DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 900

[Docket No. 95N–0192]
RIN 0910-AA24

Quality Mammography Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing mammography. Amendments are being made to the requirements for accreditation bodies; procedures for facility certification; and quality standards for mammography personnel, equipment and practices, including quality assurance. This action is being taken to provide increased assurance of adequate and consistent evaluation of mammography facilities on a nationwide level and compliance of the facilities with quality standards. It also carries out the intent of Congress that FDA replace the existing interim rules with more comprehensive final regulations.

DATES: This regulation is effective April 28, 1999; except §§ 900.12(b)(8), 900.12(e)(4)(iii), 900.12(e)(5)(i), 900.12(e)(5)(iii), and 900.12(e)(5)(x), which become effective October 28, 2002.

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SUPPLEMENTARY INFORMATION:

I. Background

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

The MQSA was enacted in response to the growing incidence of breast cancer and its associated mortality rate. Breast cancer is now the most common nonskin cancer and is the second leading cause of cancer deaths among women, after lung cancer. Early detection of breast cancer, typically involving breast physical examination and mammography, is the best means of preventing deaths that can result if the diagnosis is delayed until the onset of more advanced symptoms. Mammograms can reveal breast cancer up to 2 years before a woman or her doctor can feel a lump. In addition, over 90 percent of these early stage cancers can be cured (Ref. 1).

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

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

A. Provisions of the MQSA

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

Specifically, the MQSA required the following:

(1) Accreditation of mammography facilities by private, nonprofit organizations or State agencies that have been approved by FDA as meeting the standards established by FDA for accreditation bodies and that continue to pass annual FDA reviews of their activities. The MQSA also requires that, as part of the overall accreditation process, actual clinical mammograms from each facility be evaluated for quality by the accreditation body.

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

(3) Annual inspection of mammography facilities, to be performed by FDA-certified Federal or State inspectors. If State inspectors are used, the MQSA requires a Federal audit of the State inspection program by direct Federal inspections of a sample of State-inspected facilities.

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

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

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

(7) Standards governing recordkeeping for patient files and requirements for mammography reporting and patient notification by physicians.

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

The MQSA replaced a patchwork of Federal, State, and private standards. Its purpose is to guarantee sufficient oversight of mammography facilities to ensure that all women nationwide receive adequate quality mammography services.

B. Interim Regulations

On December 14, 1993, the President signed legislation (H. Rept. 2202) granting authority to the Secretary (and by delegation, to FDA) to issue temporary interim regulations setting forth standards for approving accreditation bodies and establishing quality standards for mammography facilities. This authorization was provided in recognition of the fact that FDA certification of the approximately 10,000 mammography facilities in the United States could not be accomplished by the October 1, 1994, statutory deadline without streamlining

the rulemaking process for issuing initial standards. Because of the urgent public health need for national mammography standards, Congress decided to grant this interim rule authority rather than extend the deadline to develop standards.

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

C. Accreditation and Certification

Operating under the interim regulations, FDA approved the American College of Radiology (the ACR) and the State of Iowa as accreditation bodies and issued certificates to more than 5,000 facilities accredited by these 2 bodies before the October 1, 1994, statutory deadline. Over 4,500 of the remaining facilities were actively involved in becoming accredited on that date. In the fall of 1994, FDA also approved the States of Arkansas and California as accreditation bodies.

In recognition of the fact that a large number of facilities were working to meet accreditation standards at the same time, and cognizant of the extremely heavy demands this placed upon the accreditation bodies, FDA used authority provided by the MQSA to issue 6-month provisional certificates on October 1, 1994, to facilities whose applications for accreditation were sufficiently complete for review and which, on preliminary examination, appeared reasonably likely to receive accreditation. This avoided the major reduction in access to mammography that would have resulted had several thousand facilities been forced to close their doors until the accreditation and certification process could be completed.

By March 31, 1995, the expiration date for the 6-month provisional certificates issued on October 1, 1994, over 8,200 facilities had become fully accredited and certified. Most of the facilities whose accreditation was still in progress satisfied the criteria for the 1-time 90-day extension of the provisional certificate provided by the MQSA and were granted such extensions.

By June 30, 1995, approximately 9,400 facilities had become fully accredited and certified. Several hundred more, primarily facilities that had begun operation after October 1, 1994, or facilities that had previously failed accreditation and were seeking approval after having taken corrective actions, were operating under provisional certificates or 90-day extensions of these certificates. FDA estimates that approximately 800 facilities closed between October 1993 and June 1995. The closings were due to a number of reasons, including failure to apply for certification, voluntary closure, and failure to meet the standards for accreditation, and other reasons unrelated to the MQSA, such as retirement.

D. Onsite Inspection of Facilities

At the same time FDA was working with the four accreditation bodies to accredit and certify facilities, the agency was also meeting the MQSA requirement to establish an annual onsite inspection program to monitor facility compliance with the MQSA standards. The bulk of these inspections are performed by State inspectors operating under the contracts that FDA has with 49 States, Puerto Rico, the District of Columbia, and New York City. Federal inspectors inspect Federal facilities and facilities in the remaining States and do audits of the State inspections. FDA has trained and certified approximately 250 Federal and State inspectors for this program. All facilities that completed the certification process had received their first inspections by September 1996 and approximately 70 percent had received their second inspections by the end of March 1997. FDA was pleased to find widespread compliance with the quality standards during these inspections. Only 2 percent of the facilities had one or more of the most serious findings (referred to by FDA as Level 1 findings) during the first round of inspections and that proportion has dropped to less than 1 percent of the facilities inspected so far in the second round.

E. Development of Proposed Regulations

In granting interim rule authority to FDA, Congress made clear its intention that the agency replace the interim regulations with more comprehensive regulations as soon as possible. These more extensive regulations were to be developed using the normal ''notice and comment'' rulemaking process and consultation with the NMQAAC.

Apart from the strong congressional encouragement, there were also other reasons why it was important to replace the existing interim regulations for quality mammography with more comprehensive final regulations. The interim regulations were based primarily on the voluntary standards of the ACR's Mammography Accreditation Program (MAP). Utilization of the MAP standards aided greatly in meeting the October 1, 1994, deadline for accreditation and certification of facilities. The application of these standards to all facilities, instead of just those that had sought voluntary accreditation from the ACR, had a significant impact on mammography nationwide. However, the MAP provisions did not cover all areas that required standards under the MQSA, such as mammography of patients with breast implants and experience requirements for some personnel of mammography facilities. Furthermore, in many situations where MAP voluntary standards were relevant, their wording needed to be changed and clarified for use as part of a regulatory program.

One especially significant gap was in the equipment area where the standards under the interim regulations were minimal. To provide greater assurances of quality equipment performance, the ACR, with the Centers for Disease Control and Prevention (CDC), had previously convened expert committees to develop specifications for mammography equipment. The reports of these expert committees were an important basis for the equipment provisions of the proposed regulations.

In addition, the interim standards were required to be issued and implemented prior to FDA developing any significant experience regulating mammography. Because the statute was new and the regulatory scheme it established presented a different and innovative approach, the agency would inevitably develop ideas for improvement in quality and efficiency of implementation as the program developed.

For all of these reasons, it was necessary to replace the interim regulations with more comprehensive final regulations in order to obtain the highest quality mammography that is reasonably achievable. Coincident with the implementation of the interim rules, work was proceeding on the development of final regulations. This effort was aided by the agency's ongoing experience under the interim rules and the advice of members of the NMQAAC. The NMQAAC membership includes health professionals whose work focuses significantly on mammography and representatives of consumer groups. NMQAAC was chartered on July 7,

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

Another valuable resource utilized by FDA in the development of the proposed regulations was the guideline entitled, *Quality Determinants of Mammography* (Ref. 2). This guideline was developed by the Quality Determinants of Mammography Panel, with support from the Agency for Health Care Policy and Research (AHCPR), to help eliminate low quality mammography and, thereby, eliminate the adverse consequences it causes. The Panel consisted of a diverse group representing many medical specialties and consumer representatives knowledgeable about mammography.

Proposed regulations were published in the **Federal Register** of April 3, 1996 (61 FR 14856). To facilitate review by the public, they were published in 5 separate documents, as described in the introduction to section III of this document.

F. Development of the Final Regulations

A 90-day public comment period ending July 3, 1996, was provided for the proposed regulations. During that time, extensive efforts were made to encourage public comments. Approximately 17,000 copies of the proposed regulations were mailed to the organizations and individuals on FDA's MQSA mailing list, including 1 to every certified mammography facility. The availability of the proposal was announced in Mammography Matters, the newsletter of FDA's Division of Mammography Quality and Radiation Programs (DMQRP), and in the newsletters of professional groups. Copies were also distributed by FDA personnel at professional meetings. By the end of the comment period, approximately 1,900 responses, containing approximately 8000 individual comments, had been received from organizations and individuals. NMQAAC also provided additional comments on the proposal during an April 1996 meeting.

Analysis of the many comments began after the end of the comment period. At the October 1996 meeting, FDA consulted the NMQAAC for advice with respect to some of the more controversial issues raised by the comments. During the January 1997 meeting, the Committee reviewed the entire set of regulations in light of the comments received. The public comments and the advice received from the NMQAAC were used to develop a draft of final regulations, which the members of the NMQAAC had an opportunity to review individually in March 1997.

The majority of the final regulations will become effective April 28, 1999. The interim rules will continue to apply until that date. Certain equipment-related regulations, in § 900.12(b) and (e), will become effective October 28, 2002. This delay in the effective date for certain equipment requirements is intended to minimize the costs associated with equipment improvements. The cost savings are achieved by permitting facilities to implement the improvements as they follow their normal equipment replacement schedule instead of requiring an immediate purchase of new equipment or equipment upgrades.

II. Highlights of the Final Rule

This section highlights the major features of the final regulations, as compared to the interim and the proposed regulations, and their potential for achieving the MQSA goals of establishing nationwide quality standards for mammography, while maintaining a broad patient access to mammography services. A detailed discussion of the public comments and FDA's response to them is provided under section III of this document.

These final regulations fulfill FDA's responsibility under the MQSA to establish national quality standards for mammography services, with extensive input from NMQAAC. These Federal regulations will be implemented under the MQSA framework whereby mammography facilities are accredited once every 3 years by FDA-approved State or private not-for-profit accreditation bodies, and inspected once every year by FDA-trained and certified State (or in some cases Federal) inspectors. The Federal-State-private sector partnership provides the necessary tools to successfully implement these regulations and realize the MQSA's goal of assuring high quality mammography services for every American woman.

Accordingly, these regulations establish rigorous criteria designed to enhance the quality of mammography services in a manner that is reasonably achievable by mammography facilities. The regulations provide facilities with flexibility in needed areas to meet the important public health goals of these standards. Taken as a whole, the regulations are expected to provide substantial consumer benefits in a reasoned and cost-effective manner.

The final regulations consist of two subparts. Subpart A is composed primarily of the requirements to be met by the accreditation bodies who perform the crucial initial screening of mammography facilities for quality, including clinical image review, subpart B establishes quality standards to be met by the mammography facilities and administrative procedures.

A. Accreditation Body Requirements

The final regulations refine and codify policies FDA had developed under the interim regulations for the initial approval of accreditation bodies by FDA, and for defining the ongoing responsibilities of these bodies and the agency's oversight of them. The primary goal of the accreditation body requirements is to ensure that there is nationwide consistency, both within and between accreditation bodies, in the evaluation of mammography units and procedures to determine if they meet the standards for quality mammography.

The major change made from proposed §§ 900.3 through 900.7 was the removal of several provisions that would have assigned compliance responsibilities to the accreditation bodies. Removal of these provisions ensures that the activities of the accreditation bodies will have their proper focus, which is to identify facilities that are not performing adequate quality mammography and to advise such facilities on the nature of their problems and how to correct them. Compliance activities under the MQSA are reserved for FDA.

B. Facility Quality Standards

1. Personnel Standards

The personnel standards of § 900.12(a) cover interpreting physicians, radiologic technologists, and medical physicists who provide services to mammography facilities. The goals of the standards are to ensure that personnel: (1) Have general qualifications in radiology; (2) possess specific qualifications in mammography; and (3) keep their qualifications up-to-date.

Most of the proposed changes in the personnel area were intended to clarify general statements in the interim regulations that have caused confusion in interpretation. A major step to improve quality of personnel

performance, however, was the proposed establishment of initial and continuing experience requirements for radiologic technologists and medical physicists. These requirements are parallel to requirements already in the interim regulations for physicians and, like the physician requirements, are intended to make sure that individuals have supervised clinical experience before they begin to provide mammography services independently, and that they maintain their skills through regular performance of their duties. These new experience requirements have been codified in the final rule after some adjustments in the amount of experience required due to practical considerations, such as the difficulties that medical physicists under contract to one facility would face in attempting to meet the proposed requirement to do surveys in several facilities.

Another significant change from the proposed personnel standards is that the final rule ''grand parents'' technologists who met the personnel requirements under the interim regulations. Without grand parenting technologists already in the system, there was the possibility that localized shortages of technologists would occur, resulting in a serious, short-term impact on access to mammography. Because the agency believes that most technologists presently providing mammography services either meet, or have qualifications comparable to the final requirements, grand parenting could be permitted to relieve these concerns without any significant impact on quality.

2. Equipment

The equipment standards in § 900.12(b) are intended to ensure that mammography equipment has the capability of producing quality mammograms over the full range of clinical conditions. The equipment area was addressed only briefly in the interim regulations. To better define the equipment capabilities needed for high quality mammography, equipment specification standards were proposed for all equipment components of the mammography system from the X-ray generator to the view box. These proposals relied heavily upon the recommendations of the equipment focus groups convened in the early part of the decade by the ACR, with the support of CDC.

After reviewing the information provided in the public comments and by the NMQAAC, FDA revisited the question of the proper balance between the economic impact of new standards and the associated gains to the public health. This reconsideration led the agency to conclude that the expected benefits from some of the proposed equipment specifications would not compensate for the cost to replace or retrofit mammography systems to meet them. The agency has concluded that, in some cases, the same public health goals could be accomplished through specified quality assurance procedures. Accordingly, specifications related to source-image receptor distance (SID), focal spot location, filtration, and film processors have been eliminated and specifications related to compression and radiation output are being treated as performance standards under the quality assurance section of the regulations. Similarly, performance outcome aspects of the requirements for alignment have been moved to the quality assurance section. Finally, requirements related to system resolution were eliminated as duplicating performance standards already in the quality assurance section, and the requirements related to the examination of disabled patients were eliminated in part because of a lack of consensus about the need for such requirements.

In an effort to reduce costs, FDA is phasing in the equipment requirements, with some becoming effective the same time (18 months) as the rest of the regulations and others within 5 years. However, based on the desire not to impede technological advances, the uncertainty in estimating needs further in the future, and an assessment of the associated costs, the agency has eliminated the proposed 10-year phase-in requirements and some of the 5-year phase-in requirements. The agency intends to reassess the need for the deleted requirements at a future time.

3. Recordkeeping and Reporting Requirements

The recordkeeping and reporting requirements of § 900.12(c) are intended to: (1) Ensure that all patients and their referring physicians receive timely and adequate notification of the results of examinations, and (2) assist in diagnosis by ensuring that records of past examinations, including the original mammograms, are available when needed for comparison with the images produced during new examinations.

With respect to patient notification of examination results, the final rule codified this essential reporting requirement as a performance outcome standard. The proposed rule would have required the facilities to have a system to ensure that all patients received written notification of their examination results, and further specified what should be included in that notification. The final rule requires that each facility have a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. Thus, the focus is placed on the desired performance outcome, the notification of the patient in a timely manner, and not on the method or specific conduit of the notification. Under the final rule, the facility has the flexibility to use the method of notification that is most effective in its situation and to convey the information to the patient that it deems to be most important. In the part of the preamble discussing this provision, FDA continues to endorse the use of written notification as the most reliable way to guarantee that each patient is notified of results and that any necessary followup will occur and recommends that facilities follow the AHCPR guidelines on direct written notification to all patients. The agency also describes other methods that may achieve the desired outcome equally well in specific situations.

With respect to providing patients with original mammograms upon request, the final rule was modified to make it clear that the original mammograms must be made available to other medical facilities, at the patient's request, whether the transfer is permanent or temporary. It is expected that this change will end the difficulties in obtaining previous original mammograms for comparison with new mammograms (an essential aid to diagnosis) that many patients have experienced under the interim regulations.

4. Quality Assurance

The goal of the quality assurance requirements of § 900.12(d), (e), and (f) are to ensure that equipment and personnel continue to perform at adequate levels. Section 900(d) defines staff responsibilities and recordkeeping requirements for the quality assurance program, § 900.12(e) establishes equipment QC requirements, and § 900.12(f) outlines the requirements for mammography medical outcome audits.

The proposed equipment QC requirements represented a major transition towards performance outcome standards. The interim regulations had referenced the ACR quality assurance manuals and thus specified not only the performance outcomes to be achieved but the test procedures to be followed. The proposed rule was intended to establish the desired performance outcomes and the required frequency of testing at levels nearly identical to those in the interim regulations, but sought to give the mammography facilities some

flexibility in the testing procedures to be used.

The final rule leaves the testing frequencies and the performance outcomes largely unchanged from the proposal, with the exception that standards have been added for radiation output, alignment, and compression, parameters previously considered under the equipment specifications. The provisions related to retesting after equipment failure and taking equipment out-of-service until problems are solved have also been modified to give the facility more flexibility in determining when performance is compromised sufficiently to warrant such actions.

5. Medical Outcomes Audit

A comprehensive mammography medical outcomes audit program can ensure that a facility is providing its patients with accurate mammography examinations and followup care and has the potential to provide the basis for performance outcome standards. However, the public comments made it clear that more research is needed before the state-of-the-art will be sufficiently advanced to support regulatory performance outcome requirements based on audits. FDA did move a step beyond the interim requirement that each facility have a system for reviewing outcome data by codifying requirements related to the analysis of the data collected.

6. Consumer Complaint Mechanism

Under the interim regulations, accreditation bodies have developed mechanisms for addressing consumer complaints about the quality of mammography services received. Requirements for such mechanisms have been continued in § 900.4(g) of the final regulations. FDA recognized, however, that consumer complaints usually can be addressed most effectively at the facility level. For this reason, FDA proposed to require each facility to develop a system for collecting and resolving consumer complaints, with special emphasis placed on the resolution of serious complaints. This requirement has been codified with little change in § 900.12(h). The accreditation body and FDA retain the responsibility for addressing complaints that cannot be resolved at the facility level.

7. Alternative Requirements

The alternative requirements in § 900.18 provide a mechanism for implementing advances in mammography that meet quality standards more rapidly than would be possible through amending the regulations. This mechanism will be used only when the potential public health benefits justify such actions.

This section was incorporated into the proposed rule from the interim regulations with little change. Before codification in the final rule, the section was modified to give the agency the authority to allow an approved alternative to be used by entities other than the entity that applied for approval. This change was made in response to concerns that it would be an unnecessary duplication of effort for the agency and for the applicants if multiple applications were required for the approval of the same advance in mammography.

8. Performance Outcomes

FDA's proposed rule invited comments on the possibility of taking a performance outcomes approach to mammography quality standards. Suggestions and comments on possible performance outcome indicators were also invited. As discussed in more detail elsewhere in this document, the consensus of the public comments was that while the performance outcome concept was attractive in theory, much additional research will be needed before a performance outcome system to ensure mammography quality can be issued. The agency agrees with this consensus but also believes that it is possible to start moving in that direction in certain areas as noted in the previous discussion.

III. Provisions of the Final Rule

The proposed regulations that published in the **Federal Register** of April 3, 1996, consisted of five separate documents. The first, ''Quality Mammography Standards; General Preamble and Proposed Alternative Approaches'' (61 FR 14856 (Docket No. 95N–0192)): (1) Surveyed the history of efforts to implement the MQSA; (2) summarized FDA's analysis of the environmental, economic, and paperwork impacts of the final regulations; and (3) set out the agency's proposed ''scope'' and ''definitions'' sections (§§ 900.1 and 900.2). In that document, the agency also invited public comments on the concept of performance-based outcomes regulations and the feasibility of recasting the proposed design and process requirements into performance-based outcomes requirements.

The second, ''Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements'' (61 FR 14870 (Docket No. 93N–0351)), proposed regulations covering a variety of areas, including: (1) Applicability (§ 900.10); (2) requirements for certification (§ 900.11); (3) procedures for suspension or revocation of accreditation; (4) accreditation body approval; (5) facility certificates (§§ 900.13 and 900.14); (6) the process for appealing agency decisions (§ 900.15); and (7) an alternative requirement process (§ 900.18). Some aspects of the facility standards were also covered. These included medical records and recordkeeping (§ 900.12(c)); general quality assurance requirements (§ 900.12(d)); mammography medical outcome audits (§ 900.12(f)); mammography of examinees with breast implants (§ 900.12(g)); the consumer complaint process (§ 900.12(h)); and additional clinical image review and patient notification (§ 900.12(I)).

The third, ''Proposed Requirements for Accreditation Bodies of Mammography Facilities'' (61 FR 14884 (Docket No. 95N–0192)), covered the approval, responsibilities, and withdrawal of approval of accreditation bodies (§§ 900.3 to 900.7).

The fourth, ''Quality Standards and Certification Requirements for Mammography Facilities; Personnel Requirements'' (61 FR 14898 (Docket No. 95N–0215)), proposed standards to be met by interpreting physicians (§ 900.12(a)(1)), radiologic technologists (§ 900.12(a)(2)), and medical physicists (§ 900.12(a)(3)) working in mammography facilities.

The fifth, ''Proposed Quality Standards for Mammography Equipment Quality Assurance'' (61 FR 14908 (Docket No. 95N–0195)), proposed equipment specifications (§ 900.12(b)) and requirements for the equipment quality assurance program (§ 900.12(e)).

The proposed regulations were published in these five segments to facilitate review and make it easier for members of the public to focus on the sections of most interest to them. Because the final regulations are being issued as a single document, the comments received in response to the proposed regulations are addressed as part of this single preamble rather than in separate documents relating to each of the five proposal documents. General comments are treated first, followed by a discussion of the public response to the concept of performance outcome requirements and their feasibility. Then comments on the individual components of the final regulations are discussed in the order that each component appears in the final regulations.

Finally, the comments on the FDA's analyses of impact are discussed in sections V of this document, and section VI covers the Paperwork Reduction Act of 1995 provisions. Citations for individual provisions of the regulations

generally have remained the same; the preamble clearly notes any instance in which a provision has been codified under a new citation.

Each of the five proposed regulations was preceded by a preamble containing a wide range of information intended as background and information for the final regulations. Comments that the agency received relating to preamble discussions have been addressed either with the general comments or with the specific regulation sections to which they are most closely related.

A. General Comments

Many comments received on the proposed regulations raised issues or concerns that were broader in scope than any specific provision. These more general comments are responded to first, before turning to the more specific comments.

1. The Overall Value of the Quality Standards

(Comment 1). A number of the comments stated opposing positions on the overall value of the quality standards established by these regulations. Seventeen comments supported the quality standards with only minor modifications, noting that they would strengthen radiology practices and enhance the quality of mammography. Twenty-six comments, on the other hand, opposed the quality standards in their entirety. Reasons given included concern about costs and the resultant impact on access, opposition to the regulation of medicine, a characterization of the standards as unnecessary micro-management, belief that more stringent standards were unnecessary or ineffective in improving quality, and an opposition to ''international'' requirements for mammography practice.

The agency recognizes the need to balance the benefits to be achieved from improved quality of mammography with the cost of those improvements and the impact such cost might have on access to mammography. Congress addressed the concern with that balance in drafting the MQSA and has guided the agency in its efforts to implement the statute. An independent evaluation of the program performed by GAO determined that the interim regulations had a positive effect on the quality of mammography without a serious adverse impact on access (Ref. 2). Although, as previously mentioned, a number of facilities did close for various reasons, service from another provider was generally available within 25 miles. Newly established facilities have continued to be certified, further mitigating any impact on access. Based upon its experience with the interim regulations and advice from NMQAAC members, FDA believes that the proposed regulations will achieve further improvements in quality at a cost that will not impact access significantly. The public comments on the proposal led to a further refinement of the regulations, including removal of requirements when the comments persuaded the agency that the requirement was not essential. These changes, and the associated reduction in cost, should provide an even more favorable ratio of benefit to cost.

In answer to concerns about micro-management, many of the specific provisions added in the final regulations reflect practices and policies that were developed under the interim regulations. These policies were developed in response to requests from mammography facilities for information on how to meet the requirements of interim regulations and are already being followed by most facilities. Incorporating these policies into the final regulations gave interested parties the opportunity to comment on them. In response to the comments, requirements have been refined to achieve the most favorable balance between benefit and cost.

Finally, FDA notes that the system for ensuring quality mammography established by the MQSA and these regulations is unique to the United States and is not a duplicate of, or related to any international requirements or systems established in any other country.

(Comment 2). Two comments, while apparently not in total opposition to the regulations, did express their authors' opinions that the personnel and recordkeeping and reporting requirements went ''far beyond FDA's medical device mandate.''

FDA notes that the authors of these comments have overlooked the fact that these regulations are issued under the MQSA, which amended the Public Health Service Act, not under the Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act (the act). The MQSA specifically requires the agency to develop standards for personnel qualifications and for reporting and recordkeeping (42 U.S.C. 263b(f)).

