice in advance in order to prevent expenditure of efforts and resources on testing that may later be determined to be unacceptable because it does not establish the adequacy of image quality following a move.

## 4. Use of Test Results

Proposed § 900.12(e)(8) describes how results from the tests specified in paragraphs (e)(1) through (e)(7) would be used to ensure that problems are detected and corrected before they adversely affect the quality of examinations.

## 5. Survey

Proposed § 900.12(e)(9) describes the activities that would have to be carried out by the medical physicist as part of the annual evaluation of facility equipment performance and quality assurance programs. A concern raised at the February 1994 NMQAAC meeting and elsewhere was that qualified medical physicists might delegate the onsite survey work to less qualified personnel and merely review and sign the survey report.

Because FDA is also concerned about such delegation occurring, the agency is proposing in § 900.12(e)(9)(i) that only qualified medical physicists be authorized to conduct the surveys. The agency is further proposing to require in § 900.12(e)(9)(V) that the report be signed and dated by the individual who

performs the survey. As is the case with the signature of the interpreting physician on the mammography report (see discussion of § 900.12(c)(1) published elsewhere in this issue of the Federal Register), the purpose of the signature requirement is to identify the individual who performed or provided direct supervision of the work. Therefore, in addition to handwritten signatures, FDA will accept "signatures" that are generated from computer systems, typewritten, name stamped, and possibly provided in other ways. These requirements would not prohibit physicists-in-training from performing surveys to gain experience, but would require that such surveys be done under the direct supervision of a fully qualified medical physicist, who would have to sign the report as the responsible physicist. If another individual performs any part or all of the survey under the direct supervision of a medical physicist, that person and the part of the survey that person performed must also be identified on the survey report.

#### 6. Mammography Equipment Evaluation

Proposed § 900.12(e)(10) would require a mammography equipment evaluation to be performed whenever a mammography unit or image processor is installed or major components of that unit or processor are changed. This requirement was added to ensure that the performance of new or significantly changed equipment is evaluated, and problems corrected, before such equipment is used during examinations. FDA believes mammography equipment evaluation, rather than a complete survey of the facility as described in § 900.12(e)(9), is adequate for this purpose because not all aspects of the facility operation which are checked during a survey would be affected by the installation of new equipment or the modification of old equipment.

The agency will describe its current thinking about appropriate procedures for carrying out these evaluations in guidance documents and will update that guidance, when warranted, to reflect scientific and professional developments. Similarly, the agency will describe in guidance its current thinking about appropriate qualifications for persons doing this work. As discussed previously with respect to agency guidance for testing mobile units, facilities will have the option of using procedures other than those described in guidance or employing individuals with qualifications different than those listed in guidance, assuming such alternative procedures or qualifications are

adequate to examine equipment for such purposes. The guidance issued by FDA will not be binding on either the facility or the agency. Once again, however, FDA encourages facilities that choose alternative personnel or procedures, to discuss the choice in advance in order to prevent expenditure of efforts and resources on evaluations that may later be determined to be inadequate.

FDA realizes that § 900.12(e)(10), as presently proposed, raises the question as to what constitutes a "major component" of the equipment, i.e., what components would have a significant impact on the performance of the equipment if their repair or replacement were done improperly. The agency specifically requests comments on this issue.

#### 7. Housekeeping and Maintenance Tasks

At its July 1994 meeting, the NMQAAC stressed the importance of carrying out regular maintenance and housekeeping activities as well as properly storing film and processing chemicals. However, the agency decided, for two reasons, not to propose detailed and comprehensive requirements for such activities.

First, failure to follow proper maintenance and housekeeping activities at a facility will be revealed through failure of the tests outlined in § 900.12(e)(1) through (e)(6) and through adverse findings in the physicist's survey. Additional detailed requirements would be redundant.

Second, there are a wide variety of effective maintenance and housekeeping activities. The agency believes that it would be overly prescriptive to limit facilities to one set of activities in this area by regulation.