(Comment 3). Several comments, while expressing varying degrees of support or opposition to the requirements, asked why mammography has been singled out for such attention. Some suggested that other diseases were as serious or more serious than breast cancer, while one comment pointed out that the radiation levels in mammography are quite low.

Although a case might be made for developing similar programs for diagnosis of other diseases, Congress decided that mammography should be the subject of this legislation. Congress found the evidence sufficiently convincing that breast cancer was a significant public health risk that could be reduced by improved mammography and, furthermore, that the performance of mammography nationwide was in need of improvement. Congress responded with the MQSA, and FDA is carrying out the mandate of that statute. FDA agrees with the comment that observed that the radiation levels in mammography are much lower than they were 20 years ago (largely as a result of a cooperative government, industry, and facility effort) and lower than those used in many other examinations. However, the primary concerns addressed by the MQSA are not radiation levels but poor image quality and interpretation.

(Comment 4). One comment criticized the proposed regulations for not sufficiently recognizing local facility condition variations, indicating that standards appropriate for some facilities might be unduly burdensome to others. In contrast, another comment strongly supported the application of uniform standards in both rural and nonrural areas. It stated that this would ensure that women in rural areas received optimum care.

FDA believes that all women are entitled to high quality mammography, no matter where they live, and so has not issued lesser standards for rural areas or any other subset of facilities. The agency further notes that the fear that applying uniform minimum standards would cause an undue burden to rural facilities is refuted by the experience of Michigan, where such uniform standards have been applied to all facilities in that State since 1989 (Ref. 3), and by experience under the Federal interim regulations.

(Comment 5). Ten comments stated that ''the regulations and the complaint process may confuse the public by bringing up more issues than it is necessary for them to be concerned with and confusing the role of mammography in the overall diagnosis and treatment of breast cancer.''

The purpose of the MQSA is to ensure adequate quality mammography for all patients. If this purpose is achieved, members of the public will be able to receive mammography at any facility in the country without having to be concerned about the issues covered by the regulations. Thus, public

''confusion'' should decrease rather than increase as a result of these regulations. Without additional details, FDA cannot respond further to the concern expressed by the comments about confusion over the role of mammography. The agency assumes, however, that any such problems could be handled through educational efforts.

2. Division of Responsibility

The MQSA established a system of checks and balances involving the interaction of several groups, including FDA, the States, and the accreditation bodies. A number of comments expressed varied concerns about the division of responsibility established by the proposal.

(Comment 6). One of these comments stated that oversight and review of mammography facilities is the backbone of the MQSA program. Along with a second comment, it noted that FDA, not the accreditation bodies, should be responsible for enforcement actions.

FDA agrees with this comment and believes that the final regulations clearly give the agency the primary responsibility for this function. However, the regulations also establish that the accreditation bodies have responsibility for notifying FDA when they have information that enforcement actions may be needed and for assisting in related investigations.

(Comment 7). Two comments stated that the regulations should allow States to eliminate overlapping functions if they are serving as both accreditation bodies and inspection agencies. A third comment stated that more leeway should be given to State accreditation bodies, which have enforcement capability, than to non-State accreditation bodies. A fourth comment recommended eliminating some unspecified requirements if a State agency holds both accreditation body status and an inspection contract.

FDA agrees that states that are both accreditation bodies and inspection agencies may be able to combine some functions and, in fact, some steps have been taken under the interim regulations. However, it is important that all facilities meet the same accreditation and inspection requirements. The agency believes it is unlikely that any requirements pertaining to accreditation bodies or facility standards can be eliminated entirely in States with dual status. The need for consistency also explains why FDA disagrees with the third comment; State accreditation bodies may have enforcement capability under State law but this capability could vary greatly from State to State. As the author of the fourth comment did not give specific examples of requirements to be eliminated, the agency cannot respond further to that comment.

(Comment 8). Three comments suggested that to reduce costs there should be one comprehensive system to accomplish all the necessary accreditations within any State that already has in place a mechanism for accreditation of facilities and licensure of technologists. The comment observed that the Federal Government would have to subsidize States for this work.

States are permitted under the MQSA to apply to become FDA-approved accreditation bodies (42 U.S.C. 263b(e)(1)(A)) and three States have already done so. FDA disagrees that the agency should merely substitute existing State accreditation and licensing systems for the MQSA standards. States may have widely different accreditation standards under their State laws, while the drafters of the MQSA envisioned a system that would establish uniform, minimum national standards for all mammography facilities. The MQSA, however, expressly permits State laws relating to mammography that are more stringent to be issued or to remain in effect (42 U.S.C. 263b(m)). Furthermore, the drafters of the MQSA did not provide for Federal subsidies for any accreditation body; the statute instead expects those bodies to be supported by their accreditation fees.

(Comment 9). One comment recommended the adoption of only one set of rules, whether it be established by the State, ACR, or FDA, to govern mammography, while a second recommended combining FDA and ACR into one ''accreditation body'' to reduce the problems of complying with the requirements of both. Another comment objected to FDA permitting States to pass additional laws and regulations governing mammography in addition to the MQSA requirements. It stated that this would prevent the establishment of consistent nationwide standards. Another comment objected to the absence of a preemption clause in the MQSA, fearing that would lead to overlapping State and Federal regulations.

FDA notes that, within the limits of the authority given to it by the MQSA, it has worked towards the goal of one set of rules. The MQSA authorizes FDA to establish one set of uniform baseline standards and to require that all approved accreditation bodies, including ACR, enforce standards substantially the same as these. The agency has taken this step. FDA also notes that the Health Care Financing Administration (HCFA) has agreed to accept the MQSA regulations and inspections in lieu of the regulations and inspection system it had previously established to govern mammography under Medicare, thus reducing duplication. The MQSA also requires State standards to be at least as rigorous as those of FDA. However, as noted by the comment that there is no preemption clause in the statute, the MQSA explicitly gives States authority to develop additional regulations governing mammography, as long as they are more stringent than the MQSA requirements (42 U.S.C. 263b(m)). The intention of the MQSA was to create a uniform nationwide baseline quality level for mammography, while permitting individual States to strive for higher levels. Only Congress can make changes in this approach, not FDA.

(Comment 10). One comment expressed concern that the nature of the State/Federal agency relationship may be an impediment to ensuring quality mammography. The author cited two GAO reports criticizing the oversight of State programs by other Federal agencies. FDA notes that the agency has a long history of Federal-State cooperative programs, especially with respect to educational efforts and inspections in the medical X-ray area, and that, in general, these programs have been very successful. As the agency moves into new areas of cooperation with the States, it is studying the experiences of other Federal agencies in an effort to avoid any difficulties they may have experienced in working with the States.

(Comment 11). One comment recommended that FDA's mammography oversight be limited to equipment standards and requiring that facilities be accredited and that oversight of the accreditation bodies by FDA be reduced. Another comment suggested limiting FDA's oversight only to ensuring that facilities are accredited properly by the accreditation bodies.

FDA notes that the MQSA gives FDA far greater responsibilities than either of these comments would permit and the regulations are intended to help the agency continue to fulfill its obligations under the statute.

(Comment 12). Similarly, two comments made the general recommendation that the accreditation bodies be given expanded responsibilities. Other comments had more specific opinions, for or against, certain expanded responsibilities for the accreditation bodies. Two comments stated that the accreditation body should be the sole evaluator of the annual physicist survey, with the MQSA inspector merely accepting the

accreditation body's review. A third comment argued, however, that valuable information would be lost if the inspector accepted the accreditation body's review of the report and a fourth comment agreed that, if duplicate review is not cost effective, it would be more appropriate for the inspector to review the survey than the accreditation bodies. Three comments stated that the accreditation body should be responsible for tracking all personnel requirements for a facility, while a fourth would give the accreditation body responsibility for review of continuing education credentials. Similarly, a fifth comment would limit the inspections to review of the physicist survey and the QC program, plus taking a phantom image, leaving oversight of the other areas to some unspecified group. Another comment on the appropriate division of responsibilities stated that FDA should not have inspectors performing tests that have already been conducted by medical physicists and technologists.

FDA has utilized, and plans to continue utilizing, the expertise of the accreditation bodies to the maximum extent permitted by the statute. The agency also realizes that the checks and balances system required by the MQSA leads to some duplication of effort between the accreditation body and the inspectors or the inspectors and the medical physicists. However, one of the weaknesses of the pre-MQSA oversight system for mammography was the lack of an onsite evaluation of the facility programs by an individual independent of the facility. Experience with the interim regulations has demonstrated the value of such inspections; the great majority of findings were for situations that had not been identified by the accreditation bodies or the medical physicists. On the other hand, there is no doubt that the accreditation bodies and the medical physicists have prompted the correction of many problems before the inspections took place. These activities and results demonstrate the strength of the program. The agency believes that the drafters of the MQSA were correct in concluding that a checks and balances system, involving two or more entities, would be more effective in ensuring the continued maintenance of high quality mammography than the use of only one entity or the other.

(Comment 13). Two comments recommended that the information obtained by either the accreditation bodies or the inspectors should be shared with the other groups to cut down on unnecessary duplication of information collection activities or submission requirements for the facilities.

FDA agrees with this comment and the statute itself supports elimination of collection of duplicative information (42 U.S.C. 263b(d)). Under the interim regulations, the agency has been working with the accreditation bodies on the electronic exchange of information and will continue to do so under the final regulations.

3. Inspections and Inspectors

A number of the more general comments addressed various aspects of the annual and audit inspections.

(Comment 14). Two comments suggested that the FDA facility inspections should be reduced or eliminated in order to reduce the costs to facilities or because annual inspections are not needed. A third comment urged that inspection frequencies not be included in regulations.

Annual onsite inspections are required by the MQSA (42 U.S.C. 263b(g)); that requirement cannot be changed by the agency, even if it is not in regulations. The agency is evaluating alternative ways for conducting inspections in the hopes of reducing costs for facilities.

(Comment 15). One comment stated that it was inconsistent for FDA to inspect every facility every year while the accreditation bodies are required to visit a much smaller number of facilities annually. The comment further maintained that the MQSA inspections duplicated other inspections.

The FDA inspections and the accreditation body visits serve two different purposes. The MQSA inspections, which are required to be annual, are intended to ensure that all facilities continue to meet the MQSA quality standards. The MQSA requirement that accreditation bodies visit a sample of their facilities each year serves an additional purpose, which is to have accreditation bodies evaluate their own performance and the effectiveness of their accreditation procedures (42 U.S.C. 263b(e)(4)(A)). In addition, accreditation bodies, at FDA's request or on their own authority, will visit facilities that have been identified as potential problem facilities for the purpose of identifying the problems and assisting the facility in correcting them.

(Comment 16). Eleven comments suggested that ACR be designated as the inspection organization in New Mexico.

FDA is unable to consider this suggestion because the MQSA specifically limits inspectors to Federal or State personnel (42 U.S.C. 263b(g)).

(Comment 17). Three comments were concerned about the standards for FDA inspectors and two more urged additional training for inspectors. Another comment was very complimentary of inspectors in Iowa. Fifteen other comments expressed various concerns about the inspection fees.

These issues are beyond the scope of these regulations, which cover requirements for accreditation bodies and quality standards for facilities only. FDA has referred these comments directly to the components of FDA that deal with inspector training and inspection fees.

4. Public Participation in the Process

(Comment 18). Three comments expressed concern that not enough public input has been obtained during the regulation development process and suggested that facilities, manufacturers, and personnel should be interviewed.

The NMQAAC is composed of representatives of the mammography community and consumer groups and has been a valuable conduit of public input during the eight meetings at which it discussed the final regulations before and after they were published. Furthermore, each meeting included an open session during which members of the public could make statements and many individuals took advantage of these opportunities. Finally, there were three public comment periods during the development of the regulations. The first of these was for comments on the interim regulations. A great deal of information was gained for use in the development of the final regulations from comments received at this time. The second was after preliminary drafts of the equipment and medical physicist standards were released and again valuable information was obtained from the public. The third opportunity to comment was after the publication of the proposed regulations and, as previously discussed, approximately 1,900 responses covering every area of the regulations were received from a broad spectrum of organizations and individuals. FDA believes that the public has had ample opportunity to participate in the regulation development and reiterates that this public participation had a significant impact on its final form.

(Comment 19). Another comment recommended prohibiting NMQAAC members from also serving on advisory boards or as consultants to accreditation bodies in order to avoid the possibility that a limited number of people will have disproportionate influence on the program.

In forming the NMQAAC and its other advisory panels, FDA has complied with the Federal Advisory Committee

Act (the FACA), the agency's implementing regulations at 21 CFR part 14, and the MQSA. The FACA requires each advisory committee to be fairly balanced in terms of the points of view represented and the MQSA expressly describes the constituent segments of the affected community that are to have representatives on the Committee (42 U.S.C. 263b(n)). Because advisory committees enlist the expertise of outside consultants to advise the government, it is frequently the case that well-qualified members are nationally recognized experts who are also called upon to play leadership and consultant roles for private groups. The agency does not prohibit such individuals from providing government service if the agency determines that such participation is in the best interest of the government because the need for such participation outweighs the potential conflict of interest. The existence of any potential conflicts are stated for the public record at the beginning of each advisory committee meeting and panel members who have conflicts on particular matters may be prohibited from voting on those issues.

5. Double Reading

In the preamble to the proposed rule (61 FR 14870 at 14876, April 13, 1996), FDA noted that one of the comments received on the interim regulations suggested that all mammograms be read a second time by a second qualified physician. The author of the comment stated that this would avoid unnecessary surgery and emotional stress that can arise from a false positive reading and the lack of appropriate followup in the case of a false negative reading. The agency did not include such a requirement in the final regulations but asked for further comments on the issue.

(Comment 20). Twenty four comments argued against a double reading requirement, basing their opposition on such reasons as the cost, the difficulty of achieving double reading, the delays in reporting to the referring physician leading to patient dissatisfaction, and the belief that it would be a meaningless exercise and only a few abnormalities would be picked up. Comments asserted that the burden would be especially great in rural and isolated areas and could reduce access to mammography services. Twelve of these comments also questioned where the notion of double reading would lead; and would there be a press for triple and quadruple reading. One of these comments urged that the focus be on training for the first reader so that double reading is not necessary. On the other hand, three comments offered strong support for the use of double reading and one comment went so far as to say that all films should be double read in order to eliminate the trauma and psychological stress associated with false positives. One comment suggested requiring double reading for all positive mammograms.

FDA has determined not to include a double reading requirement in the final regulations. Double or multi-reading (as it is now called by the agency for reasons discussed with the comments on § 900.2) is referenced in the regulations only as a way for interpreting physicians at low-workload facilities to meet their continuing experience requirements. Although this practice is not being required, the regulations do not preclude double reading. FDA encourages facilities that believe their services will benefit from such procedures to establish the practice as a quality assurance measure.

6. The Organization of the Final Regulation

(Comment 21). A number of comments were extremely critical of the organization of the proposal, finding it difficult to read and to see the relationship between the five separate divisions, each with its own docket number, preamble, and regulatory content. Several of these comments stated that information on the organization of the proposal should have been provided, while others made suggestions for reorganization of the material when it was published as a final regulation.

FDA adopted the method of presentation in the preamble of the proposals in an effort to make it easier for readers to focus on the provisions that were of most concern to them. Readers interested primarily in the personnel requirements, for example, would need consider only the fourth division, while those whose concerns were primarily equipment-related, could focus on the last division. Although the summary section of each of the five divisions identified the material being provided in the other divisions, it is clear from the comments that further explanation would have been helpful.

The final regulations are being published in a single document. This single document follows the usual **Federal Register** format of a preamble and a regulation section. The regulation section combines the regulations from the five divisions of the proposal in numerical order from §§ 900.1 to 900.18, with some sections reserved for later use. For the convenience of the reader, a table of contents is provided.

7. Other Comments

(Comment 22). Additional comments were received on widely varied topics. One comment noted that mammography services are provided for men and women, and suggested that any mention of ''women'' should be replaced by ''women and men.''

FDA agrees that men are also consumers of mammography services. However, because breast disease and diagnosis overwhelmingly affects women, that word seems more appropriate. However, the agency notes that in the regulations themselves and at many places in the preamble, the term ''patient'' is used. FDA believes this terminology addresses the comment's concern.

(Comment 23). Four comments took issue with statements in the preamble to the proposed regulations concerning the expected benefits from improved mammography and the number of expected deaths from breast cancer.

FDA is aware that several aspects of these issues are unsettled and that authorities may draw different conclusions from the same data. However, the authors of the comments did not appear to challenge the statute's underlying assumption that mammography can be valuable in combating a serious public health threat, even though they might disagree on the quantification of that value.

(Comment 24). Three comments urged FDA to delay the final regulations until a study of the impact of the interim regulations could be conducted to determine what changes were needed or even if the MQSA itself were necessary. Congress intended that final regulations be in place before October 1, 1994, so that the benefits of improved mammography could be realized as soon as possible. Recognizing the magnitude of the task, Congress provided FDA with interim rule authority that would require regulations to be issued in two steps. The first step was the interim regulations, which led to significant benefits. Neither Congress nor the agency believes that any further delay in completing the second stage and achieving the increased benefits of the final regulations can be justified. The agency notes, however, that facilities have been operating under the interim rules for over 2½ years and inspections against the interim regulations have been occurring for over 2 years. This experience with the interim regulations and the problem areas that were identified have contributed significantly to the provisions of the final regulations.

(Comment 25). One comment asked the agency to clarify who makes the decisions about the MQSA regulations.

FDA assumes that the author is referring to decisions about interpretations of the regulations, including decisions about the adequacy of particular training programs for mammography personnel. These decisions are made primarily in FDA's DMQRP (address above).

(Comment 26). Four comments expressed concern that the more unique mammography regulations become, the greater the likelihood that generalists will be forced out of the field.

Many of the personnel requirements, such as licensing and certification, are general requirements of the medical field. In addition, Congress determined, and FDA agrees, that mammography is a sufficiently unique and difficult examination to require specialized training and experience in the production and interpretation of the images and in the testing and maintenance of the equipment. However, it does not require a full-time mammography practice to meet the experience requirements specific to mammography and the specific training requirements are only a fraction of what is required for other purposes, such as completing a residency program or maintaining certification from the American Registry of Radiologic Technologists (ARRT). Thus, individuals will be able to meet the MQSA requirements without limiting their activities to mammography and so there will still be room for generalists.

(Comment 27). A number of comments expressed a variety of concerns about matters outside the scope of these regulations or beyond FDA's authority. These concerns included: (1) Questions about the appropriate frequency for screening mammography and the levels of Medicare reimbursement; (2) a recommendation that a State advisory board be created to monitor each State's mammography program; and (3) a concern about the perceived domination of medicine by big business. Because these comments are beyond the scope of these regulations, these comments will not be addressed.

B. Alternative Approaches to Quality Mammography

Executive Order 12866 requires Federal agencies to identify and assess alternative forms of regulation and, where feasible, specify performance objectives (performance or outcome-based standards), rather than specifying the behavior and manner of compliance that regulated entities must adopt (design-specification standards). In addition, Executive Order 12866 requires each agency to avoid regulations that duplicate other regulations. In response to this Executive Order, under Docket No. 95N–0192, in the **Federal Register** of April 3, 1996 (61 FR 14856 at 14859) FDA invited comments on the feasibility of developing performance-based regulations. Although the agency did not propose specific regulations in this area, it did suggest several possible performance measures for mammography and requested comments on their value and feasibility. The agency also invited the public to suggest other performance outcomes that might provide a basis for performance-based standards. FDA also invited comments on suggestions for other possible alternative approaches. While the standards that were proposed were not designed to be performance-based standards, there are elements of performance requirements throughout the final regulations. For example, most of the QC standards in the final regulations are performance based. The discussion in the proposal was to consider extending such performance criteria to areas not now covered by that type of requirement and to make the performance standards that had been proposed more general, thereby possibly reducing the burden on facilities.

1. General Comments

(Comment 28). Sixteen comments asserted that the goal of the quality mammography efforts by FDA should be to reduce burdens on the medical community by not requesting comments and review of additional regulations. Some of the comments stated that ACR should be the entity designated to define performance standards and that compliance with such standards should be voluntary. Five additional comments suggested that it was more appropriate for ACR and ARRT to oversee and govern mammography quality.

FDA notes that these comments are in conflict with the statutory provisions of the MQSA (42 U.S.C. 263b)), which mandate that the government have authority and responsibility to establish standards for the performance of quality mammography. However, in carrying out that mandate, FDA has solicited and considered comments from the members of the mammography community, including comments from ACR, ARRT, and members of NMQAAC.

(Comment 29). Several individual comments addressed the general issue of alternative approaches for quality mammography. One comment favored FDA's role in establishing and strengthening standards for quality mammography. Another suggested that FDA work with volunteers who have an interest in alternative compliance options in order to learn what is best.

Although FDA intends to continue to gather ideas and information from experts in the field, the agency believes that the opportunity for public review and comment on proposed regulations that will affect members of the mammography community is the most equitable approach and will minimize potential problems of ''standardization without representation.''

(Comment 30). Four comments addressed the issue of FDA establishing another set of interim rules, to be in effect while necessary research on performance outcomes-based standards was conducted, or simply going forward with the final regulations as proposed. These comments supported finalizing the proposed regulations and suggested change only if new technologies or alternative compliance options are identified at a later time.

Three comments focused on the cost of changing the regulations and discouraged change to the final regulations if any additional costs were to be borne by the mammography facilities.

FDA is sensitive to the issue of costs associated with the regulations and will keep this issue in mind whenever considering changes to the regulations.

(Comment 31). Two comments expressed concerns that the general aim of alternative approaches to achieve compliance would result in loopholes that would allow facilities *not* performing at acceptable levels to continue to perform substandard mammography.

The agency recognizes the importance of issuing performance standards that do not allow loopholes. As with provisions that specify the manner of compliance facilities must adopt, FDA intends to review performance-based approaches for potential gaps that could defeat efforts to achieve quality mammography.

(Comment 32). One comment stated that the ideas presented in the alternative approaches section are unworkable and were not discussed with the members of NMQAAC.

FDA acknowledges that NMQAAC did not have the opportunity to discuss the alternative approaches material before publication (61 FR 14856). However, NMQAAC members did have the opportunity to review this material and to make comments and recommendations at two meetings after the proposal was published.

Generally, the NMQAAC comments did not support increasing the number of performance-based standards at this time. They pointed out that the

proposed regulations were actually a mix of performance- and specification-based standards. While NMQAAC agreed that increased reliance on performance-based standards might have promise for the future, after further research is done, there are insufficient data at this time to base the entire set of standards on performance criteria.

(Comment 33). One comment stated that the current tests specified in the existing regulations are more thorough and complete than alternative performance approaches that were identified in the preamble to the proposed rules. A similar comment stated that the current tests should be used by all facilities, with the exception of those facilities that might develop improved, innovative strategies or methods. The comment recommended that these facilities apply to FDA for exemptions to use the innovative strategies or alternative methods. FDA notes that a process for accepting and reviewing such applications is provided by § 900.18.

An additional comment expressed support for the intent of Executive Order 12866, but at the same time argued that it is in the best interests of FDA to be more specific in the final rules about those instances where there are multiple methods or procedures to accomplish the same task. The comment further stated that it was unclear how the agency decided whether to use a performance outcome-based or a design-based requirement in a particular situation. A second comment expressed a similar opinion.

FDA notes that the comments on performance outcome-based standards discussed above and in the following pages point out many difficulties at the present time in establishing regulatory requirements to ensure quality mammography that are based totally on performance outcomes. However, the agency believes that in certain areas, for example, quality assurance, performance outcome standards can and should be established. In developing standards in a particular area, the agency first considered whether it was feasible to ensure quality in that area with performance-outcome standards. If it was not possible to issue adequate performance-outcome standards in that area, the agency then turned to design standards. Along those lines, FDA disagrees with the statement in the comment that specific-design standards should always be issued in cases where there are multiple ways of adequately achieving a particular task or goal. On the contrary, the agency believes that performance-outcome standards should be strongly considered in such areas in order to give facilities the flexibility to chose the method of achieving the goal that bests fits its particular circumstances, instead of requiring that all facilities follow the same path.

One other general comment similar to those of NMQAAC, asserted that it was premature to try to identify alternative performance-based approaches due to inadequate research and testing of these alternative methods at this time. Another comment indicated that FDA did not comply with Executive Order 12866 because the agency did not make a real effort to identify alternative approaches. Similarly, one comment argued that the FDA regulations ignored duplication with other regulations, although no examples were given.

FDA notes that it did include a number of possible performance outcomes measures in the proposal. There may be other possibilities of which the agency is unaware, but the fact that no alternatives were suggested by the author of these comments, or in any other comment, suggests that few, if any, other options are currently available. FDA further notes that the attempt to elicit public comment, recommendations, and opinions concerning performance-based standards through the proposal will not end its efforts to identify such alternatives. FDA is unable to respond to the criticism that its efforts duplicate other regulations in the absence of information on where the author of the comment believes this has occurred. However, HCFA has agreed to set aside its regulations in the mammography area and to accept FDA-certified facilities as meeting its requirements for reimbursement under Medicare and Medicaid. This eliminated one possible source of regulation duplication.

FDA strongly supports the use of performance standards, however, it recognizes that additional research is needed in the scientific community before it can support additional regulations based on performance outcomes. FDA encourages continued research in this area, and will actively work to develop performance standards in the future.

2. Performance Standards and Outcomes Measures Suggested in the Proposal

A large number of comments were received on the various performance outcomes measures identified as possible alternatives by FDA. These are reviewed in the following narrative in connection with the identified alternative.

3. Mammography Medical Outcomes Audit

(Comment 34). FDA in the preamble to the proposed rules, FDA suggested that the results of a mammography medical outcomes audit might be used as the basis for a performance-based standard for each mammography facility. A significant number of comments expressed concerns about one particular aspect of the audit, namely, requirements for patient followup that might be necessary to obtain outcomes data. The major issues raised were the cost of such followup and the lack of evidence that feedback about outcomes improves practitioner performance. The authors of the 10 comments believed that individual practitioners would never have sufficient cases to calculate meaningful statistical outcomes.

Concerns were also expressed that there were no protections for the confidentiality of outcomes data and that medical outcomes-based standards could motivate practitioners to avoid challenging or difficult cases. Eleven comments expressed objections to any performance standard that would require mammography facilities and interpreting physicians to collect followup data on films interpreted as negative or to require the calculation of statistics relating to sensitivity, specificity, or minimal cancer detection rates. One comment objected on the basis that requiring the collection of such data would imply that standards were required to force physicians to do the best possible job and that this was necessary because it was the norm for physicians to cheat or be dishonest. One comment expressed the view that use of cancer registries to accumulate data for monitoring outcomes was clumsy and expensive.

A related set of comments directed toward use of the positive predictive value (PPV) statistic as a measure of quality mammography performance was overwhelmingly negative. Nine comments pointed out that there are varying definitions of PPV and that this is not a measure familiar and understandable to the general public. The general consensus was that this statistic was not useful and should not be required to be published outside the physician's practice. Six respondents argued that it was completely unacceptable to use the physician's outcomes data as a measure of performance. Two comments expressed the viewpoint that collection of information about PPV was not appropriate because it was affected by many factors beyond the control of the facility. Three comments vehemently opposed the public disclosure of outcomes data, arguing that there would be a high likelihood of misinterpretation by the public and incentives for

facilities to falsify data. Two comments stated that data collection and review alone would not have any significant influence on radiologists' behavior, and consequently, that collection of statistical data was not worth the effort. Finally, one comment agreed that it would be valuable to find valid process and outcomes measures for mammography but concluded that it would be premature to focus on PPV, which is subject to influence by so many factors external to the radiologist.

In contrast to these negative comments on using the results of the mammography medical outcomes audit as the basis for performance standards, one comment strongly supported the idea of the medical audit as the basis for a performance standard and argued for the publication of such findings in order to ensure that the public had access to information that would allow them to select a reputable institution. Another supportive comment asserted that the agency should develop performance standards for medical outcomes audit statistics, which could then be used to evaluate physician performance. A third respondent urged that medical outcomes could and should be used as more comprehensive measures of competence and compliance. Another comment suggested that standardized values for sensitivity and specificity could support a reduction in personnel requirements for facilities that met the performance standards for these two statistics. One final comment applauded the possibility of change from specification of the manner of compliance to specification of performance objectives.

FDA observes that the majority of the comments received oppose the use of the results of the mammography medical outcomes audit as the basis for performance-based standards, at least at this time. The agency recognizes that the issues of the confidentiality of data collected and the limitations of PPV as an indicator of performance, and the other problems identified in the comments, are concerns that would have to be addressed before the audit could become the basis for performance-based standards. The agency has concluded that it is premature to establish performance standards based upon the mammography medical outcomes audit, primarily because the necessary data to establish such standards and to resolve the concerns expressed in the comments are not yet available.

FDA is aware that the National Cancer Institute's Breast Cancer Surveillance Consortium (NCI BCSC) has been actively engaged in research to understand the full effect of breast cancer screening on cancer outcomes through a collaborative effort with academic and community-based mammography facilities. Through linkages of data from mammography facilities with pathology data on cancer outcomes from population-based cancer registries, outcomes data will be correlated to interpretation. One of the goals of this research is to help establish realistic targets for mammography performance. FDA participates with the NCI BCSC and has staff expertise in the medical outcomes audit area to further assist standards development of outcomes measures. FDA will evaluate results from this research project as well as other projects to determine the best approach to promote improved mammography performance through performance-based outcome measures. FDA anticipates issuing regulations in the future that would have appropriate medical outcomes-based measures.

To this end, facilities are actively encouraged to develop their medical audit programs and pursue outcomes-based measures. Information to assist facilities in conducting and interpreting the mammography medical outcomes audit can be found in the medial literature. In addition, in 1994 the Agency for Health Care Policy and Research published, ''Quality Mammography: Clinical Practice Guidelines.'' This primer has a complete discussion of issues surrounding the medical audit and has references to aid facilities. Meanwhile, the suggestions contained in the comments to FDA's proposed rule supporting the use of the audit as a basis for performance standards will be considered by FDA in further efforts to develop performance-based standards. In addition, FDA specifically invites comments on this issue for future consideration. Please submit comments on this issue to the contact person listed above.

4. Performance-based or Proficiency Testing

With respect to personnel, FDA raised the possibility in the proposal that standards based on successfully passing proficiency tests might be the basis for replacement of design specification standards requiring certain levels of training and experience.

(Comment 35). The general consensus of 34 comments on proficiency testing was that such requirements would be excessive, unnecessary, costly, impractical, and duplicative of examinations already in place, such as those administered by the American Board of Medical Physics, the American Board of Radiology (ABR), and the American Board of Health Physics. Twenty comments criticized the use of performance-based standards in this area because they asserted that such standards are not yet developed to a level where they can substitute for current requirements. Two comments stated that it is better if FDA does not become involved in personnel performance-based standards as part of the MQSA. Rather, continuing medical education (CME) requirements as they currently exist should be satisfactory for this part of the education process. Three respondents indicated that the term ''performance-based testing'' is too vague and could include even such simple things as the radiologist's observation of the technologist performing an examination.

After reviewing these general comments and the specific ones that are discussed later in this document, FDA has concluded that it would be premature to establish general performance standards based on proficiency testing because there is no consensus among experts about what those standards should be or how they should be measured. The topic of proficiency testing for specific professional groups drew a number of responses varying in their level of support for such testing. Specific comments are noted and discussed as follows:

a. *Proficiency testing for radiologists* (Comment 36). Proficiency testing for radiologists drew divergent responses. Three comments urged that FDA, in collaboration with NMQAAC, develop a proficiency test that physicians must pass prior to initiating the practice of mammography interpretation. Four additional comments favored proficiency testing for radiologists, but only as an initial requirement. Thirteen comments indicated unqualified support for proficiency testing for physicians. In contrast, five comments maintained that board certification could replace proficiency testing with intermittent retesting at 5- to 8-year intervals. Such examinations could be handled by the accreditation bodies. Another comment stated that random clinical image review at the time of the MQSA annual inspection could substitute for proficiency testing. Six comments agreed with the basic premise that performance evaluation is important in order to determine accurate standards but that more time is required to determine appropriate testing devices and standards. One comment stated that training and experience requirements for interpreting physicians should be sufficient and there was no need for periodic testing. Similarly, one comment stated that the

medical audit could function as a proficiency test for radiologists. Two comments expressed a total lack of support for proficiency testing, arguing that such testing is time consuming, costly, unnecessary, redundant, and not done in any other area of medicine. One comment stated that periodic proficiency testing is appropriate for nonradiologists reading mammograms but not for trained radiologists. In lieu of proficiency testing, this comment suggested a special certificate as part of designated continuing education courses as a simpler way to establish a measure of proficiency. One final comment stated that proficiency testing would impose undue hardship on the radiologist whose practice is not exclusively devoted to mammography. A total of 79 respondents argued that the cost of proficiency testing would be too high and that the additional expenses would be passed along to consumers.

FDA observes that support for proficiency testing for interpreting physicians is somewhat stronger than for proficiency testing in general, but that the majority of respondents still opposed the idea. Given the diversity of response to the possible use of proficiency testing for radiologists, and the fact that no existing tests were identified in the comments, FDA has concluded that it is not in the interest of quality mammography to mandate such testing at this time. The agency believes that proficiency testing for physicians, if feasible at all, would have to undergo further development before it could be the basis of a performance standard.

b. *Proficiency testing for technologists* (Comment 37). Three respondents stated that proficiency testing every 3 to 5 years would be beneficial to technologists. One additional comment concurred, but recommended testing every 2 years. Overall, however, there was a general lack of support in the comments for proficiency testing of technologists.

Sixty-one comments stated that such testing for technologists cannot be conducted objectively and also indicated that the final requirements were adequate to ensure the qualifications of technologists. Ten additional comments claimed that proficiency testing for technologists is impractical because of the lack of established criteria and the absence of an appropriate body to administer such tests. Three respondents argued that the medical audit served as a proxy proficiency test for technologists. Twenty comments stated that the proposed continuing education requirements were sufficient and it was not necessary to administer recertification examinations. Thirty-seven comments argued that technologist proficiency testing was redundant with the other initial and continuing education requirements.

One comment stated that at one time, the ARRT had considered adding a practical exam to its evaluation of mammography competency but deferred doing so until credible analyses would establish that such an examination would result in improved quality of performance. Four comments stated that proficiency testing for technologists would drive technologists away from the field of mammography. One comment expressed the view that annual testing was unnecessary because mammography does not change that rapidly. Another comment stated that a requirement for proficiency testing for technologists would have a negative impact on the availability of mammography in rural and mountainous regions. An additional respondent argued that the annual requirements for technologists are already excessive and the addition of competency or proficiency testing would simply raise costs or close mammography facilities. Four other comments expressed similar sentiments, stating that technologists already have to meet sufficient requirements, and the addition of proficiency testing would be excessive. Concerns also were raised about who would administer such testing and the method of payment. One comment urged that, if proficiency testing became a requirement for recertification, it should be offered at no cost to the technologist.

One comment argued that incompetent technologists could pass a proficiency test and further stated that proficiency testing was a measure of test-taking skills, not of mammographic competency. Two comments expressed the point of view that proficiency testing is useless and insulting. Several comments stated that recertification, if required in addition to continuing education, is redundant, time-consuming, and costly. These comments asserted that retesting is valuable only in instances of significant changes in the mammography modality. One comment pointed out that the ARDMS (a sonographer's organization not further identified) had tried to offer a practical examination, but abandoned the project because it proved too costly. The remaining comments were all generally opposed to proficiency testing for technologists. One comment suggested that a better way to evaluate technologists would be to require performance at a seminar that would assess their clinical competence. Another comment concurred with this viewpoint, saying that a written exam cannot measure competence in a hands-on field such as mammography. Finally, one comment argued that further examination is not necessary if the technologist remains active in the field of mammography and maintains proper licensure.

The agency is persuaded that regulations requiring such testing would be premature. FDA believes some of the objections raised, as with the objections to radiologist testing, can be addressed and overcome; e.g., to the extent comments argued that proficiency testing was duplicative of current training, education, and experience requirements, FDA could consider eliminating some of those requirements. However, the agency agrees with the general consensus expressed by the comments and concludes that proficiency testing for technologists currently cannot provide the basis for a performance standard.

c. *Proficiency testing for physicists* (Comment 38). The agency received 17 comments about this topic. Of the 17, 3 were in favor of proficiency testing for physicists, with 1 additional comment asserting that is would be possible to conduct such a test, but only at great cost. Other comments stated that proficiency testing for physicists was simply a bad idea. Two comments argued that the proposed standards of a written examination and a practical survey test were sufficient proficiency measures for physicists. Two comments stated that a doctorate in physical science and board certification in an appropriate medical physics sub-specialty provided a better assurance of professional integrity than written and practical examinations. Another comment suggested that it would be more appropriate for physicists' accreditation bodies to administer such tests because FDA lacked the necessary experience and knowledge in this area. One comment expressed concern about the possibility of computer errors if the examinations relied on computer programs for test administration and scoring. One comment recommended that the idea of a qualifying examination for physicists should be further explored, especially because the proposed regulations do not adequately address the issue of how detailed an annual survey should be.

One comment asked whether a performance-based standard would help physicists working at small institutions to meet the training requirements. Although it is possible that proficiency

testing could alleviate difficulties involving access to training for some physicists, FDA notes that it is not possible to determine whether such an approach would permit these physicists to qualify until such a time as the form and nature of a possible proficiency test is better known.

As with proficiency testing for interpreting physicians and radiologic technologists, the comments have persuaded FDA that it would be premature to require such testing for physicists as the basis of a performance standard. The agency, however, will continue to explore the feasibility of such testing for radiologists, technologists, and physicists.

5. Mammography Equipment and QC

The preamble to the proposals (61 FR 14860) suggested possible performance-based substitutes for equipment specification and QC testing in the proposed rule. One general comment recommended that FDA retain the existing QC tests as proposed to ensure adequate mammography equipment and QC. The author was of the opinion that one or two performance-based criteria would not be adequate to serve as QC measures.

a. *Phantom image testing*

FDA suggested that one possibility was that a more sophisticated phantom might be developed for use in a single QC test that would provide the same information on equipment performance as some or all of the separate tests and specifications. A performance-based standard predicated on test results using this phantom and falling within defined limits might provide the same assurance of image quality as a number of the design specifications and, therefore, could replace the design specifications in the regulations.

(Comment 39). One comment stated that it was possible to develop a single system test with an alternative phantom. The comment stated that one distinct advantage of a single system test would be to replace the present daily processor quality control (QC) test with sensitometry based on the actual light emission of the radiographic screen and at the same time check the performance of the rest of the imaging system. The comment stated that the final regulations should allow facilities and accreditation bodies to work together to adopt a suitable phantom to be used as a daily total system test. The majority of the comments received, however, were opposed to using phantom image testing as a comprehensive equipment test, even if such testing would permit alternative tests to be performed less frequently. There was strong support for FDA to implement the mammography performance and design requirements described in the proposed rules. Overall, a total of nine comments opposed use of the phantom as a daily test that would replace other QC tests. It was noted that more frequent use of the phantom would increase costs, would not yield an adequate measure of quality, would be useful only as a supplement to other QC tests, and would yield results that were highly variable. Three comments remarked that phantom testing is a good measure of quality but cannot replace all other QC tests. Finally, it was noted that the STEP test should be added to the phantom image analysis.

FDA observes that the general consensus of these comments is that it is unlikely that testing with a more sophisticated phantom, if one is made available through further research, will be an adequate substitute for other QC tests.

b. *Repeat rate*

Another measure that was suggested as a possible performance standard was the facility's repeat rate. Under the final regulations, a repeat rate is to be analyzed every 3 months, and include up to 250 examinations. In the preamble to the proposal (61 FR 14860), FDA asked for comments on the possibility of using the repeat analysis rate in some modified form, such as conducting the test continuously, as the basis for a performance standard. The agency also noted that such a use would have to take into account the possibility that the repeat rate could be altered through the acceptance by a mammography facility of all images of any quality performed.

(Comment 40). Responses to this possible alternative were generally negative. Three comments contended that the repeat rate could not serve as an alternative to existing equipment and QC tests. Specifically, it was noted that ongoing repeat analyses could not substitute for QC tests. Four comments raised concerns about the possibilities for altering or falsifying findings and lack of consistency within and between mammography facilities in performing repeat analyses. A related comment stated that technologists will not repeat images that should be redone if they think the repeated images will affect their job. This means poorer images may be submitted to radiologists for interpretation.

FDA recognizes the validity of the concerns raised by these comments and has concluded that a performance standard based on repeat rate analyses is not likely to enhance quality mammography nationwide.

c. *Clinical image review*

FDA identified clinical image review as a possible basis for performance-based standards. General comments regarding clinical image review for this purpose were largely unfavorable.

(Comment 41). Nine respondents argued that random selection of images for review is unnecessary because the review is conducted by the accreditation body. It is better therefore, these comments continued, to select previous images of the same patients to document improvements in image quality between examinations rather than random selection of images. Thirteen comments stated that the supervising radiologist ultimately is responsible for assessment of clinical image quality. Four comments questioned who would do the clinical image reviews for all facilities and suggested that this would require a new government agency in a time when government has been directed to downsize. Two comments stated that clinical image review is only useful as a learning tool in difficult cases and is not useful as a general test of proficiency.

Additional comments were received on the possibility of using clinical image review to evaluate the performance of the radiologic technologist. Twelve comments were openly opposed to clinical image review for assessment of technologists, arguing that it would require a large investment of effort and financial resources. One comment said that the radiologist, not the technologist, is responsible for the quality of images and, consequently, it would be inappropriate to use this as a performance assessment for technologists. Another comment expressed the point of view that clinical image review was unnecessary if technologists remain active in performing mammography and also maintain proper licensure.

The question of who would do the image reviews drew a number of comments. One comment said that clinical image review by technologists had been tried previously with poor success, although specifics about the problems were not mentioned. Nine comments asserted that clinical image review to assess technologist performance should be done under physician review, rather than by sending images to an outside bureaucracy, which would be very costly for facilities. Cost was raised as an issue by another respondent who argued that a facility with many mammography technologists would have many images out for review, which would be both costly and a threat to patient confidentiality. One comment suggested that the FDA inspector review

clinical images at the time of the annual MQSA inspection, rather than the facility submitting the images to some central point. Under this approach, technologists and radiologists would complete critique forms of their images to explain any difficulties or problems in taking or reading the films.

On the more positive side, twelve comments stated that clinical image review under the MQSA, combined with additional actions, would ensure proper mammography performance sufficient to assess technologists' clinical skills. The additional action suggested by 10 of these comments was yearly attendance at hands-on workshops, while another comment suggested periodic recertification examinations, and the 12th advocated use of repeat analysis. This last comment also suggested that such an evaluation could even substitute for the practice volume requirement for technologists in the proposal.

FDA observes that opinion is divided more evenly on the feasibility of using clinical image review as a performance standard for technologists than on the feasibility of the other possible bases for performance standards mentioned in the proposal. The major problem seems to be how to establish an effective system at a reasonable cost. Although clinical image review will not substitute for the radiologic technologist requirements being finalized in the regulations, FDA will continue to evaluate this issue in collaboration with the members of NMQAAC and other agencies involved with mammography QC.

6. General Observations

As discussed above, FDA sought public comment on the possibility of taking an alternative approach to assuring the quality of mammography nationwide. The alternative approach would be the greater use of performance-based standards in place of the primarily design specification standards established in the interim regulations and proposed for the final regulations. Several possible measures or mechanisms that could form the basis for performance-based standards were identified and the public was invited to comment on their feasibility and also to suggest other options. The agency also asked for comments on how it should proceed with regulation development if performance-based standards were considered feasible. If such standards could be developed relatively quickly, FDA could consider maintaining the interim standards and delaying the issuance of final regulations until performance-based standards were developed. Conversely, if the expected time for the development of performance-based standards was lengthy, in the interest of achieving additional improvement in mammography more rapidly, the agency might appropriately proceed with finalizing the proposed rules (as modified in response to public comment) and replace them at a later date with performance-based standards after the necessary research for those standards was complete.

(Comment 42). Only four comments addressed these questions directly and, as noted above, they urged FDA to proceed with publication of the final regulations. FDA also notes, as described above, that the comments on the possible mechanisms for performance-based standards identified by the agency were predominantly negative. Furthermore, none of the comments suggested any other possibilities for performance-based standards. This would seem to support the view that performance-based standards, if feasible, will require further research. Based on this, FDA concluded that it should proceed with the publication of these final regulations. If further research and development suggest that performance-based standards can replace these regulations, FDA will propose amendments to the MQSA rules.

C. Scope § 900.1

This section briefly summarized the content of the following regulatory sections. No comments were received and it was codified unchanged.

D. Definitions § 900.2

This section defines terms used in the regulations whose meaning would not be common knowledge or for which there exists more than one definition, making it necessary to specify which is to be used for the purposes of these regulations. Comments received on the definitions in the proposal are discussed first. This is followed by a consideration of comments that recommended adding new definitions or made other more general comments on the proposed definitions. Discussed third are definitions that have been added to, or changed from, those in the proposal due to changes in other parts of the regulations.

1. Comments on the Proposed Definitions

a. *General comments on several related definitions*

The following closely related definitions were included in the proposal in order to identify which consumer complaints must be considered by the facility and the accreditation bodies in the complaint process required by the MQSA:

- Adverse event
- Consumer
- Serious adverse event
- Serious complaint

The purpose of these definitions, as explained in the preamble to the proposal (61 FR 14863), is to ensure that serious complaints about the quality of the MQSA-related mammography services are adequately addressed without placing an undue burden on facilities and accreditation bodies by requiring extensive consideration for relatively minor complaints.

''Adverse event'' is defined to mean an undesirable experience associated with mammography activities within the scope of 42 U.S.C. 263b. Examples were included in the definition.

The definition of a ''consumer'' is intended to make it clear that a patient or a representative of the patient (for example, family members or referring physicians) can file complaints.

''Serious adverse event'' is defined to mean an adverse event that could significantly compromise clinical outcomes or for which a facility failed to take appropriate corrective action in a timely manner. Finally, ''serious complaint'' is defined to mean a report of a serious adverse event. Facilities, under § 900.12(h), and accreditation bodies, under § 900.4(g), are required to carry out specified activities in response to serious complaints.

(Comment 43). A number of general comments were received on these related definitions. One comment stated that using the severity levels outlined in current inspection procedures would be more applicable for complaint activities than the proposed definitions.

FDA disagrees with this comment. The severity levels used for the MQSA inspection program were developed for use by inspectors. They are too technical and not necessarily relevant for consumer complaint purposes.

(Comment 44). One comment recommended removing the terms ''adverse event'' and ''serious adverse event'' and the addition of the definition of ''complaint'' to mean the report of any undesirable experience associated with mammography activities. These experiences may include poor image quality, failure to send mammography reports within 30 days, or the use of personnel who do not meet regulatory requirements. Another comment also suggested adding a definition for complaint without specifying what it should be.

FDA believes that the definition offered by the first comment could result in complaints unrelated to the

MQSA (e.g., billing procedures) and complaints that would not ordinarily be considered serious by most patients (e.g., facility temperature) being forwarded to the accreditation bodies and FDA when they have the greatest chance for resolution at the facility. The final regulations require facilities to record all serious complaints. The facility will forward unresolved serious complaints to the accreditation body and/or FDA for further action. In addition, the agency notes that the definitions of ''adverse event'' and ''serious adverse event'' give examples of the kind of complaints that are within the parameters of the consumer complaint mechanism. All of the examples noted in the comment would fall within the scope of consumer complaints subject to further accreditation body and FDA review.

b. *Adverse event*

(Comment 45). One comment agreed that the definition of ''adverse event'' should include failure to send mammography reports in a timely fashion to the referring physician or self-referred patient, but argued that 30 days is an unreasonably long time for communication of adverse events. FDA notes that the 30-day period referenced in the definition is intended as the maximum amount of time that may elapse and that the regulations state that the results should be communicated as soon as possible.

This is discussed further in section III.L.3 of this document, where FDA's responses to comments received on §§ 900.12(c)(2) *Communication of mammography results to the patient*, and 900.12(c)(3) *Communication of mammography results to health care providers*, are given.

(Comment 46). Several comments requested greater clarity or additional explanation for the term ''poor image quality'' (used in the definition of adverse event), and FDA's criteria to determine when image quality is poor. The comment observed that the definition of poor image quality is likely to be very subjective.

FDA agrees that a single definition for poor image quality would be subjective and, therefore, has not included such a definition in order to give facilities and accreditation bodies the flexibility to evaluate such performance in a particular situation on a case-by-case basis. However, criteria to be considered by accreditation bodies in evaluating acceptable image quality are specified in § 900.4(c)(2). Consumers who decide to complain about poor image quality would generally have assistance from health professionals (for example, referring or consulting physicians, or accreditation body) in making this determination. In situations in which FDA has reason to believe image quality at a particular facility is poor, FDA may consult with accreditation bodies for additional mammography review in order to determine whether corrective or enforcement actions are appropriate.

c. *Serious adverse event*

The regulation defines ''serious adverse event'' as ''an adverse event that may significantly compromise clinical outcomes, or an adverse event for which a facility fails to take appropriate corrective action in a timely manner.''

(Comment 47). Four comments recommended that the definition of ''serious adverse event'' should be revised. They stated that failure to take action on a nonserious event should not turn the event into a serious complaint. The comments recommended that ''serious complaint'' should be written to preclude common and potentially unavoidable complaints about mammography (e.g., compression hurts, room too cold).

FDA disagrees that the definition should be revised. Failure to take action on certain nonserious events may indeed result in a serious adverse event. For example, it is generally accepted that most compression complaints are considered to be minor. However, there may be instances in which compression is unusually severe and, therefore, the complaint would be considered serious. FDA believes the definition should remain flexible to allow for this type of situation.

(Comment 48). One comment suggested changing ''may significantly compromise clinical outcomes'' to ''has significantly compromised clinical outcomes.''

FDA disagrees. A primary goal of the consumer complaint mechanism is to improve mammography services by providing facilities with data and information they might not otherwise receive or analyze. It is preferable to correct a potentially serious situation before harm occurs, rather than after the harm has affected the patient.

d. *Serious complaint*

(Comment 49). A ''serious complaint'' is defined as ''a report of a serious adverse event.'' Two comments suggested that descriptions of the type of serious complaints to be reported to the accreditation body should be specified.