At its January 1995 meeting, the NMQAAC agreed that the details of these activities could be incorporated into guidance materials rather than regulatory requirements. However, the members believed that general requirements should be established for certain especially important activities. Therefore, FDA is proposing to require in § 900.12(e)(11) that facilities establish and follow protocols for the maintenance of darkroom, screen, and view box cleanliness.

#### 8. Calibration of Exposure Measuring Instruments

In order to have reliable uniform dose measurements in facilities all across the United States, it is important to have proper traceability of the instruments used to measure x-ray exposure. The agency is proposing to add in § 900.12(e)(12) a requirement for annual

calibration of such instruments, which must be traceable to a national standard.

#### 9. Infection Control

Concern was expressed during the open public portion of several NMQAAC meetings and by one comment on the interim regulations that, because of the possibility of nipple discharge during mammography, FDA should mandate the use of universal precautions during all mammography examinations to protect examinees and health care workers from possible transmission of bloodborne pathogens. The comment also expressed concern that present procedures used to disinfect mammography equipment between examinations are inadequate to prevent disease transmission.

FDA notes that the concept of "universal precautions" is an approach to infection control stipulating that all human blood and certain human body fluids should be treated as if known to be infectious for human immunodeficiency virus (HIV), hepatitis B and C viruses (HBV, HCV), and other bloodborne pathogens. The Occupational Safety and Health Administration (OSHA) already mandates the use of universal precautions for all situations where occupational exposure can reasonably be anticipated (29 CFR 1910.1030). Although staff at the Centers for Disease Control (CDC) have advised FDA that there have been no reported cases of transmission of HIV, HBV, or HCV to examinees or health care workers during mammography, such transmission is theoretically possible (if no infection control precautions are taken). Therefore, the OSHA regulations are applicable to the practice of mammography, and it would be redundant for FDA to issue a universal precautions requirement under the MQSA authority.

With respect to appropriate decontamination practices, members of the NMQAAC noted during an advisory committee meeting that guidelines and regulations addressing infection control practices relevant to mammography are available from CDC (Ref. 4) and OSHA (29 CFR 1910.1030(d)(4)). These guidelines and regulations specifically address the decontamination of medical equipment and working surfaces after contact with blood or other potentially infectious materials. Local infection control policies are also in effect in many locations.

In addition, the Association for the Advancement of Medical Instrumentation (AAMI) recently published a technical information report on reprocessing of reusable medical

devices (Ref. 5). Several other national and international standards setting organizations are developing guidance in this area as well. However, these guidelines, regulations, reports, and standards do not completely cover all aspects of reprocessing mammography equipment, because they may not address the special concerns of disinfecting electrical equipment, and may not consider the effect of the disinfecting agent upon the equipment. For these reasons, FDA is developing a guidance document regarding labeling of reusable medical devices for reprocessing in health care facilities (Ref. 6). A notice of availability requesting comments on this guidance document was published in the Federal Register on June 15, 1995 (60 FR 31484). FDA and industry will utilize this document to ensure appropriate labeling for new devices as well as for improving labeling for currently marketed devices.

FDA believes that the concern raised by the comment transcends the issue of reuse of mammography devices and addresses the broader general issue of safe reuse of any reusable medical device. Therefore, it is an issue to be resolved under the agency's general medical device authority, rather than under the authority of the MQSA. In light of the concerns raised, however, FDA is reviewing current guidance and regulations, as well as additional guidance under development by the agency, to determine whether new labeling information or accessories are necessary with respect to reuse of mammography devices. FDA encourages interested parties to communicate to the agency any concerns and proposed solutions in this area.

To ensure that the practice of mammography benefits from infection control guidance already available, FDA is proposing to require that facilities establish, adhere to, and document their compliance with a system of infection control. In addition to requiring compliance with any applicable infection control regulations, each facility's system would have to require adherence to infection control recommendations provided by the manufacturer(s) of the mammography equipment used in the facility, or, if adequate manufacturer's recommendations are not available, adherence to generally accepted guidance on infection control (e.g., Refs. 4 and 5), until such recommendations become available.

### III. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(3) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

### IV. Analysis of Impacts

FDA has examined together the impacts of this proposed rule and the proposed rules on accreditation bodies, general facility requirements, and personnel, 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 no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1995.