FDA agrees that additional descriptions will be helpful and intends to make such information available through guidance. The agency believes that making this information available in guidance, rather than in regulations, will give facilities, accreditation bodies, and FDA the flexibility to determine on a case-by-case basis whether or not an event should be classified as serious.

e. *Contact hour*

''Contact hour'' was defined in the proposal as an hour of training received through direct instruction.

(Comment 50). One comment recommended that it be defined as 50 minutes.

FDA is aware that in academic institutions an hour of didactic training is frequently only 50 minutes long. However, in clinical and continuing education situations, an hour of instruction is usually a full 60 minutes. Reducing the figure from 60 to 50 minutes would reduce the training requirements 16 percent. Because those training requirements were proposed at what are believed to be the minimum adequate levels, the agency did not change the definition.

f. *Direct instruction*

Direct instruction requires instructor-student interaction, either face-to-face or through examination.

(Comment 51). One comment stated that the definition is too vague, especially when compared to mammography equipment evaluation.

FDA disagrees. The agency believes the definition is sufficiently specific to give a clear idea of what is required, while also preserving the flexibility to accept possible new approaches to instruction.

g. *Direct supervision*

The definition of direct supervision was designed to permit ''trainees'' to lawfully obtain the experience in interpreting or producing mammograms or surveying mammography units that they needed to become qualified or requalified. At the same time, by having the trainee's work checked and, if necessary, corrected before any clinical care might be jeopardized, the patient's right to adequate quality mammography is protected.

(Comment 52). One comment supported this definition. A second comment asked if direct supervision was needed for ''nonqualified'' people doing the QC tests.

In accordance with 42 U.S.C. 263b(f)(1), personnel qualifications were established only for interpreting physicians, radiologic technologists, and medical physicists. As a result, tests performed by medical physicist ''trainees'' would have to be done under this definition of direct supervision, although tests performed by QC technologist ''trainees'' would not. However, the agency notes that § 900.12(d)(1)(iv) makes the QC technologist responsible for ensuring the quality of performance of those

doing QC tests. The definition of QC technologist in § 900.2(pp) requires the QC technologists to meet the requirements for a radiologic technologist, including training in quality assurance/QC. Taken together, these requirements provide for a level of supervision similar to that provided under this definition.

h. *Facility*

The definition of ''facility'' is provided by the law itself in 42 U.S.C. 263b(a)(3). It includes a variety of types of locations where mammograms are produced, processed, or interpreted.

(Comment 53). Three comments either inquired if processing and interpreting facilities would have to be certified and inspected or asked that these facilities be excluded from the requirements. The law defines locations where mammograms are processed or interpreted, and where mammograms are produced, as facilities (42 U.S.C. 263b(a)(3)). The agency's approach under the interim regulations, which is expected to continue under the final regulations, has been a systems approach. The facility producing the mammograms receives the certificate and is responsible for ensuring that the facilities at which their mammograms are processed and interpreted, if separate, meet the applicable quality standards. This is consistent with the statutory provision that requires the facility performing the mammography to be responsible for meeting quality standards (42 U.S.C. 263b(a)(3)(B)). FDA has not set up a separate certification and inspection system for facilities that process or interpret only. However, because a certification system for ''partial'' providers may have some advantages for such facilities, the agency may consider such an approach in the future.

(Comment 54). Two comments requested that the definition be expanded to address situations involving multiple locations under the same certificate or temporary locations where a unit (stationary, portable, or mobile) is used more than a minimum number of days.

FDA's experience under the interim regulations shows there is wide variety in the locations at which mammography is performed and in the corporate and business relationships among these locations. Presently, such situations are handled on a case-by-case basis in consultation with the facilities and accreditation bodies involved. The agency believes that it is essential that this flexibility be maintained and that it would be unduly restrictive to prescribe permissible locality arrangements in regulation.

i. *First allowable time*

The proposal defined ''first allowable time'' as the earliest time a physician is eligible to take the diagnostic radiology boards of an eligible certifying body. Because the ''first allowable time'' a resident physician becomes eligible to take the boards may vary with the certifying body, the definition cannot be more specific. If a resident physician wishes to use the exemption from the initial experience requirement described in § 900.12(a)(1)(iii)(B), it is the physician's responsibility to ascertain the requirements of the body by which he or she wishes to become certified and to seek that certification as soon as he or she becomes eligible to do so.

(Comment 55). Three comments stated that this definition was unclear and were unsure how or why this related to resident physicians who would be interpreting 240 mammograms during a 6-month period. NMQAAC also stated that the concept of ''first allowable time'' required further explanation.

This term is used in § 900.12(a)(1)(iii)(B). That provision is an exemption that allows resident physicians to interpret the 240 mammograms required for initial experience in any 6-month period during the last 2 years of their residency program (rather than during the last 6 months immediately prior to the date that the physician qualifies as an interpreting physician as required under § 900.12(a)(1)(D)). This exemption is available as long as these physicians become board certified the first time they are eligible. This provision allows residency programs to be flexible in scheduling training for their resident physicians and eliminates the need to put all senior resident physicians on their mammography rotation during the last 6 months of their program.

(Comment 56). Two comments stated that because the ''first allowable time'' may vary with the certifying body, a more uniform standard would be preferable.

FDA believes that the term ''first allowable time'' must be defined as proposed in order to allow flexibility, because certifying bodies differ in the scheduling of their examinations. Anything more proscriptive could penalize future resident physicians if the certifying body wished to change its examination schedule.

j. *Lead interpreting physician*

This term was included in the proposal to identify the interpreting physician who has the general responsibility for ensuring that the facility meets the quality assurance requirements.

(Comment 57). One comment stated that the definition was not needed because this person is easily identified, while a second comment wanted the term changed to supervising interpreting physician.

FDA agrees that in most facilities the person with this responsibility can be easily identified, but also believes there is an advantage in having a term that can be used to designate and reference this individual, both for the benefit of the employee and patients of the facilities and for the accreditation bodies and the government regulators. The possibility of using ''supervising'' was discussed with NMQAAC but was rejected out of concern about possible confusion between this individual and administrative supervisors who may have different responsibilities.

k. *Mammographic modality*

''Modality,'' as proposed, means a technology, within the scope of 42 U.S.C. 263b, for radiography of the breast. Screen-film and xeromammography were given as examples of a modality. In fact, at present, they are the only examples in general use.

(Comment 58). Two comments stated that the term modality has other uses in medicine and that the definition could be confusing to facilities. Twelve other comments also found the term unclear.

FDA notes that NMQAAC spent some time discussing other possible terms that could be used before concluding that this was the most appropriate. The agency is aware that the term modality is used in different ways in different areas, which is why a definition of its meaning with respect to the MQSA is needed. In an effort to distinguish it further from the other meanings of modality, FDA has changed the name of the term being defined from ''modality'' to ''mammographic modality.'' The definition now appears in the final regulations at § 900.2(z).

(Comment 59). Two comments recommended that the term ''modality'' be replaced with ''specialized techniques in mammography.''

FDA did not accept this suggestion because both ''techniques'' and ''specialized techniques'' already have a variety of meanings in radiology and the agency concluded that the recommended change would increase rather than reduce confusion.

(Comment 60). Nine comments suggested that the definition be broadened to include other technology. Stereotactic, ultrasound, digital, nuclear medicine, Magnetic Resonance Imaging (MRI), and CT were all suggested for addition.

FDA does not believe that the definition should be broadened. The definition is intended to clarify training requirements for personnel providing mammography services. These individuals are required to have training in each mammographic modality with which they work. Because ultrasound, nuclear medicine, and MRI fall outside the statutory definition of mammography as radiography of the breast, the agency cannot include training related to those technologies as part of the regulatory requirements. Digital, CT, and stereotactic do fall under the authority granted by 42 U.S.C. 263b but have been temporarily exempted from the regulatory requirements. When and if training and other requirements related to these technologies are issued, the proposed definition will not delay such requirements from taking effect for those modalities.

(Comment 61). One comment recommended that xeromammography be excluded from the definition because it produced less than optimal mammograms at a higher dose.

FDA agrees that there have been problems with the use of xeromammography and notes that these problems have led to its near disappearance. However, the effect of removing xeromammography from the definition would be to exempt those who use the technology from having to obtain training. FDA expects such a change would increase, not decrease, the problems with the modality.

l. *Mammography*

This definition incorporates the definition of mammography as ''radiography of the breast'' provided by 42 U.S.C. 263b(a)(6), but temporarily excludes from the quality standards radiography of the breast performed in interventional mammography or with an investigational mammography device during a scientific study conducted in accordance with FDA's investigational device exemption regulations.

(Comment 62). One comment suggested that ''for the purposes of these regulations'' should be inserted in this definition.

FDA believes that it is well understood that all definitions that appear with any regulation are for the purposes of those regulations.

(Comment 63). Another comment suggested expanding the wording of the definition to specifically mention X-ray radiation and several types of image receptors. FDA notes that the term radiography implies the use of X-rays.

The agency further notes that if the changes were made, and a new, yet unimagined type of image receptor was approved following investigational device studies, the definition would have to be amended before the new device could be put into general use. To avoid such a delay in the use of an advance in image receptor technology, the agency has retained the proposed general definition.

m. *Exclusion of interventional mammography*

In the proposal (61 FR 14862), FDA temporarily excluded interventional mammography (radiography performed during invasive interventions for localizations or biopsy procedures) from the definition of mammography. This had the effect of exempting such mammography from the requirements of the regulations. A similar exemption has been in effect under the September 30, 1994, amendments to the interim regulations (59 FR 49808–49813). The basis for the exclusion, as explained in the preamble to the proposal (61 FR 14862), was the agency's belief that science had not advanced to the point where effective national quality standards could be developed for these devices.

(Comment 64). Over 90 comments supported the exclusion of interventional mammography. Many of these agreed that there currently is no consensus with respect to appropriate standards for stereotactic units, and until regulations based on scientific data can be developed, it is inappropriate to include interventional procedures within the scope of the regulations. In addition, the comments stated that surgeons have extensive experience in dealing with breast disease and breast biopsy and they are best suited to manage the patient. These comments noted that many surgeons have had extensive experience performing stereotactically guided breast biopsies and have achieved good results with this procedure. Others wrote that in this procedure, the surgeon knows that the lesion is present and is merely using stereotactic images to guide the needle to the proper position for biopsy. Other comments stated that while radiologists have only one method to biopsy the breast, surgeons have several options and can offer the patient the best biopsy option for her clinical status. Some comments stated that surgeons have a long history of providing followup care for patients and for many years have used radiographic equipment in the operating room and are familiar with its use. Several comments said that surgeons have used mammography for many years in the diagnosis and treatment planning for breast cancer patients. Still others said that these biopsy procedures will evolve into therapeutic procedures that are best handled by the surgeon and that surgeons are best equipped to handle any followup or complications associated with these biopsy procedures.

NMQAAC and over 100 comments opposed the exclusion of interventional mammography. Many of these asserted that it is counterproductive to set quality standards for mammographic diagnosis while having none for mammographically guided invasive breast procedures and that only interpreting physicians have the expertise and experience necessary to perform this procedure. Authors of other comments wrote that interpreting physicians have experience dealing with the quality assurance and QC issues necessary to maintain stereotactic biopsy equipment and that the failure to regulate this procedure places the public at risk. Some said that the lack of adequate mammographic training could lead to the lesion in question being missed during tissue sampling and that the abilities and training required to localize a small subtle suspicious area are the same as those for interpreting a mammogram. Other comments stated that only interpreting physicians will be able to interpret the original mammograms to determine if a needle biopsy is appropriate.

FDA agrees with the comments stating that interventional mammography can be of great use in the evaluation of breast disease, but only if optimally performed. Until recently, the science had not advanced to the point where effective national quality standards could be developed for these procedures. Since the publication of the proposed regulations on April 3, 1996, significant progress has occurred in the professional community and FDA now believes that there is enough information to begin the development of interventional mammographic regulations. However, that development requires a comprehensive and careful approach that addresses all the factors involved in such procedures. The agency has already begun the development process by bringing this issue before NMQAAC during its October 1996 meeting and is continuing to gather information and data. Although the agency has concluded that the final regulations should exclude coverage of interventional mammography, FDA expects to propose regulations covering all aspects of interventional mammography in the near future.

n. *Exclusion of investigational devices*

In the proposal, FDA also excluded from the definition of mammography,

and thus from the regulatory requirements, investigational mammography devices that were being evaluated in accordance with FDA's investigational device exemption regulations in 21 CFR part 812. This provision extended the exclusion for investigational devices previously established under the September 30, 1994, amendments to the interim regulations. The agency believes that it is obvious that it would be premature to establish standards for devices still in the experimental stage. FDA also believes that the precautions built into the agency's general investigational device exemption regulations provide adequate protection for the public health during the use of these devices. However, the agency made clear in the preamble to the proposal (61 FR 14862) that any conventional mammography device used during the scientific study to provide baseline data for evaluating the safety and efficacy of the investigational device was not within the scope of the exclusion and would have to meet the MQSA requirements.

(Comment 65). Two comments stated that the wording of this section would make MRI for mammography investigations or use of full field digital mammography illegal, unless they are performed by a radiologist specializing in mammography.

MRI is not radiography of the breast and, therefore, does not come under the definition of mammography. Similarly, investigational studies, such as those involving full field digital mammography, are specifically excluded under the definition of mammography in § 900.2(z)(2) of the final regulations. FDA concludes, therefore, that the regulations will not prevent such research from occurring. However, any conventional mammography performed as part of a study is not excluded and does have to meet all the requirements of the final regulations. FDA has modified the definition to clarify this issue.

o. *Mammography medical outcomes audit*

''Mammography medical outcomes audit'' means a systematic collection of mammography results and the comparison of those results with outcomes data.

(Comment 66). One comment stated that the term ''medical audit'' was self-explanatory and did not need a definition.

FDA disagrees. There are many different working definitions of this term being used in the professional community. FDA's definition of what minimally constitutes a mammography medical outcomes audit is for the purposes of the MQSA requirements and may be different from recommended guidelines and definitions of other organizations.

p. *Mammography unit or units*

The definition for ''mammography unit or units'' is an assemblage of components for the production of X-rays for use during mammography. Several components were listed.

(Comment 67). Two comments suggested that compression device, breast support, and components associated with the image receptor and grid be added to the list.

These suggestions would not fit the general criterion of a component for the production of X-rays and the agency is not adding them to the list.

q. *Mean optical density*

''Mean optical density'' was defined as the average of the optical densities measured for phantom thicknesses of 2 to 6 centimeters (cm) using kilovolt peak (kVp) values clinically appropriate for the thicknesses.

(Comment 68). Three comments were received on this definition. One suggested that the thickness range should be changed to 3 to 7 cm. A second also supported a 3 to 7 cm range, but stated it would be prudent to check at 2 and 8 cm as well. The third comment stated that, because the thicknesses chosen could influence the result, the definition should specify the thicknesses to be used. The comment further suggested that 2, 4, and 6 cm should be used.

This definition is used in connection with a QC test of Automatic Exposure Control performance. The test procedures recommended by the ACR manuals and incorporated by reference into the interim regulations requires the use of 2, 4, and 6 cm thicknesses. The agency agrees with the third comment that it would be of value to add the exact thicknesses to the definition and has done so. FDA does not believe there is justification for changing the range of thicknesses used in this standard test, as suggested by the other two comments.

r. *Medical physicist*

''Medical physicist'' is defined as a person trained in evaluating the performance of mammography equipment and quality assurance programs and who meets the requirements of § 900.12(a)(3).

(Comment 69). One comment stated that the MQSA does not provide statutory authority to FDA to define the profession of medical physicist.

It is not FDA's intention to define the profession of medical physicist in general and the agency also agrees that it lacks the authority to do so. However, the MQSA requires that the agency establish qualifications for those medical physicists providing mammography services to mammography facilities (42 U.S.C. 263b(f)(1)(E) and (F)). This provides both the authority and responsibility to define ''medical physicist'' for the purpose of these regulations. Again, this definition applies only to medical physicists who wish to provide services to mammography facilities under the MQSA and not to the profession as a whole.

s. *Multi-reading*

''Double reading,'' defined as two or more interpreting physicians interpreting the same clinical image, was included in the proposal to describe one of the options that interpreting physicians can use to meet the experience requirements.

(Comment 70). Several comments, including a consensus of NMQAAC, requested further clarification of this term. Confusion apparently has arisen due to the fact that ''double reading'' commonly is used to describe the situation where a mammogram is read by two interpreting physicians in an attempt to improve the accuracy of the interpretation. Two comments, including a consensus comment from NMQAAC, suggested that another term be used to describe multiple interpretation as it applies to the final regulations.

In response to these comments, FDA has substituted the term ''multi-read'' to describe interpretation of mammograms by two or more physicians. Multi-reading can be used by physicians to meet continuing experience requirements. Multi-reading can also be used by physicians to meet initial and/or requalification requirements if it is done under direct supervision.

(Comment 71). Some of the comments incorrectly assumed that FDA was forcing facilities to have all their mammograms read by two interpreting physicians.

While facilities are free to perform this type of ''multi-reading'' as a means to improve accuracy, FDA does not require that any mammogram be read by more than one interpreting physician.

(Comment 72). One comment suggested adding the words ''that has not been marked as to possible pathology'' at the end of the definition of ''double read'' (now changed to multi-read).

FDA disagrees and believes that an interpreting physician benefits from reviewing mammograms, even those that have been marked by another physician. Requiring the removal of such marks would be overly burdensome and might even be

detrimental to the patient if the original marks were not put back on the images.

(Comment 73). One comment requested clarification as to whether physicians must independently interpret the same clinical image, or is it within the intent of the definition to include two or more physicians in consultation interpreting the image together.

FDA intends the concept of ''multi-reading'' to include both independent and consultative reading. If the multi-reading is done under direct supervision, there must be a consultative component to the supervision.

t. *Patient*

In the proposal, FDA used ''examinee'' to refer to any individual undergoing a mammography examination. This was a change from the term ''patient,'' which was used in the interim regulations. As explained in the preamble to the proposal (61 FR 14862), the change was made in recognition of the fact that most individuals who undergo mammography are not ill and do not have a condition requiring medical care.

(Comment 74). Eighteen comments stated that it was not necessary to replace ''patient'' with ''examinee,'' because patient is a term used universally. One comment objected to the proposed use of ''examinee'' and preferred ''patient'' because ''patient'' conveys the ethical protections of a doctor-patient relationship, confers malpractice protection, and ensures that third party payers recognize the examination as required care. One comment agreed with the definition of examinee and the inclusion of self-referred persons.

NMQAAC discussed these comments and there was general consensus to recommend that FDA use the term ''patient,'' provided the definition would include people who did not have health care providers and people without medical symptoms. Finally it should be noted that the MQSA uses the term patient. In light of these comments, FDA has decided to return to the use of ''patient,'' which is defined in the final regulations as anyone undergoing a mammographic procedure.

u. *Phantom*

''Phantom'' is defined as a test object used to simulate radiographic characteristics of compressed breast tissue and containing components that radiographically model aspects of breast tissue and disease.

(Comment 75). One comment on this definition requested that FDA specify the phantom contents and measurements. A second comment urged FDA not to change the current phantom unless the new phantom decreased the frequency of other testing.

FDA believes that the accreditation bodies should establish the phantom specifications and related performance criteria, rather than the agency establishing them through regulation. However, as part of its responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specifications and performance requirements to ensure that they are substantially the same among different accreditation bodies.

FDA believes that the second comment was in response to the suggestion that a more sophisticated phantom might facilitate the establishment of performance outcomes standards based on the new phantom's use that would take the place of several of the existing tests. This issue was discussed previously with other comments on that subject under section III.B of this document, where the agency concluded that performance standards based on a new phantom were not practical at this time.

v. *Physical science*

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

(Comment 76). One comment received on this definition stated that the engineering part of this definition should be limited to electrical and nuclear engineering only, while a second comment opposed the inclusion of engineering and chemistry at all.

FDA notes that this term is used to establish the qualifications to be met by medical physicists, which include a degree in the physical sciences on an appropriate level. The purpose of that part of the requirements is to ensure that the individual has a general familiarity with the scientific concepts, calculations, and techniques that provide a basis for understanding and completing more specialized work in medical physics, not that he or she has already achieved the training in medical physics. The agency further notes that this general requirement is reinforced with a more specific requirement for training in physics. Because meeting these two requirements provides an adequate foundation for meeting the more specialized medical physics requirements, the agency does not believe the definition needs to be narrowed by eliminating the fields suggested in the comments.

w. *Positive mammogram*

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

(Comment 77). One comment stated that the term positive mammogram was self-explanatory and did not need a definition. FDA disagrees. There are many different working definitions of this term being used in the professional community. Because the final regulations require all positive mammograms to be entered into the facility's medical audit system, it is necessary to retain a definition of ''positive mammogram'' in order to clarify the scope of the audit.

x. *QC technologist*

This term was defined to mean the individual who is responsible for the segments of the quality assurance program that are not the responsibility of the lead interpreting physician or the medical physicist. In general, this responsibility consists of the routine QC testing and some data analysis and corrective actions related to the results of that testing.

(Comment 78). One comment stated that it is not necessary to identify or define this position because the person with this responsibility is easily identified.

FDA does not agree with this comment for the same reason it disagreed with the similar comment about the definition of lead interpreting physician. In addition, the title of QC technologist is already widely used in mammography facilities.

This definition was changed, however, as a result of discussions at the January 1997 NMQAAC meeting. It is often possible for a single individual to perform the duties of a QC technologist for an entire radiology facility. That individual ordinarily is a technologist, but may not meet the qualifications to do mammography. At early meetings, NMQAAC had agreed that this person should be a qualified technologist, but did not necessarily have to be qualified to perform mammography. This would avoid the possibility that the mammography department of a radiology facility might have to have its own QC technologist, thus forcing the facility to assign two persons to meet the responsibilities previously handled by one. NMQAAC reconsidered its position at the January 1997 meeting, however, and concluded that the advantages of having the QC technologist in the mammography department be qualified to do mammography outweighed the possible extra costs. FDA accepted NMQAAC's advice on this matter and changed the wording in the definition to require the QC technologist to meet all the qualifications in § 900.12(a)(2) for

radiologic technologists doing mammography.

(Comment 79). Three comments disagreed with the proposed definition because it barred qualified biomedical engineers, manufacturer's representatives, and other individuals the authors believed were qualified from serving as QC technologists. Although NMQAAC has changed its position from time to time on whether the QC technologist must be qualified to do mammography, it has never wavered from its advice that the individual in this position should be a radiologic technologist. FDA concurs with that view. However, as discussed below in connection with the quality assurance requirements under § 900.12(d)(1)(iv), the final regulations permit nontechnologists to perform certain QC tasks as long as the QC technologist ensures that the performance is adequate.

y. *Traceable to a national standard*

Traceability refers to the ability to show that an instrument has been calibrated by a process that eventually led back to a standard established by the National Institute of Standards and Technology (NIST).

(Comment 80). A number of comments requested further clarification of traceability. A few comments requested that the requirement for annual calibration be changed to every 3 years.

In response to these comments and after discussion with calibration experts, FDA has revised the definition of traceability. The term itself has been changed to ''traceable to a national standard'' to more clearly reflect what is needed. Other changes have clarified that the ultimate source of the calibration may be either NIST or a calibration facility that participates in a proficiency program with NIST at least once every 2 years during which the calibration facility achieves agreement within + 3 percent of the NIST standard at mammography energy levels.

2. New Definitions Suggested by the Comments

a. *Category I*

(Comment 81). Several comments suggested that the meaning of the term ''Category I,'' as used in the regulations, was unclear.

In response, FDA has defined Category I, at § 900.2(g), to mean medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education, the American Osteopathic Association, a State medical society, or an equivalent organization.

b. *Contact mammography*

(Comment 82). One comment recommended that this term from the final regulations should be defined. However, in the revisions of the regulations following the public comments, this term has been eliminated, so a definition is no longer needed.

c. *Continuing education unit*

(Comment 83). One comment warned that it would be difficult to interpret the personnel training requirements if the term continuing education unit was not defined.

FDA agrees with this comment and has added a new § 900.2(l), which states that continuing education unit or continuing education credit means 1 contact hour.

d. *Diagnostic and screening mammography*

(Comment 84). Over 30 comments stated that diagnostic and screening mammography should be defined and asserted that vacillation over these definitions only confuses the public and those who are to measure outcomes.

As explained in the proposed rule (61 FR 14862), FDA is eliminating these terms from the definitions section because differences of opinion within the professional community regarding the distinction between these two types of mammography procedures remain unresolved. These terms can have different meanings depending upon their context. For example, HCFA has defined screening and diagnostic mammography for claim processing purposes. AHCPR has defined these terms in their guidelines for medical audits. On the other hand, some facilities do not distinguish between screening and diagnostic mammography. Facilities also differ on categorizing certain circumstances as screening or diagnostic, as in the example of a healthy, asymptomatic woman with breast implants who has diagnostic views performed during ''routine screening.'' The terms screening and diagnostic mammography, along with other terms and definitions associated with the medical audit, are in the process of obtaining consensus within the scientific community. At present, FDA recommends that each facility choose and consistently utilize HCFA, AHCPR, or other definitions in the medical literature for medical audit purposes.

e. *Established operating level*

(Comment 85). One comment noted that this term was used in connection with a number of QC tests and suggested that it be defined as ''the single point for a particular quality assurance parameter set by the lead interpreting physician.''