### VI. 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 at the heading of this document. Information submitted in response to this notice may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

### VII. References

The following information 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," U.S. Senate, Report 102-448, October 1, 1992.

2. American College of Radiology, "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," February, 1992.

3. American College of Radiology, "Mammography Quality Control: Radiologist's Manual, Radiologic Technologist's Manual, and Medical Physicist's Manual," 1994.

4. Centers for Disease Control, "Recommendations for Prevention of HIV Transmission in Health-Care Settings," *Morbidity and Mortality Weekly Report*, 36(2S):3S-18S, 1987.

5. AAMI TIR No. 12-1994, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers," Association for the Advancement of Medical Instrumentation, 3330 Washington Blvd., suite 400, Arlington, VA 22201-4598, 1995.

6. Food and Drug Administration, "Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: FDA Reviewer Guidance," Rockville, MD, March, 1995.

### 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 to follow:

### PART 900—MAMMOGRAPHY

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

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

2. Section 900.12 is amended by revising paragraphs (b) and (e) to read as follows:

#### § 900.12 Quality standards.

\* \* \* \* \*

(b) *Equipment*—(1) Prohibited equipment. Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This includes systems that have been modified or equipped with special attachments for mammography. This requirement supersedes the implied acceptance of such systems in § 1020.31(f)(3) of this chapter.

(2) General. All radiographic equipment used for mammography shall

be specifically designed for mammography and shall be certified pursuant to § 1010.2 of this chapter as meeting the applicable requirements of §§ 1020.30 and 1020.31 of this chapter in effect at the date of manufacture.

(3) Motion of Tube-Image receptor assembly. (i) Gantry assembly motion.

(A) The gantry assembly shall be capable of being rigidly fixed in any position where it is designed to operate. Once fixed in any such position, the gantry shall not move without operator intervention.

(B) The mechanism assuring compliance with paragraph (b)(2)(A) of this section shall not fail in the event of power interruption.

(ii) Effective October 1, 2000, the gantry assembly shall allow continuous rotation of at least 180° from vertical (cranio-caudal position) in one direction and of at least 105° from vertical in the other direction.

(iii) Effective October 1, 2005, the gantry assembly shall allow continuous rotation of at least 180° from vertical (cranio-caudal position) in one direction and of at least 135° from vertical in the other direction.

(iv) Effective October 1, 2005, the system shall provide visual indication of the gantry angle to within  $\pm 5^\circ$ .

(4) Image receptor sizes. (i) Systems using screen-film image receptors shall provide, at a minimum, for operation with image receptors of 18 x 24 centimeters (cm) and 24 x 30 cm.

(ii) Systems using screen-film image receptors shall be equipped with moving grids matched to all image receptor sizes provided.

(iii) Systems used for magnification procedures shall be capable of operation with the grid removed.

(iv) Grid motion shall not be impeded when a breast is subjected to compression during mammography. For each size of breast support device provided with the system, compliance shall be determined by applying compression to, and exposing, a 12-cm diameter acrylic disk, 1.5 cm-thick, placed with its center located 4 cm in from the center of the chest wall edge of the breast support surface. A 4-cm thick homogeneous acrylic attenuator with rounded edges shall be located in the beam between the source and the compression paddle during the exposure. A film exposed at 28 kilovoltage peak (kVp) to obtain an optical density as close to 1.3 as possible shall be examined for grid-related artifacts. For equipment provided with automatic exposure control (AEC), the test shall be performed in the AEC mode. The

compression to be applied during these tests shall be determined as follows:

(A) Before October 1, 2000, for systems meeting the requirements in paragraph (b)(12)(i)(C) of this section, the maximum attainable power driven compression shall be used; and for systems not meeting the requirements in paragraph (b)(12)(i)(C) of this section, the compression applied shall be as close to 200 newtons (45 pounds) as possible, using manual compression or a combination of manual and power driven compression.

(B) Effective October 1, 2000, the maximum attainable power-drive compression shall be used to determine compliance.