FDA agrees that a definition of established operating level is needed and has added, at § 900.2(p), that ''established operating level means the value of a particular quality assurance parameter that has been established as acceptable by the facility's quality assurance program.'' This definition indicates that the level should not be merely set but also should be determined to be acceptable. The responsibility for making that determination will belong primarily to the lead interpreting physician, as the comment suggested. However, the definition being issued refers to acceptance as part of the entire quality assurance program because additional facility and FDA personnel also may be consulted when the level is established.

f. *Image receptor*

(Comment 86). Two comments suggested that a definition of image receptor be included in the final regulations. FDA notes that there is a general understanding within the radiology and general medical community of what this means and if a specific definition is needed, one is already available in 21 CFR 1020.30(b). The agency does not believe that it needs to be repeated here.

g. *Image receptor support device*

(Comment 87). One comment suggested that a definition of image receptor support device as that part of the mammography X-ray unit that is designed by the manufacturer to hold the cassette be added to clarify § 900.12(b)(5).

FDA agrees that this is a useful suggestion. However, as a result of other revisions that have been made to the proposal, the term ''image receptor support device'' is no longer used in the regulations and, therefore, a definition is no longer needed.

h. *Laterality*

(Comment 88). Several comments found the meaning of the term ''laterality,'' as used in the regulations, to be unclear.

In response to these comments, FDA has defined laterality, at § 900.2(w), to mean the designation of either the right or left breast.

i. *Mammography equipment*

(Comment 89). One comment suggested that a definition of ''mammography equipment'' should be added and further suggested that the definition include all physical components of a mammography facility needed to produce an interpretable film. The author believed that this would more clearly define the components that the physicist would need to include in the required ''survey'' of ''mammography equipment'' for which

he or she has been assigned responsibility under § 900.12(d)(1)(iii).

FDA considered the possibility of adding this definition, but notes that § 900.12(e)(9) already establishes the evaluations that, at a minimum, are to be included in the survey. Because of this, the agency decided that an additional definition was not needed.

j. *Mobile unit*

(Comment 90). Three comments suggested that mobile units should be defined in such a way as to clarify when mammography units used under a variety of different circumstances are to be included in this category.

FDA notes that the term mobile unit is relevant to compliance with these regulations only in determining when the additional testing required by § 900.12(e)(7) needs to be performed. Under § 900.12(e)(7), a mobile unit is one that is used to produce mammograms at more than one location. The agency believes § 900.12(e)(7) makes it sufficiently clear when the additional testing is needed.

k. *Quality assurance, quality assurance program, and QC*

(Comment 91). Two comments recommended that these terms be defined. FDA notes that one or more of these terms have been defined in 21 CFR 1000.55, in the ACR Quality Assurance manuals, or by various other authorities. While the wording of these definitions may vary, the basic concepts are the same and are widely understood. The agency does not believe that they need to be defined again.

l. *Technique chart*

(Comment 92). One comment among those that suggested that a technique chart should be part of the quality assurance manual also noted that this would require defining technique chart. The comment also made some suggestions for the definition.

FDA notes that, as will be discussed with other comments related to quality assurance records required under § 900.12(d)(2), a technique chart is not being required to be included in the facility's quality assurance manual. Because the term is not used in the regulations, a definition is not needed.

m. *Other comments on the proposed definitions*

(Comment 93). Thirteen identical comments wanted the quality assurance definitions changed, stating that, ''it is objectionable to have the FDA creating definitions of medical terms not agreed on by physicians.''

Quality assurance is not defined in the regulations and, as discussed above, the agency does not believe such a definition is needed. From other information in the letters containing the comments, it appears that they are actually referring to specific definitions discussed under the heading of ''Quality Assurance'' in the preamble to the proposal. There were four such definitions: ''lead interpreting physician,'' ''QC technologist,'' ''time cycle,'' and ''traceability.''

FDA agrees that, to the extent possible, the agency should adopt definitions for medical terms that have widespread agreement among physicians. In fact, QC technologist, as discussed above, is already a title widely used in facilities and in the ACR manuals. It appears that medical facilities have already reached consensus on its use as an administrative title, although there may be differences on the necessary qualifications of such individuals.

The agency does not agree that the other three terms are medical terms whose definitions require agreement among physicians. ''Time cycle'' and ''traceability'' are technical terms related to the film development time and the calibration of radiation measuring instruments. These are not terms that physicians use regularly or about which they are likely to discuss and reach consensus. The remaining term, lead interpreting physician, is an administrative term, not a medical one. As discussed previously, this term has been defined as the designation of an individual physician at each facility who has certain responsibilities under these regulations; that identification will make it easier for facilities, accreditation bodies, and government regulators to ensure and monitor compliance with the MQSA standards.

3. New or Changed Definitions Made Necessary by Changes in the Regulations

a. *Air kerma and kerma*

The Omnibus Trade and Competitiveness Act of 1988 amended the Metric Conversion Act of 1975 to require each Federal agency to use the International Systems of Units (SI) in its activities. The SI is also known as the metric system although it makes use of only some of the metric quantities and units. In accordance with this requirement, a memorandum dated March 19, 1990, from FDA's Associate Commissioners of Regulatory Affairs and Public Affairs, established the FDA policy for the use of SI metric measurement. Since 1990, FDA has been undergoing a transition to SI quantities and units in its regulatory activities. To this end, air kerma, which is an SI quantity, has been introduced as a replacement for the quantity of exposure previously referenced in § 900.12(e)(5)(v). Definitions of ''air kerma'' and ''kerma'' were also added as §§ 900.2(d) and 900.2(v), respectively, in the final regulations.

b. *Calendar quarter*

To give facilities more flexibility in maintaining their records on personnel qualifications, changes were made in several provisions of § 900.12(a). These changes allow the facility to use a variety of methods to calculate the time periods necessary to establish compliance with personnel requirements. In calculating these time periods, the facility may designate any one of the following as the endpoint for the period of time used to determine if their staff met the continuing education and experience requirements: (1) The date of the inspection; (2) the last day of the last calendar quarter before the inspection; or (3) any date in between those two. To avoid any misunderstandings, FDA added a definition of calendar quarter, under § 900.2(f), that establishes the endpoints of the 4 quarters as March 31, June 30, September 30, and December 31.

c. *Interim regulations*

Reference was made to the interim regulations several times in the final regulations. For the benefit of those unfamiliar with those regulations, FDA defined them by citing, under § 900.2(t) of the final regulations, the **Federal Register** publication of December 21, 1993, as amended on September 30, 1994.

d. *Interpreting physician*

This definition was modified from the proposed definition by adding the term ''licensed'' in order to clarify the intent of the statute that the physician maintain a valid State license to practice medicine.

e. *Qualified instructor*

During the revisions of the training requirements for radiologic technologists, the term ''qualified individual'' and its definition in § 900.12(a)(2)(ii) were replaced by the term ''qualified instructor'' in referring to the individuals providing the training and the category of such individuals was expanded. These changes made it necessary to add, as § 900.2(oo), a definition of ''qualified instructor'' as an individual whose training and experience adequately prepares him or her to carry out specified training assignments. The new definition also includes examples.

f. *Standard breast*

Although the term standard breast was used and defined at several points in the proposed regulations, it had not been included in the definitions section. It has now been added as § 900.2(uu) in the final regulations.

E. The Accreditation Body Application (§ 900.3)

In this section, FDA proposed procedures to be followed by organizations or agencies applying to become FDA-approved accreditation bodies. It also proposed criteria for evaluation and approval of prospective accreditation bodies.

1. General Comments on the Accreditation Process

(Comment 94). Several comments supported portions of the rule, and the initial accreditation process in general, stating that it had elevated the quality of many facilities under the interim regulations. Other comments, including some from members of NMQAAC, expressed a variety of concerns, including possible conflict of interest and lack of uniformity that may result if States become certifying bodies. One general comment recommended that FDA monitor ACR, rather than facilities.

Comments about the States as certifiers go beyond the scope of this document and will be addressed in future proposed regulations covering States as certifying agents. However, the agency notes that the MQSA expressly provides that States may serve as certifying bodies (42 U.S.C. 263b(q)). Preparations are under way to draft proposed regulations that would govern State agencies that wish to become certifying bodies. Just as these final regulations establish standards and procedures for accreditation bodies, including State agencies that serve in that capacity, provisions regulating States as certifying bodies would establish standards and procedures that States must meet to assume that responsibility. Those standards and procedures would address uniformity of standards and include conflict of interest provisions, as do the regulations governing accreditation bodies.

Members of the public will have full opportunity to comment further on States as certifiers when those regulations are proposed. In response to the comment that urged FDA to monitor ACR rather than facilities, the agency notes that the statute requires FDA to monitor both accreditation bodies and facilities in a variety of ways.

(Comment 95). One comment wanted FDA to promote multiple accreditation bodies because of concerns that States approved as accreditation bodies will have overly stringent requirements.

States approved as accreditation bodies are required to accredit facilities under the MQSA in accordance with standards that are substantially the same as those applied by all approved accreditation bodies. However, the MQSA does not prohibit State regulations from being more rigorous than those of FDA. Although more stringent State requirements cannot be used to deny accreditation under the MQSA, facilities may be required by a State to meet such additional requirements in order to practice mammography in that State.

2. The Clinical and Phantom Image Review Process (§ 900.3(b)(3)(iii)(A) and (B))

These provisions require the prospective accreditation body to provide information that describes its clinical and phantom image review process in its application to FDA.

(Comment 96). One comment requested that this information also be provided to all mammography facilities, stating that it would result in improved overall image quality and would assist facilities denied accreditation to prepare for appeals hearings.

FDA understands that facilities may believe they could prepare better for accreditation review if they had details relating to the procedures the accreditation bodies would be applying during clinical and phantom image review. However, FDA also recognizes that disclosure of the details of such procedures may undermine the integrity of the review process under certain circumstances. FDA concludes that this is a matter for accreditation body policy rather than regulations. The actual clinical attributes reviewed during accreditation are described in the final regulations.

3. Policies and Procedures (§ 900.3(b)(3)(iii)(J))

This provision requires prospective accreditation bodies to provide FDA with information describing policies and procedures that will ensure timely processing of facility applications for accreditation.

(Comment 97). One comment on this section requested FDA to require accreditation bodies to respond to requests for information or to written communications expressing concerns from facility personnel or other interested parties about the accreditation process. Another comment suggested including a review of the consistency of the accreditation body's responses to facility and industry inquiries as part of the annual evaluation of the accreditation body by FDA.

FDA agrees that timely processing of facility accreditation applications is important to meet statutory certification deadlines and that good communication between accreditation bodies and facilities can improve such timeliness. However, FDA disagrees that specific prescriptive regulations are needed concerning communications between the accreditation body and facilities.

4. Education and Experience Criteria (§ 900.3(b)(3)(iv))

(Comment 98). One comment stated that this subparagraph, requiring that prospective accreditation bodies provide information describing education and experience criteria for its staff, fails to specify minimum acceptable values for these criteria. It also asked for clarification of ''professional staff.''

By professional staff, FDA means those persons evaluating and making decisions on accreditation applications. FDA has established minimum requirements for the clinical image reviewers under § 900.4(c)(5) and for phantom image reviewers under § 900.4(d)(5), but has not issued minimum requirements for other accreditation body staff in order to maintain flexibility for accreditation bodies and to be able to consider alternatives on a case by case basis. FDA's experience under the interim regulations is that every professional member of an accreditation body staff is qualified to perform his or her assigned functions.

5. Resources (§ 900.3(b)(3)(vi))

This provision requires prospective accreditation bodies to provide information in their application to aid FDA in determining if the body has adequate resources to carry out its responsibilities.

(Comment 99). One comment asked what constitutes adequate funding, what specific additional resources are required and in what amount, and how FDA expects to evaluate the adequacy of an application if no minimum requirements exist for such resources.

Funding and other resource needs, e.g., personnel and data systems, are a function of the variable conditions under which accreditation bodies may operate and the populations they may serve.

FDA could not establish rigid funding or staffing requirements to apply to every accreditation body applicant. As issued, the regulations provide FDA with authority to obtain information to evaluate the individual circumstances of each applicant.

6. Other Information (§ 900.3(b)(3)(xiii))

This subparagraph requires a prospective accreditation body to provide any information required by FDA beyond that specifically listed in § 900.3(b)(3).

(Comment 100). One comment described this requirement as exceedingly vague and recommended it be deleted.

FDA must reject this suggestion because the requirements that accreditation bodies provide FDA with additional information is in the statute itself (42 U.S.C. 263b(e)(1)(vii)). The drafters of the MQSA recognized that it would be impossible to foresee in advance when circumstances might create the need for additional information.

FDA has added one provision to § 900.3(b)(3) to obtain information from prospective accreditation bodies about procedures and policies they would implement to protect confidential information. This requirement is at § 900.3(b)(3)(ix) and its addition has caused the subsequent sections to be renumbered.

7. Term of Approval (§ 900.3(g))

(Comment 101). A small number of comments, both pro and con, were received concerning the accreditation body's term of approval, proposed by FDA to be 5 years. Some, including members of NMQAAC, stated that this term was too short, particularly in light of FDA's annual accreditation body evaluation. These comments also expressed concern about the amount of paperwork required for renewal.

In response to these concerns, FDA has increased the renewal period in the final regulation to 7 years. Because FDA shares the concern about the amount of paperwork required for renewal of accreditation body approval, the agency plans to limit the data required to be submitted to only that information necessary to justify renewal. FDA will hold discussions with each accreditation body prior to renewal to identify the information that will be required. Such information may include, but is not limited to, information and data pertaining to the accreditation body's program not previously submitted to FDA and all proposed changes to the accreditation body's program or standards.

F. Standards for Accreditation Bodies (§ 900.4)

Accreditation bodies are responsible for the initial screening of mammography facilities. They are to ensure that the facilities they accredit meet the quality standards established by FDA, both initially and on an ongoing basis. They also have unique responsibility for conducting reviews of clinical images from the facilities to determine if the images meet the image quality standards established by the accreditation body with FDA approval. This section of the regulations outlines the requirements that FDA-approved accreditation bodies must meet in carrying out these responsibilities.

1. General Comments on the Standards for Accreditation

(Comment 102). One comment generally supported this section as written, while a second applauded the regulations for not requiring specific measures of interpretive performance. Other comments encouraged FDA to add additional requirements and responsibilities for accreditation bodies, but did not identify what these should be. One comment stated that the proposed rules for accreditation bodies suffered from a lack of either design or performance-based criteria, but failed to suggest any design or performance-based criteria that should be applied.

FDA believes that the final regulations governing accreditation bodies are sufficiently detailed without being overly prescriptive. Although particular performance-based requirements were not identified by these comments, FDA notes that some performance data on accreditation body activities are available and are used by FDA in its annual evaluation of each accreditation body.

(Comment 103). One comment recommended that each accreditation body be required to demonstrate expertise in recordkeeping and epidemiology.

FDA believes that its review of the accreditation body's application will provide sufficient information to establish that the accreditation body has recordkeeping capability. Although accreditation bodies may employ epidemiologists, nothing in the MQSA suggests that FDA should make this a requirement.

(Comment 104). One comment stated that excessive requirements for accreditation bodies will destroy the basic concept behind the idea for accreditation bodies, i.e., significant involvement of the public and professional sector. The comment warned that detailed rules could reduce the opportunity for creative approaches and innovative development of new QC tests and procedures. A second comment stated that FDA should not hinder the accreditation bodies from performing as independent entities.

FDA shares concerns that overly detailed requirements may limit professional involvement and useful innovation. Although it may appear that the final regulations include many new requirements for accreditation bodies, to a large extent the provisions reflect procedures and criteria that the current accreditation bodies already are following under the interim regulations. In fact, many were first devised by the accreditation bodies themselves and are examples of accreditation body innovation, e.g., development, submission, evaluation, and monitoring completion of corrective action plans by facilities found to have problems producing quality mammograms. FDA has taken great care to delete or amend requirements that might limit creative approaches and innovation. Because the comment does not identify specific rules in the proposal that might cause such problems, the agency cannot respond further.

In response to the second comment, the agency notes that the MQSA requires FDA to establish standards for, and to approve accreditation bodies. Entities that apply to become accreditation bodies must comply with those standards. FDA does not believe that compliance with those standards will diminish the ability and obligation of accreditation bodies to make independent professional judgments. Those judgments, however, must be consistent with statutory obligations to ensure that facilities comply with the Federal standards and work with FDA to improve the practice of mammography. Accreditation bodies are free to encourage innovation, conduct research, develop new standards, and apply for appropriate variances when a particular practice or procedure presents an opportunity to enhance mammography quality.

2. Code of Conduct and General Responsibilities (§ 900.4(a))

These provisions were intended to describe the responsibilities of the accreditation body when there is a possibility that mammography practice at an accredited facility poses a risk to human health. As proposed, those sections set forth particular actions an accreditation body would be required to take in those circumstances.

a. *Image quality (§ 900.4(a)(1) and (a)(2))*

(Comment 105). One comment stated that the accreditation body should have the discretion to determine the appropriate review for a given circumstance and the option to initiate other actions FDA had not described in the proposal (e.g., random film checks followed by a site visit, if necessary). Three other comments recommended deletion of these paragraphs and the substitution of guidance documents that would give accreditation bodies more flexibility.

FDA generally agrees with these comments and has eliminated most of the detailed provisions of these paragraphs (including all of proposed paragraph § 900.4(a)(2)). The final provisions establish that the accreditation body has a responsibility to review clinical images or other

aspects of a facility's practice any time it obtains or receives information that suggests a facility is not in compliance with the MQSA standards, or upon request from FDA. The accreditation body also has responsibility to require and monitor corrective actions or to suspend or revoke a facility's accreditation if the accreditation body's, or FDA's, review confirms that a problem exists. These responsibilities are integral to the role accreditation bodies play under the MQSA to assist the government in establishing and monitoring quality standards for mammography. Nothing in the final regulations precludes an accreditation body from initiating investigations on its own.

b. *Equipment or practices that pose a serious risk (§ 900.4(a)(2))*

(Comment 106). Six comments recommended changing the requirement that an accreditation body inform FDA on becoming aware of situations of potentially serious risk to the public health from ''within 5 business days'' to ''the next business day.''

FDA agrees with concerns raised by these comments and has changed the requirement to ''as soon as possible but in no case later than 2 business days.'' The standard that triggers such responses has been amended to those that ''pose a serious risk to human health'' in order to ensure that FDA is informed of all problems that may require immediate followup.

c. *Conflict of interest (§ 900.4(a)(4))*

The goal of this provision was to ensure that actions of the accreditation body's clinical or phantom image reviewers were not affected by any conflict of interest, and to ensure that accreditation bodies avoid the appearance of such conflicts in order to establish and maintain confidence in the accreditation process.

(Comment 107). Four comments recommended expanding clinical image reviewer conflict of interest concerns to include the individual's family, corporations, partnerships, and associations.

FDA disagrees with these comments. The comments provided no arguments to support this recommendation and no evidence to suggest that the present conflict of interest provision is inadequate. In addition, FDA believes limitations suggested by the comment would eliminate some highly qualified clinical image reviewers from eligibility without commensurate benefit to the system. The agency notes that, if similar conflict of interest provisions had been applied to membership on NMQAAC, many of the members that played a major role in developing final regulations would not have been eligible to serve on the committee.

(Comment 108). One comment recommended expanding the conflict of interest provision to specify that clinical and phantom image reviewers must not review images from facilities within the State in which they reside. A second comment also expressed concern about clinical image reviewers evaluating images from their own States or geographically limited areas. The comment proposed that FDA require ''blind'' readings of all images by reviewers and prohibit review if there is potential conflict of interest.

FDA disagrees with the suggestion that reviewers should be barred from reviewing images from the State in which the reviewer resides. Such a requirement would effectively preclude State accreditation bodies from having independent clinical image review programs. All present State accreditation bodies with independent clinical image review programs require and take measures to ensure blind reading to preclude bias, and FDA expects that any future State or national accreditation bodies will have similar safeguards as part of their QC, clinical image review, and conflict of interest standards.

(Comment 109). One comment recommended that ACR and any other professional organizations acting as accreditation bodies randomly select clinical image reviewers and phantom image reviewers from a pool to reduce the possibility of reviewer bias.

FDA agrees in principle that accreditation body reviews should not be biased, but finds no compelling reason to require use of pools and random selection. Under the MQSA, FDA has issued minimum requirements for all interpreting physicians and these requirements apply to any clinical image reviewer employed by an accreditation body. In addition, with these provisions, FDA is requiring each accreditation body to establish and implement procedures to train and evaluate its reviewers and to avoid conflict of interest. Within this framework, FDA concludes that the assignment of clinical image reviewers for any applicant facility is best left to the accreditation body.

d. *Equipment performance and design characteristics (§ 900.4(a)(5))*

These provisions are intended to prevent conflict of interest situations that could arise if the use of specific products were required by an accreditation body as a condition of accreditation.

(Comment 110). One comment stated that there may be an appearance of a conflict of interest by accreditation bodies in these situations and that special care must be taken with respect to the promotion of any product. The comment expressed the conclusion that the possibility of conflict is so great that it should never be acceptable for an accreditation body to require use of a particular product. A related comment stated that the accreditation bodies should not be able to require use of their own products by facilities they accredit. Over 15 additional comments opposed allowing the accreditation bodies to require the use of their products as a condition of accreditation or otherwise opposed commercial activities that would create a conflict of interest.

FDA understands the concerns expressed in these comments and notes that, in general, the regulation has been written to preclude accreditation bodies from requiring use of any specific brand or product. However, the agency believes exceptional situations may develop that warrant use of a particular product because of the public health benefits the product provides. The final regulation, therefore, gives FDA the flexibility to permit accreditation bodies to require the use of a specific commercial product when the agency has determined that such use is in the best interest of the public health.

(Comment 111). A few stated that conflict of interest requirements should not be an impediment to development of new technologies and services, nor be used by other entities to ''harass'' ACR and improperly influence FDA.

FDA agrees that conflict of interest provisions should not impede the development of new technologies, but also believes that it would undermine the integrity of the accreditation process if accreditation bodies could require facilities to use products the accreditation body develops as a condition of accreditation. FDA believes that the final regulations strike the proper balance between these competing interests.

(Comment 112). Over 150 comments on identical printed forms stated that FDA should prohibit conflicts of interest by accreditation bodies and should adopt the conflict of interest provision suggested by a trade association and included in the preamble to the final regulations (61 FR 14487).

FDA agrees that conflicts of interest by accreditation bodies stemming from accreditation body requirements to use specific products or services should be prohibited. However, none of these 150 comments offered arguments to support adopting the suggested provision or to explain why the agency's proposal was inadequate. FDA's experience under the

interim regulations demonstrates that potential conflicts can be addressed satisfactorily by the provisions of § 900.4(a)(6). The suggested conflict provision would effectively preclude development of products and services by an accreditation body. FDA believes that because accreditation bodies possess particular experience and expertise, such products and services have the potential to enhance practice or otherwise be beneficial to public health. For these reasons, FDA has concluded that it is unnecessary and would be inadvisable to adopt the suggested conflict provision.

(Comment 113). One comment stated that only FDA, as opposed to accreditation bodies or other entities, should be able to require the use of particular mammography related products and, if FDA does so, the use of such products should be required of all facilities.

FDA agrees with this comment as a general rule. However, FDA may approve the imposition of such a requirement by an accreditation body if the agency determines that it is in the best interest of public health to do so. Such an accreditation requirement would only apply to facilities accredited by the accreditation body that requested the approval unless FDA determined that adoption of the same requirement by all accreditation bodies was in the best interest of quality mammography.

(Comment 114). One comment requested clarification on the use of the word ''product,'' apparently asking whether the word was intended to apply to a specific item or a general category of products.

FDA believes that the word ''product'' is commonly understood. The conflict of interest provisions prohibiting an accreditation body from requiring a product to be used can apply to several product categories or to specific brands or products, depending on the circumstances.

(Comment 115). Finally, one comment made several suggestions related to these provisions. The comment contained the recommendations that FDA should require of accreditation bodies that: (1) Their accreditation and onsite inspections be managed by different departments; (2) their clinical image reviewers not review images from facilities in their home State to avoid a range of potential conflicts of interest; (3) reciprocity agreements between adjacent States be precluded; and (4) they meet at least the minimum standards of operation of the ACR program.

FDA believes that the internal division of responsibilities within accreditation bodies is not appropriate for regulation; many professional and government agencies have dual responsibilities for accreditation and inspection and are able to carry out those responsibilities fairly and effectively without necessarily using different departments. It was noted previously that the second suggestion was not accepted by FDA because it would effectively preclude State accreditation bodies from having independent clinical review programs. Because the third suggestion does not identify or otherwise describe the reciprocity agreements intended to be prohibited, the agency cannot respond. In answer to the last suggestion, FDA notes that all accreditation bodies are required to meet the final regulations governing accreditation bodies in order to become approved and maintain their accreditation authority. FDA will not approve any accreditation body that does not have standards of operation that ensure the accreditation body can meet its obligations under the MQSA. Nothing in the MQSA precludes ACR or any other accreditation body from having additional standards for aspects of mammography that are not within the scope of the MQSA. Nor does the MQSA impinge on a State's ability to enforce its own standards under State authority if those standards are at least as stringent as the MQSA's.

e. *Denial of accreditation to a facility (§ 900.4(a)(7))*

This paragraph was intended to ensure that no State accreditation body could bar facilities in that State from being accredited under the MQSA by any other FDA-approved accreditation body.