(5) Beam limitation and light fields. (i) All systems shall have beam limitation devices that provide means to restrict the useful beam so that the x-ray field can be adjusted to extend beyond the chest wall edge of the image receptor.

(ii) Any mammography system with a light field that passes through the beam-limiting device shall meet the following requirements:

(A) The light field shall be aligned with the x-ray field so that the total misalignment of the edges of the light field and the x-ray field along either the length or the width of the visually defined field at the plane of the breast support shall not exceed 2 percent of the distance from the source to the midpoint of the chest wall edge of the image receptor support device.

(B) The light field shall provide an average illumination of not less than 160 lux (15 footcandles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(iii) Effective October 1, 2000, all mammography systems shall be equipped with light fields that pass through the beam-limiting device and approximate the x-ray field.

(iv) Effective October 1, 2005, all systems shall be interlocked to prevent exposure unless appropriate combinations of beam limitation and image receptor size are selected.

(v) Effective October 1, 2005, all systems shall be interlocked to prevent exposure with an x-ray field that extends beyond the nonchest wall edges of the image receptor support device.

(6) Source-image receptor distance (SID). Effective October 1, 2000:

(i) Systems designed solely for contact mammography shall have a minimum SID of at least 55 cm.

(ii) All systems shall provide visual indication of the selected SID to within 2 percent of its actual value.

(7) Magnification. (i) Systems used for diagnostic procedures shall have

magnification capability available for use by the operator at any time.

(ii) Systems designed for magnification procedures shall provide at least one magnification setting within the range of 1.4 to 2.0.

(8) System resolution. (i) The focal spot shall be such that, with the mammography screen-film combination used in the facility, the system will provide a minimum resolution of 11 line-pairs/mm when the high contrast resolution bar pattern is oriented with the bars perpendicular to the anode-cathode axis, and 13 line-pairs/mm when the bars are parallel to that axis.

(ii) Effective October 1, 2005, for those systems providing magnification capability, a focal spot that meets the following requirements shall be provided:

(A) The resolution provided by the magnification focal spot shall meet, at a minimum, the requirements of paragraph (b)(8)(i) of this section. Compliance shall be determined with the test pattern placed 4.5 cm above the magnification breast support, under the conditions of system magnification providing a magnification factor as close to 1.5 as can be achieved with the system.

(B) When more than one target material is provided, the measurement in paragraph (b)(8)(ii)(A) of this section shall be made using the appropriate focal spot for each target material.

(C) The grid shall be removed from the imaging chain during these measurements.

(9) Focal spot selection. (i) When more than one focal spot is provided, the system shall indicate, prior to exposure, which focal spot is selected.

(ii) When more than one target material is provided, the system shall indicate, prior to exposure, the preselected target material.

(iii) When the target material is selected by the system algorithm, based on the exposure or a test exposure, the system shall display the target material selected after the exposure.

(iv) When the selected target is related to the kVp, the system shall prevent exposure unless the correct combination of target and kVp is selected.

(10) Focal spot location. (i) The focal spot shall be located so that the ray falling on the mid-point of the chest wall edge of the image receptor is within  $\pm 5^\circ$  of perpendicular to the image receptor.

(ii) Compliance shall be determined for each focal spot provided.

(11) Filtration. (i) General. Each system shall comply with the beam quality requirements of § 1020.30(m)(1)

of this chapter for the minimum half-value layer (HVL).

(ii) Variable filtration. (A) Effective October 1, 2000, systems with variable filtration type or thickness shall be interlocked to prevent exposure if the selected filtration material is inappropriate for the target chosen or is outside the allowable range specified in paragraph (b)(11)(i) of this section.

(B) If different types of filtration materials are available, the system shall display the type of filtration in use prior to exposure.

(C) Effective October 1, 2000, if the filtration is automatically selected based on a test exposure, the system shall visually indicate the filtration that was actually used after the exposure is completed.

(12) Compression. All mammography systems shall incorporate a compression device.

(i) Application of compression. Effective October 1, 2000:

(A) Power driven compression activated by foot controls operable from both sides of the examinee shall be provided.

(B) Fine adjustment compression controls operable from both sides of the examinee shall be provided.

(C) The compression device shall provide a maximum compression for the power drive between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(ii) Decompression. (A) If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the

system shall also provide an override capability to allow maintenance of compression and shall continuously display the override status.

(B) Each system shall provide a manual emergency compression release that can be activated in the event of power or automatic release failure.

(C) If a system is equipped with a remote compression release control for the operator, the release control shall be located in a position that allows the operator to observe the examinee during activation of the release control.

(iii) Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-sized image receptors provided. Compression paddles for special purposes, including those smaller than the full size of the image receptor (for "spot compression") may be provided. Such compression paddles for special purposes are not subject to the requirements of paragraphs (b)(12)(iii)(B) and (b)(12)(iv)(A) of this section.

(B) When compression is applied, the compression paddle shall be flat and parallel to the breast support table and shall not deflect from parallel by more than 1.0 cm at any point on the surface of the compression paddle. Compliance shall be determined by applying maximum system power compression to a 12-cm diameter acrylic disk 1.5-cm thick placed with its center located 4 cm in from the center of the chest wall edge of the breast support surface for each full size compression paddle provided. For systems without power driven

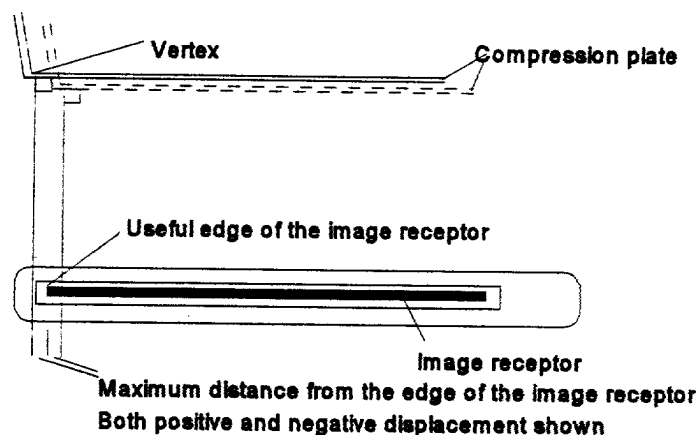
compression, or for systems which, before October 1, 2000, do not meet the requirements in paragraph (b)(12)(i)(C), compliance shall be determined by applying compression at as close to 200 newtons (45 pounds) as achievable using manual or a combination of manual and power driven compression. Vertical measurements shall be made between the breast support surface and the compression paddle at each of the four corners of the image receptor and shall be compared to each other and to the 1.5-cm thickness of the test device. The maximum difference between any two values shall not exceed 1.0 cm.

(C) The chest wall edge of the compression paddle shall be straight and parallel to the edge of the image receptor.

(D) The chest wall edge should be bent upward, forming a lip to allow for examinee comfort, but shall not interfere with the image at the chest wall.

(iv) Compression paddle alignment. (A) Effective October 1, 2000, when compression is applied, a line constructed perpendicular to the flat surface of the compression paddle through the vertex of the angle formed by the flat surface and the lip of the compression paddle and extending to the plane of the image receptor, shall intercept that plan within a distance no greater than  $\pm 1$  percent of the SID from the useful edge of the image receptor at the chest wall side (see Figure 1).

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**Figure 1**

(B) Effective October 1, 2005, when compression is applied, a line constructed perpendicular to the flat

surface of the compression paddle through the vertex of the angle formed by the flat surface and the lip of the

compression paddle and extending to the plane of the image receptor, shall pass within  $\pm 2$  millimeters of the useful

edge of the image receptor at the chest wall side.

(C) When the system is configured without magnification capability, compliance shall be determined with the bottom surface of the compression paddle placed at a distance within the range of 2.0 to 6.0 cm above the breast support.

(D) When the system is configured for magnification procedures, compliance shall be determined with the bottom surface of the compression paddle placed at a distance within the range of 2.0 to 6.0 cm above the breast support of the magnification device.

(v) Display of compressed breast thickness. Effective October 1, 2005, the compressed breast thickness shall be displayed and visible to the operator during positioning.