(Comment 116). Several comments raised questions that made it evident that this section was unclear as proposed. Comments asked whether a State accreditation body could require or restrict facilities within that State to accreditation by the State accreditation body. Other comments asked whether facilities could have more than one accreditation. This section has been rewritten so that the answers to both questions should be unambiguous.

As revised, the provision clearly states that no accreditation body can require a facility to be accredited by that accreditation body if more than one accreditation body is available. Nor can an accreditation body preclude a facility from being accredited by any other available accreditation body. Consequently, nothing in the final regulations prevents a facility from having more than one accreditation. However, FDA will issue only one certificate, usually based on the initial accreditation.

The geographic scope of authority for an accreditation body will be established through the accreditation body approval process. A State certainly could determine, as all current State accreditation bodies have, to restrict accreditation body activities to facilities within the State. A non-State accreditation body similarly could request to be approved to accredit in a limited geographic area. It would be up to the applicant to initially identify, based on its circumstances and resources, the area it intends to serve. In addition, FDA could restrict the scope of an accreditation body's authority to a geographical area that is smaller than that desired by the accreditation body if, for example, the agency had doubts about the ability of the accreditation body to provide adequate service in the desired area.

(Comment 117). One comment asserted that a State government cannot be restricted at any time from requiring its own accreditation guidelines to be met by facilities in that State.

FDA agrees that States may require facilities to meet standards under State law that are at least as stringent as those under the MQSA. However, such standards may not be required as a condition for accreditation under the MQSA.

One comment expressed the view that this provision was unnecessary because a facility accredited by a State agency would not voluntarily seek accreditation elsewhere. FDA disagrees with this comment. A small number of facilities have sought and received dual accreditation. In addition, the main point of the provision is to ensure that facilities are able to seek initial and exclusive accreditation under the MQSA from another accreditation body, even if the State acts as an accreditation body in their geographic area.

f. *Changes to standards (§ 900.4(a)(8))*

(Comment 118). FDA received two comments on this section, which requires an accreditation body to obtain FDA permission prior to changing any standards previously accepted by the agency. Both comments were generally supportive of the provision. One comment suggested verifying whether current technology is capable of meeting the requirements for any change in standards before the change is made. This will serve to minimize costs for both facilities and industry.

FDA agrees with this comment and routinely considers the adequacy of current technology during development of new standards or evaluation of

standards proposed by the accreditation bodies.

(Comment 119). One comment further stated that any proposed change to any standard by an accreditation body should be supported by scientific data and that FDA should seek industry input before authorizing the change. FDA agrees that changes in standards, and especially technical standards, benefit from the application of scientific data, where possible. The agency further agrees that industry input is often useful. However, FDA believes that, in many circumstances, the information already available to the agency is sufficient for a decision and that additional scientific data and outside comment will not be necessary. Therefore, FDA did not make this a regulatory requirement.

g. *Confidential information (§ 900.4(a)(9))*

This paragraph requires the accreditation bodies to establish procedures to protect confidential information.

(Comment 120). Ten comments asked how FDA will ensure that confidentiality will be maintained.

The intent of this provision is to guarantee that each accreditation body has in place procedures, programs, and systems that train employees to guard against unauthorized disclosure of information. Federal regulations, State laws, and contractual obligations will all play a part in determining an accreditation body's responsibility in any particular situation. In general, however, if FDA shares nonpublic information with an accreditation body about a particular facility, the record containing that information is an agency record under the control of FDA and the accreditation body would not be authorized to disclose that information without the permission of the agency. If an accreditation body, in violation of the final regulations, were to improperly use or disclose information received from a facility for purposes of accreditation, FDA believes the facility would have a private right of action against the accreditation body under the laws of most States. In addition, unauthorized disclosures of information, whether received from FDA or the facility, would be a basis for FDA to withdraw an accreditation body's approval. Nothing in these regulations, however, is intended to preclude or hinder the exchange of information between FDA and accreditation bodies when that information is required to be shared in order for the agency and the accreditation body to carry out functions under the statute.

(Comment 121). Three comments recommended allowing accreditation bodies to use and disclose information gathered during the accreditation process, if the identification of an individual, facility, or group is not compromised. Each comment cited the Freedom of Information Act (FOIA). A similar comment found this regulation to be overly restrictive, and stated that the regulation should allow use of the data for research purposes, ''so long as the released data involves only pooled information that does not allow identification of an individual, facility, or group.''

FDA generally agrees with these comments. Disclosure of aggregate information that does not reveal, directly or indirectly, the identity of particular facilities or individuals, is consistent with the FDA's regulations implementing the FOIA. However, in the event of ambiguity, accreditation bodies would consult with FDA and obtain clearance before making such disclosures. FDA does not believe data obtained from facilities for accreditation purposes should be used for purposes that have no relationship to accreditation body processes or standards, unless the accreditation body obtains the consent of the facility. This would not impede an accreditation body from using data to review and improve its internal processes, to educate personnel to improve accreditation body efficiency and performance, or to publicly discuss results of the processes using aggregate data.

(Comment 122). One comment noted that all data collected by or emanating from State agencies may be releasable under some State laws, and that nonpublic information is not necessary for accreditation. The comment also sought clarification about what would be deemed nonpublic information. A second comment stated that, in Arkansas, all information received by a publicly funded agency for accreditation review is releasable under that State's Freedom of Information (FOI) laws. A third comment, which also requested clarification on public versus nonpublic information, suggested that public information be limited to name, address, phone, and accreditation status. The comment noted that there have been complaints from radiologists about the use of information, including concerns about selling the MQSA certified facility address list.

FDA recognizes that people have varying ideas about what constitutes nonpublic information. Any information in the possession of FDA that is prohibited from disclosure under various statutes FDA enforces or that is exempt from mandatory disclosure under the FOIA is considered nonpublic information by the agency. Examples of such nonpublic information include data about the volume of business handled by any particular facility, the name or personal identifier of any mammography patient, and internal recommendations for enforcement action. FDA would not make such information public in response to a request for information under the FOIA.

As stated previously, accreditation bodies that obtain nonpublic information from FDA will be required to treat it as an FDA record and protect it accordingly. If an accreditation body obtains similar information from other sources, FDA expects the information will receive similar protection in the vast majority of cases. FDA has had public information regulations in place implementing the FOIA since 1977. During those years, FDA has found that State confidentiality laws are usually consistent with FDA's requirements. Arkansas' FOI law, e.g., which was cited by one comment, has provisions for exceptions to mandatory public disclosure that are similar to the Federal FOIA and FDA's implementing regulations. In situations where the accreditation body believes that State law requires disclosure of information that would be considered confidential if it were part of an FDA record, every effort will be made to consult State authorities and resolve the apparent inconsistencies.

In addition, FDA notes that all the currently approved accreditation bodies have had experience handling sensitive nonpublic information. ACR has done so for many years and, since the beginning of its voluntary MAP in 1987, has handled and processed information very similar to that required under the MQSA. The State accreditation bodies also have broad experience processing and protecting sensitive information because they have had previous responsibility regulating facilities under their own State laws. FDA has no evidence that any accreditation body has improperly disclosed information.

With respect to the comment that complained about the sale of a list of certified facilities, FDA notes that this sale was not by an accreditation body, and that the names and addresses of certified facilities would not, in any case, be nonpublic information. The list is available from NTIS for a nominal charge to cover the cost of reproduction and is also available from the Center for Devices and Radiological Health Internet site.

(Comment 123). Ten comments stated that permission to disclose nonpublic

information should rest with the facility, not FDA.

The final regulations are consistent with these comments. An accreditation body may not disclose to the public any nonpublic information it has obtained from a facility without the permission of that facility. If an accreditation body has obtained information about a facility from FDA or its duly designated representatives, including a State agency with responsibility for monitoring mammography facilities, the accreditation body cannot further disclose that information without the written permission of FDA. Because FDA is obligated to protect nonpublic information, it would not authorize release of information about any facility that was entitled to be protected from disclosure under the Federal law. FDA has added references in the final regulations to information obtained from or provided to State agencies because FDA's experience under the interim regulations demonstrates the necessity for sharing information among accreditation bodies, State authorities, and FDA in order to ensure quality mammography.

3. Facility Standards (§ 900.4(b))

This section outlined the responsibilities accreditation bodies must meet to ensure that facilities they accredit meet the FDA quality standards.

a. *General comments on facility standards*

(Comment 124). Seven comments requested that FDA add an additional provision to state, ''The accreditation body shall review previous inspection reports prior to issuing full accreditation.'' Eight additional comments recommended adding that sentence, plus the additional words, ''to previously accredited facilities'' at the end.

FDA appreciates the concerns of these comments that accreditation bodies have access to complete information about facilities that are applying for accreditation for the first time or to renew their accreditation. FDA disagrees that accreditation bodies should be required to review all prior inspection reports for every application it receives. Such a requirement could raise accreditation costs unnecessarily, and the prior accreditation history that each facility must submit with its accreditation application will provide a summary of significant related information. However, FDA encourages accreditation bodies to request inspection records from FDA whenever the accreditation body believes that such records would aid in review of an accreditation application.

b. *Monitoring facility compliance (§ 900.4(b)(1))*

Under this provision, an accreditation body must require each facility it accredits to meet quality standards that are substantially the same as those required by FDA.

(Comment 125). Six comments recommended using this provision to make the accreditation bodies responsible for reviewing continuing education and other personnel requirements, thereby eliminating verification of these personnel standards from the annual inspections.

FDA notes that the accreditation bodies have the responsibility under the interim regulations to ensure that personnel qualifications are met before they accredit a facility and will continue to have that responsibility under the final regulations. However, the number of personnel noncompliances found during inspections over the last 2 years illustrates the value of an onsite check of these qualifications. As experience with inspection and accreditation activities develop, FDA is working with the accreditation bodies to improve and enhance the role each plays in oversight of facility compliance with quality standards.

(Comment 126). One comment recommended replacing ''substantially the same'' with ''the same'' to ensure clarity.

FDA disagrees with this comment. The MQSA does not contemplate that the standards be identical; the statute uses the phrase ''equal to'' (42 U.S.C. 263b(e)(1)(B)(vi)). Using ''the same'' would unduly restrict accreditation bodies, and effectively preclude relatively minor differences that are necessary or appropriate because of different or changing circumstances among accreditation bodies.

c. *Facility compliance (§ 900.4(b)(2))*

(Comment 127). One comment stated that accreditation bodies should not be required to ensure that a facility correct noncompliances because accreditation bodies have no authority in these matters. Instead, the comment suggested that accreditation bodies be required to refer enforcement matters to FDA or, in the future, to a State certifying entity.

As discussed previously, FDA agrees that enforcement matters are ultimately the responsibility of the agency. This provision has been modified accordingly. As discussed previously (see section III.F.1 of this document), accreditation bodies have responsibility and authority to monitor compliance with standards and to suspend or revoke accreditation of facilities that do not maintain standards.

4. Clinical Image Review (§ 900.4(c))

FDA believes that effective clinical image review is essential for high quality mammograms. A primary purpose of the MQSA is to ensure that all mammography facilities have the benefit of such review and that accreditation bodies are qualified to perform that function. Accordingly, FDA proposed more specific requirements with respect to clinical image review than were established under the interim regulations. The proposed requirements, which were based on advice from NMQAAC and public comments, have been codified without significant changes in the final rule.

The regulations define three separate but related types of clinical image review. They are accreditation and reaccreditation clinical image review, random clinical image review, and additional mammography review. Each serves a different purpose within the framework of the MQSA and the regulations.

Accreditation and reaccreditation clinical image review is performed for each facility once every 3 years. Its purpose is to ensure that each facility is capable of producing and recognizing high quality images of fatty and dense breasts. Section 900.4(c) has been retitled in the final regulations from the general title that had been proposed, ''Clinical image review,'' to ''Clinical image review for accreditation and reaccreditation'' to clarify that the provisions of this section refer specifically to clinical image reviews performed for accreditation and reaccreditation.

In addition to clinical image review performed for routine accreditation and reaccreditation, the MQSA also requires the accreditation body to conduct random clinical image review. This type of review is performed on a selected sample of the accreditation body's facilities and serves three major purposes. Random clinical image review is an indicator of the quality of mammography performed at facilities, a measure of the performance of the accreditation body, and a method to assure the public that facilities continue to produce high quality images during the intervals between reaccreditation reviews. Under the provisions of § 900.4(f)(2), FDA is allowing each accreditation body to develop its own FDA-approved random clinical image review process to include at least 3 percent of its accredited facilities each year. This enables each body to individualize the review to best evaluate its facilities and monitor its own performance. While the accreditation bodies will be evaluating the same

attributes used for accreditation and reaccreditation clinical image review, they will have to adjust their scoring and pass-fail criteria to take into account that, due to the selection process, these studies may not be representative of the best images a facility can produce.

The third type of review is additional mammography review. This review is an evaluation of facilities that FDA has reason to believe may present a serious risk to human health due to compromised mammography quality. The term ''additional clinical image review,'' used in the proposal, was changed to ''additional mammography review'' to indicate that this review of problem facilities is not necessarily limited to an evaluation of clinical images but can involve all aspects of mammography at the facility. The requirements for this type of review are provided in § 900.12(j).

a. *Frequency of clinical image review (§ 900.4(c)(1))*

Section 900.4(c)(1) states that clinical image review for accreditation and reaccreditation shall be performed at least once every 3 years. This is in accordance with the requirements specified by the MQSA.

b. *Attribute requirements (§ 900.4(c)(2))*

Section 900.4(c)(2) lists the eight attributes to be used for evaluating clinical images.

(Comment 128). One comment agreed with the section as proposed, while another comment thought it was too proscriptive and did not allow for changes in technology and assessment. Two other comments stated that the attributes were too vague, while another said that the attributes should be identical to any existing standards and definitions currently in use.

FDA notes that the attributes described in § 900.4(c)(2) were derived from existing standards that have been used successfully for mammographic evaluation for many years. Accreditation bodies are currently using these attributes to evaluate clinical images under the interim regulations. FDA does not believe the use of these attributes will limit the introduction of new technologies because FDA has the flexibility to modify the attributes for new mammographic modalities, if necessary.

(Comment 129). One comment recommended that the contrast, sharpness, and noise attributes should be dropped because all mammograms contain some blurring and noise.

FDA agrees that some degree of blurring and noise occur on all films. However, these attributes should be evaluated to determine if the blurring or noise are of such severity as to obscure anatomical structures.

(Comment 130). Several comments addressed specific attributes. One comment stated that the positioning attribute implies that it is not necessary to get all the breast tissue on the film.

FDA notes that, due to anatomical and mammographic limitations, all breast tissue cannot be imaged on each view. The requirement was specifically written by FDA to take this fact into account.

(Comment 131). Several comments, including one from NMQAAC, urged that the word ''tissue'' be replaced with ''image'' when referring to exposure and that ''processing'' should be added to the list of ''artifacts.''

FDA agrees that ''processing'' should be added to the list of ''artifacts'' and has changed ''tissue exposure'' to ''exposure level'' to be more consistent with existing standards and definitions.

(Comment 132). One comment was unclear as to whether ''noise'' was the same as ''quantum mottle.'' FDA notes that ''quantum mottle'' is a form of ''noise,'' although it is not the only form of ''noise.''

(Comment 133). Several comments opposed the examination identification attribute as being too specific and requiring too much information to be placed in the small flasher space. Two comments supported the description of the attribute as written.

FDA has received a great deal of advice from NMQAAC regarding the importance of examination identification as an attribute of quality mammography and believes that the present requirement is in the best interest of the patient. A facility may satisfy the requirements for examination identification through the use of stick-on labels so that all the information does not have to fit within the flasher space. NMQAAC recommended specifically adding the name and an additional identifier to patient identification. FDA agrees with this suggestion and has modified this section accordingly.

(Comment 134). One comment stated that technical factors such as kVp, milliamperes (mA's), and amount of compression should be required on all films because this information would aid in evaluating problems. It noted that ACR recommends recording these technical factors.

FDA believes that facilities should have the option of recording this information if they believe it beneficial for their practice. Because many facilities have indicated that having this information on all images is not useful, the agency does not believe it is cost effective to make this a mandatory requirement for all facilities.

(Comment 135). Two comments, and several members of NMQAAC, stated that FDA must ensure that accreditation bodies prevent reviewers from knowing the identity of the facility under review, especially in the case of local reviewers.

FDA agrees that this is an important issue and has discussed it in response to comments on § 900.4(a)(4), which addresses possible conflicts of interest by image reviewers.

(Comment 136). One comment asked if the technologist identification is meant to be unique for a facility, for a particular health corporation, or nationally recognized. The technologist identification requirement is facility-based and any system that enables the facility to determine which technologist performed the examination should be acceptable.

(Comment 137). One comment agreed that mammography unit identification was important for reproducibility, while another asked whether it would be possible to have the unit identification on the patient's question and answer form rather than on the film.

FDA believes that, in cases where there is more than one unit in the facility, the unit identification should be on the film, so that this information may be obtained without referring to other sources.

c. *Scoring clinical images (§ 900.4(c)(3))*

Section 900.4(c)(3) requires the accreditation body to establish a system for scoring clinical images using the attributes in § 900.4(c)(2) and to develop pass-fail criteria for these attributes. It also requires that images be independently reviewed by two or more clinical image reviewers. This section was modified from the proposal to clarify that each attribute shall be individually evaluated.

(Comment 138). One comment warned that perfectly acceptable images can be rejected by the clinical image review process if a pass-fail system is used. The author believed that there should be some form of grading system for the evaluation of the films.

FDA agrees that a grading system should be employed in evaluating the studies. A requirement for such a system was in the proposed regulations. It has been modified in the final regulations to require that acceptable and unacceptable results be established for each of the eight attributes and an overall pass-fail system. This change ensures that each facility has the benefit of an evaluation of each attribute, providing the facility with the

information essential to take appropriate corrective actions when necessary. FDA's experience under the interim regulations indicates that failure by the clinical image review process of what are later judged to be acceptable images is an unusual occurrence. In those rare cases where the facility disputes an accreditation body clinical image review decision, the facility has the option of appealing this adverse decision to the accreditation body and then to FDA.

(Comment 139). One comment said that the specific details of the scoring process should be made public, utilized in an identical manner by all accreditation bodies, be verified, and result in a numerical score for each set of films reviewed. FDA notes that the determinants of high image quality mammography have already been made public by accreditation bodies, professional organizations, and by clinical authors publishing in peer review radiology journals. This information should be incorporated into each facility's quality assurance program and should be used for selecting the studies that are submitted to the accreditation body for clinical image review. FDA believes that the specific details of the accreditation body's scoring procedures should remain confidential to preserve the integrity of the process. However, the details will be reviewed and evaluated by the agency as part of FDA's approval and oversight responsibilities.

d. *Selection of clinical images for review (§ 900.4(c)(4))*

Section 900.4(c)(4) describes the number and types of images that shall be submitted by the facility for accreditation and reaccreditation clinical image review.

(Comment 140). Four comments stated that accreditation and reaccreditation clinical image review should be done on randomly selected images rather than the ''best'' images a facility can produce, arguing that this would give a better indication of the quality of mammography being performed. One comment agreed with § 900.4(c)(4) as proposed, but suggested adding one randomly selected set of images. One comment mistakenly believed that FDA was allowing accreditation bodies to use either random or nonrandom selection of clinical images for accreditation or reaccreditation clinical image review.

FDA has retained the provision that accreditation and reaccreditation clinical image review is to be performed using the ''best'' images a facility can produce. Using this criterion for selection allows the accreditation body to apply its highest standards to the scoring of these images. It also serves as a check on facility personnel to see if they understand what makes a high quality image. Random clinical image review, as required in § 900.4(f), serves a different purpose than accreditation and reaccreditation clinical image review. Although the accreditation body evaluates the same attributes, the scoring standards are more flexible to take into account that these may not be the ''best'' images a facility can produce.

(Comment 141). Two comments stated that clinical image review is extremely valuable, but that more films should be reviewed.

FDA disagrees. Requiring review of additional studies would serve to raise the cost and complexity of the review process without a demonstrable increase in quality. During discussions with NMQAAC, a majority of the committee agreed with FDA's position on this issue.

(Comment 142). Two comments urged FDA to replace the term ''view'' with ''projection.''

FDA discussed this with NMQAAC, who agreed with the agency that ''view'' is the correct term to use in this context.

(Comment 143). Six comments stated that clinical images for accreditation and reaccreditation review should be selected from a specified period of time. Three comments, including a consensus of NMQAAC, stated that both the clinical images and the phantom image should be from the same 30-day period.

FDA did not set timeframes for submission of images in the regulations in order to allow the accreditation bodies to establish these timeframes based on their own circumstances and experience with the review process. The agency has rejected the suggestion that phantom and clinical images be from the same 30-day period because this could create logistical problems if a second set of clinical images had to be submitted.

One comment expressed the author's belief that a national accreditation body should develop materials showing examples of acceptable dense and fat-replaced breast images. FDA encourages accreditation bodies to provide such information and education but does not believe that this is a matter that should be addressed in regulation.

(Comment 144). Several comments, including a consensus of NMQAAC, stated that it is often difficult to find images that are totally normal and suggested that images could be sent from either negative or benign assessment categories.

FDA agrees and has modified § 900.4(c)(4)(iii) accordingly.

(Comment 145). One comment suggested that § 900.4(c)(4)(iv) be revised to allow a facility to submit alternative mammograms only if the facility does not have images interpreted as normal under § 900.4(c))(4)(iii). It stated that no alternatives should be accepted for craniocaudal and mediolateral views required in § 900.4(c)(4)(I) or for dense and fatty breast images required in § 900.4(c)(4)(ii). FDA disagrees and believes that accreditation bodies should be given the flexibility to deal with these situations in an appropriate and individualized manner.

e. *Clinical image reviewers (§ 900.4(c)(5))*

Section 900.4(c)(5) requires the accreditation body to ensure that its clinical image reviewers are interpreting physicians, are trained and evaluated in the clinical image review process, document their findings and the reasons for assigning a particular score to any clinical image, and provide information to the facility for improving image quality.

(Comment 146). Several comments, including some from NMQAAC, stated that criteria for clinical image reviewers should be more detailed and that FDA should specify a minimum training and evaluation curriculum or other performance-based measure. One comment stated that it was essential for all accreditation body clinical image reviewers to meet minimum standards of reliability.

FDA notes that § 900.4(c)(5) establishes the basic requirements for clinical image reviewers and serves as the starting point for the accreditation bodies to develop their own additional requirements. Through its oversight activities, FDA ensures that the different accreditation programs are internally and externally consistent. FDA currently monitors accreditation body policies to achieve consistency in critical areas. The agency has worked and continues to work with the accreditation bodies to enhance existing procedures and establish new programs to monitor inter- and intra-accreditation body consistency for clinical image review.

(Comment 147). Five comments suggested that inspectors be trained to be clinical image reviewers. These comments reasoned that such training would permit a more accurate evaluation of clinical image quality than the current practice of letting facilities pick their best films for accreditation body evaluation. One of the comments contended that image quality would improve overall if a facility knew that

any image could be reviewed during inspections.

The MQSA assigns primary responsibility for clinical image review to accreditation bodies. The agency has established basic standards for clinical image reviewers, including that they be interpreting physicians, and will review and monitor each accreditation body's performance of this critical function. However, FDA believes the actual evaluation of clinical images should remain the role of the accreditation body. At its January 1997 meeting, NMQAAC discussed the issue of using the MQSA inspectors for clinical image review. They concluded, and the agency agrees, that inspectors do not have, nor can reasonably be given, the training and expertise required to perform clinical image review.

f. *Image management (§ 900.4(c)(6))*

Section 900.4(c)(6) requires the accreditation body to establish a tracking system for clinical images to ensure their security and return to the facility within 60 days.

(Comment 148). One comment stated that the requirement to return all clinical images within 60 days was too restrictive, because 60 days would not be adequate if a third review were required. This comment recommended 90 days. Another comment stated that the turnaround time for accreditation body image review was already too long, and that such delays limited a facility's opportunity to submit a second set of improved images within the review time cycle. A third comment stated that films should be returned to facilities in 45 to 60 days.

With respect to this matter, FDA has had to balance the needs of the facility against those of the accreditation body. Using the experience gained under the interim regulations, the agency concludes that the 60-day period is appropriate.

(Comment 149). One comment stated that § 900.4(c)(6)(ii) should clearly state that the accreditation body is obligated to inform only the facility of any abnormalities found on clinical images submitted to the accreditation body which had been interpreted by the facility as negative. The comment explained that this obligation should not extend to informing either patients or referring physicians.

FDA believes it is imperative that patients and referring physicians be notified of any suspicious abnormality detected during the clinical image review process. However, the agency has concluded that only the facility that performed the examination has access to the necessary patient and referring physician information to allow proper notification of the affected individuals. FDA has modified the regulation accordingly.

(Comment 150). One comment stated that proposed § 900.4(c)(6) implied that mammography reports would be sent to the accreditation body with the films. The comment asserted that requiring facilities to submit reports would raise concerns about patient confidentiality and establish an additional and new requirement for facilities.

FDA agrees with this comment and the regulation has been amended to delete the reference to mammography reports.

g. *Unsatisfactory image quality (§ 900.4(c)(7))*

Section 900.4(c)(7) describes the accreditation body's responsibility when it determines that clinical images from a facility that it accredits are unsatisfactory.