(A) The compressed breast thickness shall be displayed to within  $\pm 0.5$  cm.

(B) Compliance shall be determined at the maximum attainable power compression using a flat sheet of rigid material with known thickness placed between the examinee support and the compression device. This sheet shall be placed in flat contact with the top surface of the breast support. If the support is uneven or has projections around the edges, the sheet shall be in contact with that part of the surface that actually supports the breast. This test shall be performed using sheets of the following thicknesses: 3 cm, 4.5 cm, and 6 cm.

(13) Technique factor selection and display. (i) Manual selection of milliampere seconds (mAs) shall be available.

(ii) All technique factors shall be clearly displayed at the control panel prior to exposure.

(iii) When operating in AEC mode, the system shall indicate initial technique factors prior to exposure.

(iv) Following AEC mode use, the system shall indicate the actual kVp and mAs used during the exposure.

(v) All indications of kVp shall be within  $\pm 5$  percent of the actual kVp.

(vi) Effective October 1, 2005:

(A) Each system shall provide, at a minimum, for the selection of tube potentials of between 22 and 34 kVp.

(B) Selection of kVp shall be available in increments no greater than 1 kilovolt each over the entire range provided.

(C) Adjacent mAs settings shall differ by no more than 26 percent of the lower of the adjacent settings.

(D) Combinations of exposure time and tube current (mAs) shall be available over the range of at least 5 mAs to 300 mAs.

(14) Radiation output. (i) The system shall be capable of producing a

minimum output of  $1.29 \times 10^{-4}$  coulomb/kilogram (C/kg) per second (500 milliroentgen (mR) per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate. Effective October 1, 2000, the system shall be capable of producing a minimum output of  $2.06 \times 10^{-4}$  C/kg per second (800 mR per second) when operating at 28 kVp in the standard mammography mode at any SID where the system is designed to operate.

(ii) The system shall be capable of maintaining the required minimum radiation output for at least 3.0 seconds.

(iii) Compliance shall be determined with the center of the detector located 4.5 cm above the breast support device used for contact mammography and centered on the breast support 4 cm in from the chest wall edge of the support with the compression paddle in place between the source and the detector.

(15) Automatic exposure control. (i) Each system shall provide an AEC mode which is operable in all combinations of equipment configuration provided, i.e. grid, nongrid; magnification, nonmagnification; and various target-filter combinations.

(ii) The AEC shall be capable of providing automatic mAs selection.

(iii) The AEC shall provide reproducible radiation exposures with a coefficient of variation not to exceed 0.05.

(iv) The positioning or selection of the active detector shall permit flexibility in the placement of the detector under the target tissue.

(A) The size and available positions of the detector shall be clearly indicated at the input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated and visible from both sides of the examinee.

(v) The system shall provide means for the operator to vary the selected optical density from the normal (zero) setting.

(vi) Effective October 1, 2005, the system shall provide means for the operator to vary the optical density a minimum of 4 steps above and 4 steps below the normal (zero) setting of optical density. These steps shall vary in optical density increments of between 10 to 20 percent of the difference between adjacent mAs settings;

(vii) The system shall meet, at a minimum, the following requirements at all detector positions and for thicknesses of 2, 4, and 6 cm of homogeneous breast tissue-equivalent material. Compliance shall be determined using the screen-film and

processing combination used at the facility when the mean optical density is at least 1.20.

(A) Effective October 1, 2000, equipment shall produce images with optical densities that vary from the mean optical density by no more than 0.30.

(B) Effective October 1, 2005, equipment shall produce images with optical density that varies from the mean optical density by no more than 0.15.

(16) Disabled examinees. Each facility scheduling disabled individuals shall have equipment and established protocols to ensure the facility's capability to perform mammography adequately on such individuals.

(17) X-ray film. The facility shall use x-ray film for mammography that has been designated by the film manufacturer as appropriate for mammography.

(18) Intensifying screens. The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall match them to the spectral sensitivity specified by the manufacturer of the film used.

(19) Film processing solutions. For processing mammography films, the facility shall use chemical solutions that are capable of developing the films used in a manner equivalent to the minimum requirements specified by the film manufacturer.

(20) Lighting. The facility shall provide a special light with variable luminance capable of producing light levels greater than that provided by the view box.

(21) Film Masking Devices. (i) All facilities shall have film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film.

(ii) Facilities using x-ray collimation that provides nonrectangular exposed areas on the film shall provide masking devices appropriate to these fields.

(iii) Facilities shall make devices meeting the requirements of paragraphs (b)(21)(i) and (b)(21)(ii) of this section available to the interpreting physician.

(22) Film processors. Film processors used to develop mammograms shall meet the following requirements:

(i) The processor shall be adjusted and maintained to meet the technical development specifications for the mammography film in use.

(ii) Effective October 1, 2000, the processor shall indicate the selected time cycle reflecting the time from leading edge entry into the developer to leading edge entry into the fixer.

(iii) Effective October 1, 2000, the processor shall be capable of maintaining the developer temperature to within  $\pm 0.3^\circ$  Celsius ( $\pm 0.5^\circ$  F). Compliance measurements for immersion tank type processors shall be taken at the center of the surface of the developer solution and 7.5 cm (3 inches) below the surface when the developer is at the proper operating level.

(iv) Effective October 1, 2005, the processor shall clearly display the actual developer temperature to within  $\pm 0.1^\circ$  C ( $\pm 0.2^\circ$  F) of the actual temperature.

(v) Effective October 1, 2005, for processors with variable cycles, the selectable parameters shall be interlocked to prevent any initiation of changes in the parameters until any film in process is completed, and to prevent any new film from entering the process cycle until the variables are properly stabilized at the new cycle parameters. If the unit is equipped with an override of this interlock for maintenance procedures, the override status shall be clearly indicated to the operator.

\* \* \* \* \*

(e) *Quality assurance—equipment—*

(1) Daily quality control tests. Facilities with screen-film systems shall perform a processor performance test on each day that examinations are performed before any examinations are performed that day. The test shall include an assessment of base plus fog density, mid-density, and density difference, using the mammography film used clinically at the facility.

(i) The base plus fog density shall be within  $\pm 0.03$  of the established operating level.

(ii) The mid-density shall be within  $\pm 0.15$  of the established operating level of no less than 1.20 optical density (OD).

(iii) The density difference shall be within  $\pm 0.15$  of the established operating level.

(2) Weekly quality control tests. Facilities with screen-film systems shall perform an image quality evaluation test at least weekly.

(i) The optical density of the film at the center of an image of a standard FDA-accepted phantom shall be at least 1.20 when exposed under a typical clinical condition.

(ii) The optical density of the film at the center of the phantom image shall not change by more than  $\pm 0.20$  from the established operating level.

(iii) The phantom image shall achieve at least the minimum score acceptable to FDA in accordance with § 900.3(d) or § 900.4(a)(9).

(iv) The image contrast between the background of the phantom and an added test object, used to assess density difference, shall be measured and shall not vary by more than  $\pm 0.05$  from the established operating level.

(3) Quarterly quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least quarterly:

(i) Fixer retention in film. The residual fixer shall be no more than 5 micrograms per square cm.

(ii) Repeat analysis. If the total repeat or reject rate changes from the previously determined rate by more than 2.0 percent of the total films included in the analysis, the reason(s) for the change shall be determined and any corrective actions and their results shall be recorded.

(4) Semiannual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least semiannually:

(i) Darkroom fog. The optical density attributable to darkroom fog shall not exceed 0.05 when a mammography film of the type used in the facility, which has a mid-density of no less than 1.2 OD, is exposed to typical darkroom conditions for 2 minutes while such film is placed on the counter top. If the darkroom has a safelight, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh screen.

(iii) Compression. The compression device shall meet the specifications described in § 900.12(b)(12).

(5) Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) Automatic exposure control performance. (A) The AEC shall be capable of maintaining film optical density within  $\pm 0.30$  of the mean optical density when phantom thickness is varied over a range of 2 to 6 cm and the kVp is varied over the kVp range used in the facility for such thicknesses.