(Comment 151). One comment stated that the accreditation body has no direct authority to ''take appropriate action'' if corrective measures to address poor clinical image quality are not implemented by the facility.

Section 900.4(c)(7) has been modified from the proposal to address this comment. As discussed previously, FDA agrees that responsibility for enforcing compliance with the MQSA requirements rests primarily with FDA. Accreditation bodies, however, can and are expected to take action to revoke or suspend the accreditation of facilities that do not comply with standards established by the accreditation body, which include producing high quality clinical images. This section has been changed to state that the accreditation body is responsible for notifying the facility of the nature of the problem and its possible causes. The requirements that have been deleted, to monitor the progress of the facility and to take appropriate action if corrections are not made, are inherent in the accreditation process and have been stated previously in § 900.4(a)(1)(ii).

5. Phantom Image Review (§ 900.4(d))

The review of phantom images is an important part of the evaluation of a facility for accreditation. The production and evaluation of phantom images is also an important part of the medical physicist survey, of the facility inspection, and of the facility's quality assurance program. However, § 900.4(d) covers only the requirements that the accreditation body must meet to ensure that its phantom image reviews are performed accurately, in a timely fashion, and without bias.

a. *General comments on phantom image review*

(Comment 152). Two comments stated that phantom image review by the accreditation body is unnecessary because it is performed twice a year, once by the medical physicists during annual physics surveys and again by inspectors during yearly inspections.

FDA notes that, as with clinical image review, the phantom image review performed during the accreditation process and the reviews performed at other times have different purposes. The words ''for accreditation and reaccreditation'' have been added to the title of § 900.4(d) to clarify the purpose of the phantom image review in this section. During the accreditation process, phantom images are reviewed by the accreditation body to determine if the facility is producing adequate quality images to permit its accreditation or reaccreditation. The phantom image reviews conducted during a medical physicist survey, an inspection, or as part of the facility quality assurance program are intended to provide some assurance that the facility continues to produce adequate quality images during the 3-year interval between accreditations. Because of these different objectives, the agency believes that the multiple phantom image evaluations are not redundant.

b. *Phantom image reviewers (§ 900.4(d)(5))*

This paragraph discussed the requirements for and the procedures to be followed by the phantom image reviewers.

(Comment 153). Two comments stated that FDA did not provide any specific qualifications and training requirements for the accreditation body phantom image reviewers in the proposed rule. One comment wanted further clarification of these qualifications and the other expressed concern that accreditation bodies may have widely different criteria for phantom image reviewers. A few comments recommended that only medical physicists be considered qualified for phantom image review, but another comment expressly opposed that limitation. Six comments supported § 900.4(d)(5)(I) as written.

FDA has stated in § 900.4(d)(5)(I) that the accreditation bodies must ensure that their phantom image reviewers meet the requirements specified in § 900.12(a)(3) for medical physicists or alternative requirements established by the accreditation bodies and approved by FDA in accordance with § 900.3(d). The agency believes that this provides sufficient guidance to accreditation bodies with respect to qualifications and training requirements, while permitting flexibility to accommodate different

circumstances among the accreditation bodies.

FDA does not agree with the comments that only medical physicists should be allowed to perform phantom image review, although any medical physicist who met either the requirements in § 900.12(a)(3) or FDA-approved alternative requirements could serve in this capacity. The key criteria are that the individuals doing the phantom image review be adequately trained in the review process and have sufficient educational background to understand the concepts involved. The ability to carry out the full range of the responsibilities of the medical physicists under the MQSA is not required. The agency believes, therefore, with proper training and experience, individuals other than medical physicists can become qualified to evaluate phantom images.

All phantom image reviewers, whether or not they are medical physicists, must comply with the additional requirements, established by FDA in § 900.4(d)(5)(ii) and (iii), to be trained in the review process, to document scoring, and to provide feedback to facilities on improvement measures. If the accreditation bodies develop their own alternative or additional requirements for phantom image reviewers, FDA will ensure consistency among the accreditation bodies through its oversight program.

(Comment 154). Eight comments wanted the agency to require phantom image review by at least two reviewers. One comment stated that all facilities should use the same phantom and the same scoring procedure.

The agency has no evidence to suggest that double reviews are necessary for adequate evaluation and did not make this a regulatory requirement. However, FDA notes that it is currently the common practice of all accreditation bodies to have all failed phantom images evaluated by a second reviewer.

FDA disagrees with the comment regarding the same phantom and scoring procedures for all facilities. The agency wants to refrain from specifying either a phantom type or scoring methodology in order not to inhibit future advancements in phantom evaluation procedures. In addition, experience has shown that phantom type and scoring methodology is generally consistent from facility to facility even without a regulatory requirement. FDA will continue to monitor the situation and will ensure that any different phantoms or scoring methodology that may be in use will not compromise the minimum standards currently approved.

(Comment 155). Two comments on this provision expressed concerns about possible conflicts of interest for reviewers. FDA has addressed this issue in § 900.4(a)(4), which was discussed previously.

c. *Image management (§ 900.4(d)(6))*

As proposed, this paragraph required the return of the phantom image to the facility that produced it.

(Comment 156). Three comments stated that returning phantom images increases costs without benefit. Another stated that retaining the images would allow the accreditation body to compare past and current images to assess possible changes in a facility's QC program.

FDA believes that phantom images that result in a failure of accreditation should be returned to the facility in order to illustrate the accreditation body's assessment of the nature of the problem and its possible causes. Such images can be a valuable learning tool for the facility as it seeks to correct its problems. To minimize costs, however, FDA has revised this paragraph to require the accreditation body to return only those images that cause a failure.

d. *Notification measures for unsatisfactory image quality (§ 900.4(d)(7))*

As proposed, this paragraph described a variety of actions that the accreditation body should take if it finds a facility's phantom image is of insufficient quality to permit accreditation of the facility. The provision has been revised, as has the parallel provision for clinical image review discussed above, to focus on the accreditation body's obligation to notify the facility of the nature of the problem identified and of possible solutions.

(Comment 157). Six comments supported § 900.4(d)(7) as proposed. The comments stated that this requirement provides assistance to the facility and promotes timely correction of problems. Two comments expressed concern that the accreditation bodies could ''close'' a facility on the basis of inadequate quality of phantom images even if the facility had been producing high quality clinical films. The comments explained that this could happen because of the subjective nature of phantom image review and the fact that problematic phantom images are unavoidable, in spite of adequate care.

Because § 900.4(d)(7) requires the accreditation body to notify the facility of the nature of the problem and its possible causes, FDA does not believe the review process will prevent accreditation of a facility that is able and willing to devote resources to improvements in this area. It is the policy of the approved accreditation bodies to offer facilities at least two chances to improve the quality of failed images to the satisfactory level. If the facility uses the information provided by the accreditation body on the possible causes of the problem to guide corrective actions, the agency believes that a facility producing high quality work, as the comments described, should be able to achieve the minimum phantom image quality required by the accreditation body.

(Comment 158). One comment stated that the accreditation body has no direct authority to ''take appropriate action'' if corrective measures are not implemented.

As discussed previously in connection with clinical image review, nothing in the proposed provision would require the accreditation body to act beyond its authority, which includes a responsibility to deny, suspend, or revoke accreditation of facilities that do not achieve the accreditation body's standards. However, the agency has reworded the provision to focus on its primary purpose, which is to ensure that facilities who fail the phantom image review are informed of the causes.

6. Reports of Mammography Equipment Evaluations, Surveys, and QC (§ 900.4(e))

This paragraph describes the reports on the evaluations of their equipment that the accreditation body must require from each facility, the reporting schedule, and the responsibility of the accreditation body to review the reports and to use them in accreditation decisions.

(Comment 159). Several comments expressed varying viewpoints on the need for submission of this information and who should evaluate it. One comment stated that it is redundant for facilities to have to submit information about equipment to the accreditation body because each facility is inspected annually, and also may receive an onsite visit from an accreditation body. This would result in three reviews annually, which would be unnecessary and burdensome to both the facility and the accreditation body. Three other comments also stated the position that the accreditation body should be the sole evaluator of the annual physicist survey. One of the three also contended that the inspector, unless a qualified mammography medical physicist, is not qualified to review these reports. This comment suggested that the inspection review be eliminated and that the accreditation body be required to send a statement to FDA confirming that the report was received and reviewed.

On the other hand, one comment urged that both the accreditation body and the inspector continue to review the physicist survey reports. Another comment stated that, if duplicate review is not deemed cost effective, then the inspector should review the survey rather than the accreditation body. These two comments agreed that it is imperative that the facilities both read the report and correct any deficiencies that could lead to noncompliance or degradation of images, but expressed a concern that facilities would not do so unless both the accreditation body and the inspector required such actions. A third comment agreed that the inspector should not just accept the accreditation body's review of the facility survey. Valuable information would be lost if the inspector does not review the survey.

FDA believes that having both the accreditation body and the inspector review the physicist's report is consistent with the MQSA's reliance on review by different entities and is a benefit to the public health, especially during these early years of the MQSA program. The two checks are different in nature. The accreditation bodies make a complete assessment of such surveys as they are reported annually. Inspectors, on the other hand, do not evaluate the surveys the same way. Instead, inspectors check for completeness and to determine if the facility has implemented necessary corrections identified in the survey. Typically, the submission of surveys to the accreditation bodies and the occurrence of inspections are not coincident. Having the inspectors do an independent check may draw attention sooner to an incomplete survey or a problem found by the survey that has not yet been corrected.

(Comment 160). One comment asked how five facilities became accredited without physicist reports.

FDA and the accreditation bodies are unaware of any facilities that have been accredited without physicist reports. Because the facilities for which such accreditation was alleged were not identified in the comment, it is not possible to respond further.

(Comment 161). Nine comments argued, that as proposed, § 900.4(e)(2)(i) would lead to facilities changing from a 12-month cycle to a 14-month cycle for the medical physicist survey.

FDA agrees with these comments and the section has been changed accordingly.

7. Onsite Visits to Facilities and Random Clinical Image Reviews (§ 900.4(f))

The MQSA requires that accreditation bodies make a ''sufficient number'' of onsite visits to the facilities they accredit ''to allow a reasonable estimate of the performance'' of the body (42 U.S.C. 263b(e)(4)(A)). The statute also requires the accreditation body to conduct random reviews of clinical images from the facilities it accredits, in addition to the clinical image reviews required for accreditation (42 U.S.C. 263b(e)(1)(B)). Section 900.4(f) implements these requirements.

a. *General comments on onsite visits*

(Comment 162). One comment questioned the cost-effectiveness of requiring accreditation bodies to prepare three copies of a summary report describing all facility assessments conducted during that year. The comment asserted that FDA could review this information during the annual oversight inspection of the accreditation body.

Under the statute, FDA is required to evaluate the performance of each accreditation body. The summary of onsite visits provides valuable information on which to base such evaluations. FDA, therefore, retained the requirement that three copies of the summary be included in the accreditation body's annual report to FDA. Multiple copies will allow simultaneous review by multiple reviewers and, in the event that some of the materials are difficult to reproduce, will help ensure uniformity and readability of the materials.

b. *Onsite visits (§ 900.4(f)(1))*

(Comment 163). Three comments agreed with the need for onsite visits, while two comments stated that the visits were unnecessary. Two comments recommended that the onsite visit be combined with the annual inspection, while two other comments stated that the onsite visit should not be construed as a substitute for, or be conducted during, the annual inspection. One comment stated that the onsite visit process does not serve as a check of the accreditation body's quality assurance process.

FDA reiterates that the requirement for onsite visits by the accreditation bodies is established by the statute (42 U.S.C. 263b(e)(4)). The purpose of such visits is to provide a mechanism by which accreditation bodies can ensure facility compliance with quality standards and monitor their own performance of accreditation functions. The accreditation body will be able to compare the consistency of results from visits to information obtained through other accreditation body functions. These onsite visits by the accreditation bodies are different from and are intended to be complementary to the annual inspection of every certified facility performed by FDA or State inspectors. Combining the two evaluations into one review would likely undermine the effectiveness of both visits and inspections. This issue was discussed with NMQAAC and the agency's position was supported by a consensus of the committee.

(Comment 164). One comment recommended a prior notice of 5 days for onsite visits so as not to disrupt patient care. FDA believes that accreditation bodies will need flexibility in scheduling onsite visits. In some cases, particularly if an accreditation body has serious concerns about a facility's ability to meet quality standards, significant advance notice would not be appropriate. In general, for facilities selected randomly for onsite visits, FDA encourages accreditation bodies to work with facilities to schedule visits that minimize patient inconvenience and disruption to facility operations. This has been the general practice of all accreditation bodies.

c. *Sample size (§ 900.4(f)(1)(I))*

Section 900.4(f)(1)(I) requires accreditation bodies to select some facilities for onsite visits on a random basis and select other facilities based on specific reasons for concern about those facilities, such as a previous history of noncompliance with quality standards. In general, each accreditation body will have to visit annually at least 5 percent of the facilities it accredits, up to a maximum of 50 facilities, but no less than 5. The number could exceed 50 if many facilities need to be visited because of previously identified concerns.

(Comment 165). Two comments agreed with § 900.4(f)(1)(I) as proposed. However, 14 comments recommended that the maximum of 50 facilities be raised to a higher number. Reasons given for the increase included a belief that 50 is not statistically significant for a large accreditation body. Two comments wanted the number raised because they had ''seen too many certified facilities with questionable compliance.'' One comment stated that a national accreditation body should visit at least one facility from each State or region.

The agency disagrees with raising the number of onsite visits. FDA has discussed with NMQAAC and the accreditation bodies the issue of the number of onsite visits that an accreditation body can reasonably perform. There was general agreement among NMQAAC and the accreditation bodies that the regulation should not be changed. The agency has had to balance

the benefits of accreditation body onsite visits against its monetary cost. Requiring more than 5 percent or 50 facilities could significantly increase the cost of accreditation and potentially reduce the number of accredited facilities and access to mammography without commensurate benefit.

d. *Visit plan (§ 900.4(f)(1)(ii))*

Section 900.4(f)(1)(ii) establishes baseline standards for the conduct and content of the onsite visits.

(Comment 166). Four comments, including a consensus of NMQAAC, stated that the composition and qualifications of onsite visit teams should be specified. One of the comments recommended that the team be comprised of a qualified active clinical image reviewer, a phantom image reviewer, and an accreditation body staff member.

The agency believes that the accreditation body is in the best position to define the onsite visit team. This gives the accreditation body the flexibility to tailor the team to the specific needs of the facility, thereby reducing costs while maintaining quality.

(Comment 167). One comment believed that the decision to review clinical images and the selection of images should be made at the discretion of the accreditation body at the time of the visit. It stated that, if the facility has proper quality assurance procedures in place, it may not be necessary to review the clinical images. FDA disagrees. The agency believes that clinical image review is one of the most important aspects of the entire MQSA program and should be a part of every accreditation body onsite visit.

(Comment 168). Two comments, including a consensus of NMQAAC, recommended that § 900.4(f)(1)(ii)(D) be amended to require the accreditation body to ''verify the presence'' of the facility's medical outcomes audit system during an onsite visit, rather than ''review'' the system; requiring a review implies that the visit team is evaluating the audit against an agreed upon standard rather than verifying that a system is in place.

FDA agrees and has modified this section accordingly.

e. *Clinical image review for random sample of facilities (§ 900.4(f)(2))*

This paragraph establishes the requirements for the clinical image review for a random sample of facilities.

(Comment 169). Sixteen comments stated that there appears to be a contradiction in the preamble to the proposed regulations because remarks in one section questioned the effectiveness of random clinical image review, but another section stated that random visits for facilities are effective.

FDA believes that the comments are comparing the agency's views of two different processes. The agency believes that random clinical image review is a useful tool in the evaluation of facilities and accreditation bodies. However, the agency stated in the proposal's preamble (61 FR 14890) that random clinical image review would not be an effective use of accreditation body resources if applied to all facilities. Random onsite visits to a limited number of facilities represent a different tool to evaluate facilities and accreditation bodies and, as stated in the preamble to the proposal, are effective in this context.

(Comment 170). One comment stated that the goals of random clinical image review should be clearly determined prior to establishing minimum quality standards.

As previously stated, the purpose of random clinical image review is to serve as an indicator of the quality of mammography performed at facilities, a measure of the performance of the accreditation body, and a method to assure the public that facilities continue to produce high quality images during the intervals between reaccreditation reviews. In this context, FDA believes that it is important that the accreditation bodies be given the flexibility to develop a process for random clinical image review that is best suited to meet their needs and those of their accredited facilities. However, the agency notes that § 900.3(b)(3)(iii) requires a prospective accreditation body, as part of its application, to give FDA a description of its procedures for performing random clinical image review. In addition, the agency will monitor the use of random clinical image review as part of its oversight responsibilities.

Eight comments stated that the sample size for random clinical image review in proposed § 900.4(f)(2)(I) should be increased. Two of the comments recommended that all facilities undergo random clinical image review in each 3-year period. One of these comments stated that this is required by the statute.

FDA addressed this issue in the preamble to the proposed rule and believes its interpretation of the statute is reasonable. FDA's proposal changed the interim rule, which required random clinical image review at every accredited facility, to a requirement that the accreditation body select a sample of facilities for random clinical image review. The change in the sampling requirement was based on FDA's experience under the interim regulations. The agency believes that annual random clinical image review for every facility, in addition to the clinical image reviews required for initial accreditation and reaccreditation, is not an effective use of accreditation body resources. FDA does agree that, after more data are accumulated, the 3 percent sample in the proposal may prove to be too low. The agency, therefore, has revised the provision to state that at least 3 percent of the facilities be sampled annually, to allow the agency more flexibility to modify the sample size if information obtained in the future justifies such a modification.

Section 900.4(f)(2)(ii) has also been revised from the proposal to clarify that reviewers performing random clinical image review shall evaluate the same film attributes used in accreditation and reaccreditation clinical image review.

(Comment 171). One comment stated that randomly selected clinical images should not be evaluated with the same stringent requirements as those used for evaluating the ''best'' clinical images submitted for initial accreditation or reaccreditation.

As previously stated, FDA will require the accreditation body to evaluate the same attributes in the random clinical image review as are evaluated in the accreditation and reaccreditation clinical image review. As previously explained, the agency believes that accreditation bodies will have to adjust their scoring and pass-fail criteria to take into account that, due to the selection process, these examinations may not be representative of the best images a facility can produce. Such adjustments are appropriate and are permitted under the final regulations.

Section 900.4(f)(2)(iv) has been added to the regulations to clarify that the process for selection of images for random clinical image review may differ from the process for selection of images for accreditation and reaccreditation clinical image review.

(Comment 172). Two comments noted that different accreditation bodies already have instituted different selection criteria for their random clinical image review. One comment suggested that the review should be a combination of random (selected by the inspector) and nonrandom (selected by the facility) studies.

FDA recognizes that, under the interim regulations, each accreditation body has developed its own process for random clinical image review. Each is designed to best serve the needs of the accreditation body and its accredited facilities. The agency believes this

flexibility encourages efficient and effective review and has not changed the requirement. FDA believes that the selection of a combination of random and nonrandom studies would complicate the review process without a corresponding benefit. FDA is working with all of the accreditation bodies to further refine and improve their procedures and programs and will continue to do so. As noted previously, although each accreditation body can devise its own process for random clinical image review, that process must be reviewed and approved by FDA.

8. Consumer compliant mechanism (§ 900.4(g))

This paragraph describes the responsibilities of the accreditation bodies to ensure that serious consumer complaints are adequately addressed.

(Comment 173). The comments received were very similar to those received on § 900.12(h), which outlines the responsibilities of the facilities in this area. The comments on both of these paragraphs are discussed in section III.L.8 of this document in connection with § 900.12(h).

9. Reporting and recordkeeping (§ 900.4(h))

No comments were received on this paragraph, which describes the mechanisms by which the accreditation bodies provide information to FDA.

Consequently, this section was codified with only minor editorial changes.

10. Fees (§ 900.4(I))

This paragraph outlines the requirements that must be met by accreditation bodies to ensure that the accreditation fees are reasonable.

(Comment 174). Eight comments claimed that any fees are unreasonable, particularly for small practices, while another comment requested that multi-unit facilities be charged a higher fee.

The MQSA clearly intended that the accreditation process be supported through facility fees and that the agency be assigned the task of ensuring that such fees are reasonable (42 U.S.C. 263b(e)(1)(B)(iii)). FDA could not prohibit fees even if another source of funding were available. In response to the last comment, the agency notes that accreditation bodies can and do charge higher fees to multi-unit facilities.

G. Evaluation (§ 900.5)

This section states that FDA will evaluate the performance of each accreditation body annually, as required under the MQSA, and briefly outlines information that will be reviewed as part of the evaluation.

(Comment 175). One comment urged FDA to establish standard evaluation criteria and procedures to apply to the review of all accreditation bodies prior to establishing final regulations.

FDA agrees with this comment. Different accreditation bodies have different operational circumstances, e.g., geographic area and facilities served. Consequently, with FDA approval, they may have somewhat different programs. However, despite program differences, all accreditation bodies have to comply with the regulations governing accreditation body activities. Therefore, FDA has developed standard evaluation criteria that are being used to evaluate all accreditation bodies.

H. Withdrawal of Approval (§ 900.6)

This section outlines the enforcement actions available to FDA, including withdrawal of approval, if the agency determines that an approved accreditation body has not remained in substantial compliance with the requirements.

(Comment 176). One comment stated that ''major accreditation functions,'' upon which FDA could base a decision to withdraw an accreditation body approval, should be clearly identified. Another asked how FDA would verify that an accreditation body, whose approval had been withdrawn, had notified all of its facilities. Two other comments protested elimination of the mandatory schedule for accreditation bodies to submit corrective action plans for minor deficiencies.

Based upon its history of regulating accreditation body activities under the interim regulations, FDA believes that withdrawal of approval of an accreditation body would be rare and, in any case, would follow notice of problems and attempts to bring the body into full compliance. Should such a withdrawal occur, however, FDA would closely monitor the entire process of closing down the accreditation body operations, including the required notification of facilities.

FDA finds no basis for imposing mandatory schedules for correction of minor accreditation body deficiencies. Since approval of the first accreditation body in 1994, FDA has maintained a close working relationship with all the MQSA accreditation bodies. Accreditation body operational activities that might have been categorized as ''minor deficiencies'' have been resolved quickly and satisfactorily through direct communication with the accreditation bodies, rendering specific mandatory time limits for all such corrections unnecessary. The regulation continues to provide FDA with authority to specify a time period for any particular corrective action.

I. Hearings (§ 900.7)

This section describes the rights of accreditation bodies and facilities to hearings challenging adverse actions.

(Comment 177). Only one comment was received and it supported this section as written. Consequently, this section was codified with only minor editorial changes.

J. Applicability (§ 900.10)

This section of the proposal stated that the provisions of subpart B (which includes the facility quality standards) apply to all facilities under the jurisdiction of the United States that provide mammography services, except for those of the Department of Veterans Affairs (VA).

No comments were received directly on this section, although several comments on other sections questioned the exclusion of the facilities of VA. FDA notes that the wording of this section, including the exclusion, is based directly on the statute; the agency is unable to make any modifications (42 U.S.C. 263b(a)(3)(A)). However, VA is presently developing, under a separate legislative mandate, a program to ensure mammography quality equivalent to that required by the MQSA.

K. Requirements for Certification (§ 900.11)

This section establishes the requirement that mammography facilities must have an FDA certificate in order to operate lawfully and provides details on how to make application for a certificate and the time period during which the certificate may be effective. Only some of the provisions of this section drew comments. Discussion of these comments follows.

1. General (§ 900.11(a))

This paragraph requires mammography facilities to have certificates issued by FDA to operate lawfully. To obtain a certificate, facilities are required to meet the quality standards in § 900.12 and to be accredited by an approved accreditation body or other entity designated by FDA.

(Comment 178). One comment noted that FDA proposed to add that a facility may be accredited by an ''* * * other entity as designated by the FDA,'' that FDA claims to be concerned that at some time a facility may not have access to an accreditation body, and therefore an alternative accreditation body may be necessary for facilities to operate lawfully. The comment argued that there is no statutory basis for FDA to

appoint another entity and questioned under what circumstances a facility might not have access to an accreditation body. The comment closed by stating that, unless an urgent need for this provision can be clearly defined with limitations in its scope, it should be deleted from § 900.11 and elsewhere in the regulation.

The Secretary has discretion under the statute, both with respect to approving private nonprofit organizations and States as accreditation bodies and with respect to prescribing proof of accreditation. While the probability that facilities may not have access to an accreditation body is at present remote, there are neither guarantees nor requirements that any particular accreditation body will continue to serve in that capacity indefinitely. If one or more of the currently approved accreditation bodies were to become unable or unwilling to serve in that capacity, the agency wants provisions in place that will allow an alternative accreditation authority to be designated in order to ensure continuity and availability of quality mammography. Nothing in the statute precludes FDA from providing for this eventuality in its regulations or from designating other accreditation routes if that should ever become necessary to protect the public health.

(Comment 179). One comment stated that facility certification should allow interpreting physicians to work outside of the certified facility. The comment interpreted the proposal to treat an offsite reading room the same as an offsite mammography clinic and maintained that requiring the offsite reading room to be certified is burdensome and unnecessary.