(B) The operating optical density of the film in the center of the phantom image shall not be less than 1.20.

(C) If the requirement of paragraph (e)(5)(i)(A) of this section cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within  $\pm 0.30$  of the average under phototimed conditions can be produced.

(ii) Kilovoltage peak (kVp) accuracy and reproducibility.

(A) At the lowest and highest clinical values and at any other commonly used clinical settings of kVp, the kVp shall be accurate to within  $\pm 10$  percent, and

(B) At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.

(iii) System Resolution. The limiting spatial resolution shall not be less than 13 line-pairs/mm parallel to the anode-cathode axis of the x-ray tube and 11 line-pairs/mm perpendicular to the anode-cathode axis.

(iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications in paragraph (b)(11) of this section.

(v) Breast entrance exposure and AEC reproducibility. The coefficient of variation for both exposure and mAs shall not exceed 0.05.

(vi) Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a 4.2-cm thick, compressed breast consisting of 50 percent glandular and 50 percent adipose tissue, shall not exceed 3.0 milliGray (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a 4.2-cm, 50 percent glandular/50 percent adipose tissue compressed breast.

(vii) X-ray field/light field/image receptor/compression paddle alignment. The x-ray field/light field/image receptor alignment shall meet the specifications of paragraph (b)(5) of this section and § 1020.31(f)(3) of this chapter. In addition, the chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID.

(viii) Screen speed uniformity. Screen speed uniformity of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.

(ix) System artifacts. System artifacts shall be evaluated with a high-grade, defect-free phantom large enough to cover the mammography cassette.

(6) Quality control tests—other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

(7) Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any additional examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

(8) Use of test results. (i) After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for non screen-film modalities, to the manufacturer's recommended action limits; or, for post-move, pre-examination testing of mobile units, to the limits established in the test method used by the facility. The applicable tests shall be repeated immediately for any parameters found to be beyond the specified acceptable ranges.

(ii) If the repeated tests continue to produce unacceptable results, the source of the problem shall be identified and corrective actions shall be taken before any further examinations are performed.

(9) Surveys. (i) At a frequency of no less than once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test in paragraph (e)(2) of this section.

(ii) The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be

evaluated for adequacy by the medical physicist performing the survey.

(iii) The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.

(iv) The survey report shall be sent to the facility within 30 days of the date of the survey.

(v) The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.

(10) Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, or major components of a mammography unit or processor equipment are changed. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations. The mammography equipment evaluation shall be performed by an individual whose qualifications are adequate to examine equipment for this purpose and in accordance with procedures that are adequate to ensure that the examination is complete and accurate.

(11) Facility cleanliness. (i) The facility shall establish and implement adequate protocols for maintaining darkroom, screen, and view box cleanliness.

(ii) The facility shall document that all cleaning procedures are performed at the frequencies specified in the protocols.

(12) Calibration of exposure measuring instruments. (i) Instruments

used to measure the exposure or exposure rate from a mammography unit shall be traceable to a national standard.

(ii) Effective October 1, 2005, the manufacturers calibrating instruments to measure exposure or exposure rate from mammography units shall meet the requirements of a recognized quality assurance program. A calibration laboratory calibrating instruments to measure exposure or exposure rate from mammography units must be accredited by a recognized national program or an equivalent international program which requires continuing participation with NIST in measurements and testing for maintaining quality assurance appropriate for mammography.

(13) Infection control. Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials. This system shall specify the methods for documenting facility compliance with the infection control procedures established and shall:

(i) Comply with all applicable Federal, State, and local regulations pertaining to infection control; and

(ii) Comply with the manufacturer's recommended procedures for the cleaning and disinfection of the mammography equipment used in the facility; or

(iii) If adequate manufacturer's recommendations are not available, comply with generally accepted guidance on infection control, until such recommendations become available.

Dated: March 22, 1996.

David A. Kessler,

*Commissioner of Food and Drugs.*

Donna E. Shalala,

*Secretary of Health and Human Services.*

[FR Doc. 96-7833 Filed 3-29-96; 8:45 am]

BILLING CODE 4160-01-P