FDA does not, at this time, intend to require separate certification of partial providers, such as an interpreting physician with an offsite reading room. The definition of a facility in § 900.2(q) includes partial providers, and FDA recognizes that there may be future advantages to separately certifying partial providers of mammography services. For example, it may be advantageous for a radiological practice with one or more interpreting physicians to be certified as a facility. By doing so, the practice's interpreting physicians could interpret mammograms from any other certified facility without those other facilities having to demonstrate the qualifications of the interpreting physician. At the present time, however, policies and procedures have not been established for accreditation and certification of partial providers. Consequently, as is the case under the interim regulations, an interpreting physician interpreting mammograms at a remote site will be included under the certificates of the mammography facility for which he or she interprets mammographic images. The physician will have to provide information to those facilities demonstrating that the requirements regarding his or her qualifications and any other applicable MQSA standards are met.

2. Applications (for Certificates and Provisional Certificates) (§ 900.11(b)(2))

FDA has amended the language in § 900.11(b)(1)(ii), (b)(2)(ii), and (b)(3)(iii) from ''will'' to ''may'' in order to parallel the statutory language that gives the agency discretion with respect to the issuance of certificates, provisional certificates, and extensions of provisional certificates to practice mammography. Although the agency has relied on accreditation body determinations in making decisions about whether to issue certificates, and intends to continue to do so, there may be situations in which FDA has additional information not available to the accreditation body or when the agency has reason to disagree with the accreditation body's evaluation of the facility as likely to perform quality mammography. In those circumstances, the agency retains discretion to deny a certificate even if the facility has become accredited. A new provision has been added at § 900.16 to implement the agency's statutory authority to deny certification to an accredited facility and to set forth the appeal procedures available to such facilities. In general, this paragraph requires that new facilities apply for accreditation through an approved accreditation body. Once a facility's application is accepted by the accreditation body, FDA may issue a provisional certificate that will allow the facility to perform mammography for not longer than 6 months in order to obtain the clinical images necessary for accreditation. A provisional certificate may not be renewed, but a facility may apply for a one time 90-day extension of the provisional certificate under certain circumstances.

(Comment 180). One comment suggested extending the 6-month provisional certification period for facilities that failed to be accredited, and a second comment stated that a facility should make substantial changes before being granted a second provisional certificate. A third comment recommended that FDA provide for renewal of provisional certificates at the discretion of FDA because some facilities may not complete accreditation, through no fault of their own, and may not qualify for a 90-day extension. A fourth comment recommended that provisional certification should be limited to one time only and described the 90-day extension as generous, allowing facilities a 9-month period in which to achieve full compliance.

In accordance with the MQSA, provisional certificates may only be extended for facilities that can demonstrate that access to mammography would be significantly reduced in the geographic area served by the facility, and only if the facility reports the steps that will be taken to qualify the facility for certification. In response to the first comment, therefore, FDA notes that there is no statutory provision for either an additional extension or the issuance of a second provisional certificate to the same facility.

The agency recognizes the dilemma noted in the comment concerning facilities that have been unable, perhaps for reasons beyond their control, to complete accreditation within the time period. The final regulations provide for reinstatement of certain facilities that failed accreditation or failed to complete the process during the first 6 months as new facilities. To qualify for reinstatement, the facility must submit and complete a corrective action plan developed to ensure correction of any deficiencies that led to failure. That corrective plan must be approved by the accreditation body and completed by the facility before the facility can be reinstated. On reinstatement, the facility is treated as a new facility, and issued a new provisional certificate that will allow it to produce mammograms for the clinical image review, which must be passed to obtain a 3-year accreditation and certification term.

FDA understands the concern of those comments that suggested facilities should not be given additional time or a second chance to establish that they are capable of doing quality work. The agency has had to weigh those concerns against competing concerns for access and the statutory emphasis on bringing facilities into compliance rather than putting them out of business. FDA believes that its reinstatement policy strikes the proper balance.

(Comment 181). Two comments agreed with § 900.11 as proposed. Another stated that a better definition is required to differentiate between those facilities that fail the second film review and are later reinstated, and those that fail and submit a new application under the pretense of being a new facility.

FDA and the accreditation bodies recognize the risk that might be created if a facility that failed accreditation is

issued a second provisional certificate under such pretense. FDA has instituted a variety of measures under the interim regulations to avoid such occurances, including close communication among accreditation bodies, between accreditation bodies and FDA, and a policy that each facility provide a history of previous accreditation activities with its application. The facility history requirement has been codified in the final regulation to require all applicant facilities to provide a complete history of prior accreditation activities, including a statement that all information and data submitted in the application is truthful and accurate, and that no material fact has been omitted. FDA expects to continue close communication among accreditation bodies and FDA to identify potential problems with this type of misrepresentation by facilities applying for accreditation.

(Comment 182). One comment recommended that § 900.11 be revised to include the MQSA provision that authorizes States to perform certification duties.

The MQSA does provide that States may serve as certifying bodies (42 U.S.C. 263b(q)). However, this subject is beyond the scope of these proposed regulations. Preparations are under way to draft regulations that will govern State agencies that wish to become certifying bodies, and the public will have an opportunity to comment on future proposals.

3. Provisional Certification Extensions (§ 900.11(b)(3)(i))

This paragraph describes the information a facility must submit to apply for a 90-day extension of its provisional certificate.

(Comment 183). One comment noted that the statute requires FDA to evaluate requests for 90-day extensions but that this provision stipulates that a facility shall submit its evidence in support of extensions to its accreditation body. The comment asked if it is FDA's intent to transfer this authority to the accreditation bodies. If it is not FDA's intent to transfer this authority to the accreditation bodies, the comment requested that, ''* * * its accreditation body * * *'' be changed to ''the FDA.''

The MQSA gives FDA the authority to evaluate and determine whether or not a facility qualifies for a 90-day extension of its provisional certificate, and FDA does not intend to transfer this authority to the accreditation bodies. However, the agency believes that it is in a better position to render valid decisions on requests for 90-day extensions if the accreditation body first reviews and makes a recommendation on the request in light of the accreditation body's detailed knowledge of the applicant and other facilities in the area. Therefore, the final regulation has been amended to clarify that the accreditation body will forward the facility's request for an extension, along with the accreditation body's recommendation. New § 900.11(b)(3)(ii) requires accreditation bodies to forward both requests and their recommendations to FDA within 2 business days of receipt of the request.

4. Reinstatement Policy (§ 900.11(c))

This paragraph contains the requirements and procedures for reinstatement of certification. Under this provision, FDA may permit 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 suspended or revoked by FDA, to apply to have the certificate reinstated.

(Comment 184). Four comments expressed concern that reopening a facility whose accreditation has lapsed may be difficult and that reinstatement is necessary so that such facilities may qualify as new facilities and thereby qualify for issuance of provisional certificates.

Reinstatement is the appropriate procedure for reopening a facility whose certification has lapsed. The MQSA only allows a provisional certificate to be issued to new facilities. As noted in section III.K.2 of this document, any facility that seeks reinstatement under this provision of the regulations will have to provide sufficient information to its accreditation body to establish that any problems in meeting the MQSA standards have been corrected, and that circumstances are such that the facility may qualify as a new facility for purposes of reinstatement. The decision about whether to apply for reinstatement is one that each facility must make based on its own circumstances. If the costs associated with such application are too high for any particular facility, it will forgo providing mammography services. On the other hand, if a facility has determined that it can improve its practice sufficiently to warrant reinstatement, or that it wished to resume a practice it voluntarily closed, reinstatement will permit such facilities to qualify for provisional certification as new facilities, and produce the clinical images that are necessary for 3-year accreditation and certification.

5. Justification for Reinstatement (§ 900.11(c)(1)(iii))

This paragraph requires a facility applying for reinstatement to justify its application.

(Comment 185). A comment asked how this would cover a facility that allowed its certificate to expire for reasons other than failure to comply or qualify.

FDA notes that a justification is required for all applications for reinstatement. A facility whose certificate has expired but that has had no deficiencies should submit a corrective action plan that explains the reasons for expiration and what it has done or will do to ensure that the facility meets the MQSA quality standards at the time of reinstatement.

6. Provisional Certificates to Reinstated Facilities (§ 900.11(c)(2) and (c)(3))

(Comment 186). Four comments raised concerns about the appropriateness of issuing provisional certificates to reinstated facilities, as the agency had proposed.

As a result of these comments, FDA has modified § 900.11(c) to read, ''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 suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.'' This change is intended to make clear the need for a mechanism so that previously certified facilities that have instituted corrective actions or wish to resume services following voluntary cessation of mammography may be considered new facilities for purposes of issuing provision certificates as noted in section III.K.4 of this document. The agency has also changed the language of this provision from ''will'' to ''may'' in § 900.11(i)(2) to indicate that the agency retains discretion to accept facilities for reinstatement.

7. The 2-Year Waiting Period (§ 900.11(c)(4))

As proposed, this provision stated that if a facility's certificate is revoked, the facility may not be reinstated for 2 years if owned or operated by any person who owned or operated the facility at the time of revocation. Proposed § 900.11(c)(4) did not accurately reflect the MQSA requirement because it imposed the 2-year waiting period on facilities rather than on persons. The MQSA requires a 2-year waiting period before persons who own or operate a mammography facility at the time an act is committed that results in revocation of the facility's certificate may again own or operate a mammography facility (42 U.S.C. 263b(I)(3)).

Section 900.11(c)(4), therefore, has been changed to read, ''If a facility's certificate was revoked on the basis of an act described in 42 U.S.C. 263b(I)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.''

(Comment 187). More than 40 comments expressed concern about how FDA would apply revocation and about the 2-year waiting period, which many comments suggested was excessive.

These and related comments to § 900.13 suggest an unwarranted expectation that suspension and revocation of certificates will be common practice in the event of noncompliance with the regulations. As noted above, the 2-year waiting period is mandated by the MQSA in the event of revocation of a certificate. That timeframe is not subject to modification by the agency. However, after more than 2 years of enforcement of the MQSA, FDA has not revoked any certificates and has only suspended the certificate of one operating facility. This should alleviate concerns that this enforcement action is one FDA is likely to use frequently or without cause.

The conditions under which FDA may suspend or revoke a certificate are set forth in § 900.14. In most cases, a suspension would precede a revocation action. As explained in the preamble to the proposed rule (61 FR 14878), suspension of a certificate generally would occur only when all other efforts to bring a facility into compliance with the regulations have failed or if continued operation of a facility would present a serious risk to human health. Suspension allows a facility to complete corrective action under accreditation body and FDA monitoring, and subsequently to be reinstated if those corrections are adequate. FDA generally intends to revoke certificates only when corrective and voluntary measures have failed and the agency has clear evidence that a facility cannot or will not practice quality mammography, or in the event the facility made false statements to FDA.

Unless other more serious events, as indicated above, necessitate otherwise, FDA will not revoke or suspend a certificate as a result of a finding that a facility is correcting, is willing to correct, or has corrected identified deficiencies. FDA's goal is to bring noncompliant facilities into compliance with the MQSA standards so that they can produce quality mammograms, rather than to close facilities. This goal reflects the intent of the drafters of the statute; the legislative history discussing the sanctions provisions, e.g., states that ''the first priority of the Secretary is to restore a mammography facility to compliance * * *'' S. Rept. 102–448, at 2 (1192).

(Comment 188). Ten additional comments stated that this section is frightening to many radiologists and asked who decides when voluntary action or lesser sanctions have proven ineffective, and if any third party reviews agency decisions. FDA will determine when voluntary or lesser sanctions have proven ineffective. The decision to suspend or revoke a certificate, however, is subject to challenge by the facility which is entitled to an informal hearing under 21 CFR part 16, and ultimately subject to judicial review.

L. Quality Standards (§ 900.12)

1. Personnel (§ 900.12(a))

This paragraph of the regulations establishes the training and experience requirements for physicians who interpret mammograms, radiologic technologists who perform mammography examinations, and medical physicists who have responsibility for periodically surveying the mammography equipment and overseeing the facility's equipment quality assurance program. The requirements include initial qualifications that must be met before an individual can begin independently providing mammography services to the facility and continuing qualifications that must be met on an ongoing basis. Facility recordkeeping requirements related to personnel are also discussed.

The final regulations generally retain the same requirements as were outlined in the proposal. In response to comments, however, the amount of training or experience needed to satisfy particular requirements has been adjusted in several places. The final regulations also establish a ''grand parenting'' provision for radiologic technologists.

a. *General comments on personnel section*

(Comment 189). General comments submitted by the public to FDA on § 900.12(a) offered contrasting views on the value of the personnel standards. One comment applauded the increased specificity of the proposal over the interim rules because the changes clarified what requirements the facility personnel had to meet. A second comment likewise noted that the requirements were ''well presented'' and clarified a number of issues. In contrast, a third comment stated that the more specific requirements made it harder for facilities to show that the requirements were met. A fourth comment found the requirements too prescriptive (but offered no suggestions on what could be deleted as unnecessary), but a fifth comment asked for even more specificity.

This variety of opinion illustrates the difficulty of striking the proper balance between making regulatory requirements specific enough so that it is clearly understood what is required yet general enough to allow for appropriate flexibility. FDA believes that the variety of comments indicates that significant changes to the general approach taken by the proposal are not warranted. However, the question of the proper balance between specificity and flexibility was reconsidered in response to comments on particular requirements.

(Comment 190). One general comment asked for clarification on who would be qualified to teach physicians, technologists, and physicists to use new technologies as they develop.

FDA believes that the new definition of qualified instructor (§ 900.2(oo)), discussed earlier, provides an adequate means for identifying qualified instructors. Under this definition, representatives of the manufacturers who develop new technology, along with the physicians, technologists, and physicists who worked with the technology while it was in the investigational stage, would generally be accepted as qualified to be the initial instructors in the use of the new technology. This approach is consistent with the general practice in the teaching of medicine.

(Comment 191). Several of the general comments on the personnel requirements were based on a misinterpretation of the proposed regulations or of the MQSA itself. Six identical comments argued for retaining the interim regulations, not because they opposed the proposed new requirements as such, but because they believed that the choice was between either the interim regulations or performance-based outcome measures, such as proficiency testing.

As explained previously, while comments were requested on the concept of performance-based outcome requirements, new performance-based requirements are not being proposed at this time.

(Comment 192). Another comment mistakenly believed the regulations made investigational use of MRI unlawful but, in fact, MRI procedures are not within the scope of the MQSA (42 U.S.C. 263b(a)(6)). Similarly, two general comments recommended removing of this section entirely,

reasoning that because FDA does not impose training or experience requirements on users of other medical devices, there was ''no possible justification'' for mammography being treated differently.

In fact, however, Congress has directed that mammography be treated differently and required the government to establish personnel standards (42 U.S.C. 263b(f)(1)(C), (D), and (E)). The MQSA embodies Congress's determination that such standards would help ensure that mammography services are provided only by those qualified to do so.

b. *Comments on interpreting physicians (§ 900.12(a)(1))*

The final regulations for interpreting physicians establish initial professional, educational, and training qualifications, as well as requirements for continuing experience and education. Although neither a national standard nor a continuing performance competency test for mammography interpretation currently exists, the requirements of § 900.12(a)(1) for interpreting physicians will provide baseline standards to help ensure the reliability and accuracy of interpretation of mammograms for women throughout the country.

The final regulations are generally the same as those proposed. In response to comments, however, some new provisions have been added and several others were revised as follows: (1) Sixty rather than 40 hours of documented medical education in mammography must be Category I; (2) a new section was added to clarify the use of CME obtained by teaching medical education courses; (3) the mechanism to document continuing experience and education requirements has been revised to reduce the administrative burden on facilities; (4) additional pathways for physicians who need to reestablish their qualifications have been added; and (5) the initial qualifications have also been modified to clarify the conditions for ''grand parenting'' of interpreting physicians and the initial experience requirement for some residents. These changes from the proposal will be discussed below in connection with the appropriate provisions.

(Comment 193). Over 100 comments stated that only radiologists should be permitted to work as interpreting physicians.

After considering these comments, FDA continues to believe that this additional limit would not be in the interest of public health. Currently, there are some physicians, not formally trained as radiologists, who have met the requirements of the interim regulations and are competently interpreting mammograms. Therefore, FDA believes that it would be unnecessarily restrictive to limit interpreting physicians to radiologists. By requiring all physicians wishing to interpret mammograms to meet the same baseline quality standards of training, experience, and continuing education, the goal of ensuring quality mammography can be achieved without arbitrary restrictions relating to the specialty of the particular physician.

(Comment 194). One comment suggested that interpreting physicians who practice at more than one facility should be required to provide proof of credentials and qualifications only one time, rather than providing this material for each facility with which the physician is affiliated.

FDA disagrees for a number of reasons. First, the MQSA requires mammography facilities to meet certain requirements, including establishing that its personnel are qualified under the statute. Because it is the facility that is responsible and will be inspected, it is necessary for that facility to have documentation for all the interpreting physicians who work there. In addition, while several of the initial personnel requirements do not change over time, some, such as medical licenses, are time limited and need to be updated. Similarly, if the continuing experience and education requirements are not updated by the personnel, the facility can be cited for violations of the MQSA.

(Comment 195). One comment stated that interpreting physicians should be required to pass an annual, documented visual acuity test. In response to this suggestion, FDA notes that while visual acuity is important, there are no standards as to what would constitute acceptable visual acuity. The agency does not believe it is necessary to become involved in those details of physician fitness that are better handled by licensing authorities.

(Comment 196). Two comments stated that training in ultrasound should be required for interpreting physicians as part of the accreditation program.

Under the MQSA, FDA's authority to regulate mammography is limited to radiography of the breast. Therefore, requirements related to ultrasound have not been included in personnel or other facility standards.

(Comment 197). Two comments supported FDA's position that all physicians reading mammograms should be required to meet the same training standards. The comments stated that this is particularly important with regard to locum tenens and that facilities may need to be reminded that their locum tenens should provide all appropriate documentation prior to beginning independent interpretation.

FDA agrees that all personnel are required to meet the same standards regardless of whether they work full or part-time and facilities must make sure that all the personnel at their facility meet the necessary requirements.

The quality standards for interpreting physicians are divided into four sections: Initial qualifications; continuing experience and education; exemptions; and reestablishing qualifications.

Under § 900.12(a)(1)(i), the first qualification for an interpreting physician is a State license to practice medicine.

(Comment 198). Over 50 comments recommended that the proposal be changed to state that all interpreting physicians should be licensed in ''the'' State in which they practice.

FDA does not believe the proposed regulation should be amended. Although § 900.12(a)(1)(I)(A) requires the interpreting physician to have ''a'' State license to practice medicine, in the vast majority of cases, State laws require a physician to be licensed in ''the'' State in which he or she is practicing. If the State in which the mammography facility is located is different from the State that issued the license, a physician may have to meet additional State requirements in order to practice medicine lawfully at that facility. With respect to physicians practicing in Federal facilities, a valid State license from any State is sufficient. However, the Federal employee would be unable to practice outside the Federal facility unless the physician also fulfilled the requirements of that State for the practice of medicine.

Under § 900.12(a)(1)(I)(B), the second initial qualification for interpreting physicians is board certification or 3 months of documented formal training in interpreting mammograms. The training is to include radiation physics (including radiation physics specific to mammography), radiation effects, and radiation protection.

(Comment 199). Over 80 comments stated that all interpreting physicians should be board certified radiologists. The comments stated that being board certified establishes that the person reading the mammogram understands all the basic principles of physics and breast anatomy and that this would ensure the most accurate readings. In contrast, four comments disagreed with the use of specialty board certification as a measure of qualification. These comments generally argued that requiring specialty board certification will adversely affect patient access to

medical services. These comments also stated that many individuals certified by the ABR did not receive formal training in current mammography techniques because their training predated the development of modern mammography standards. One comment stated that individuals certified by ABR before 1989 were not examined in mammography techniques as part of their board certification process and that the oral examination process of ABR certification is highly subjective and influenced by personality and demeanor. The comment also claimed that ABR has awarded board certification through the ''Class A'' rule, in which favorite candidates were certified without any examination process, and that ABR does not adhere to ''due process'' by using subjective oral examinations to certify candidates.

In response to criticism of board certification as fulfillment of an initial quality standard, FDA notes that the statute specifically recognizes board certification as one of the mechanisms for meeting a portion of the interpreting physician requirements (42 U.S.C. 263b(f)(1)(D)(I)(I)). In addition, the agency continues to believe that board certification is a valid indication of overall competency. FDA recognizes that some earlier board examinations may not have included testing in mammography. FDA also recognizes that board certification that includes mammography testing cannot ensure the accuracy of outcomes in clinical mammography practices; no training or certification program can guarantee proficiency in all cases. However, board certification is evidence that the physician is knowledgeable in the basics of diagnostic radiology and can serve as a foundation for the additional requirements specific to mammography that interpreting physicians must meet under FDA's regulations. The ''Class A'' rule referenced in the comments was used in the mid 1930's during the startup phase of the ABR in order to certify those outstanding physicians who were experienced in the field of radiology. This rule has not been used in over 50 years and, since 1940, all candidates have had to take examinations. FDA does not believe that the ''Class A'' rule has a significant bearing on the radiologists practicing today. While FDA does agree that there is some subjectivity in all tests, the agency is satisfied that the accepted boards represent a valid means of determining general competency. FDA disagrees with the assertion that the boards do not adhere to due process. Formal appeals processes are available to those candidates who wish to dispute a board decision. For all these reasons, FDA believes that board certification must remain an acceptable way to meet a portion of the initial qualifications for mammography personnel.

In response to comments that questioned the validity of permitting physicians who are not board certified to practice mammography, FDA notes that Congress directed FDA to establish an alternative pathway to board certification (42 U.S.C. 263b(f)(1)(D)(I)(II)). FDA believes that the 3 months of documented formal training will ensure that all physicians interpreting mammograms have received an adequate amount of instruction.

(Comment 200). Several comments, including a consensus of NMQAAC, stated that the 3-month training alternative was appropriate, but that the topics, number of hours for each topic, and the qualifications for those teaching these topics should be specified. NMQAAC and others believed that this training should be limited to that obtained in a radiology residency program. Some, including members of NMQAAC, said that the physics training should only be obtained from a medical physicist. One comment suggested that FDA require a minimum of 200 hours of physics training.

After considering all the comments, FDA has concluded that specifying the precise number of hours spent on each topic would be too prescriptive and would curtail the ability of training programs to individualize their curricula. FDA also believes that restricting training to radiology residency programs or, in the case of physics, to training by a medical physicist, would limit adequate training opportunities. FDA's experience under the interim regulations has led the agency to conclude that adequate training opportunities are also available to physicians who are not involved in radiology residency programs.

(Comment 201). Several comments stated that FDA should notify the certifying boards, residency programs, facilities, and personnel of the new requirements so that sufficient training and proper documentation are given to all physicians. One comment suggested phasing in the 3-month training requirement to allow program directors the time needed to adjust their curricula. One comment stated that physicians should be made aware that it is their responsibility to keep track of training and continuing education.

FDA agrees with the general points being made by these comments. The agency has and continues to provide the appropriate boards, programs, facilities, and personnel with the information they need to meet and document the requirements of the MQSA. Programs should have an adequate amount of time to adapt to the new requirements, which will not go into effect until 18 months after publication of this rule.

(Comment 202). Several comments suggested that 2 months of documented formal training in the interpretation of mammography, the current requirement under the interim regulations, is more than sufficient and that the increase to 3 months was excessive. One comment proposed that the 3 months be reduced to 2 months for those who have been reading mammograms consistently for 5 years or more. Another comment suggested that individuals who have qualified under the interim regulations should not be required to reapply or provide further documentation beyond that which was previously submitted to FDA.

FDA has received advice from NMQAAC, AHCPR, and others that 2 months of training for new physicians is insufficient to cover all the required topics. AHCPR has advocated 4 months of training. FDA believes that the increase from 2 to 3 months is appropriate and can be instituted by residency and other training programs without undue burden. As explained below, interpreting physicians who began independent interpretation under the interim regulations are considered to have met the initial qualifications under the final regulations. There will be no need for them to reapply or supply additional documentation to FDA. Also, because the 3-month requirement applies only to new interpreting physicians, anyone with the suggested 5 years of consistent experience should have qualified previously under the interim regulations.

(Comment 203). One comment stated that any physician who is not a radiologist should be required to demonstrate competency in mammography through an examination, in addition to the training requirements.

FDA declines to accept this suggestion. The agency has concluded, as discussed earlier, that adequate training programs can ensure that an interpreting physician has skills to practice mammography, regardless of his or her initial specialty. In addition, FDA agrees with the many public comments the agency received concerning the difficulties associated with physician competency testing as a qualifying method. At the present time, a suitable test to judge the competency of interpreting physicians does not exist. This may become an option in the

future, but until it does, training requirements appear to offer the most satisfactory method of establishing quality standards.

(Comment 204). One comment recommended that all interpreting physicians be urged to meet exactly the same criteria without regard to board status. The comment suggested that the original alternative pathway established by the interim regulations, 2 months of documented training in interpreting mammograms, 40 hours of CME in mammography, and 15 hours of Category I CME per 3-year period, should be required for all interpreting physicians, even those who are board certified.

In response to this comment, FDA notes that the MQSA establishes an alternative rather than a cumulative requirement in this matter. While FDA always encourages individuals to strive for excellence by exceeding the requirements, either of the two pathways (board certification or 3 months training) will be sufficient training to meet this portion of the initial requirement. All interpreting physicians, including those who are board certified, are required to comply with the initial and CME requirements. This has been true under the interim regulations and will continue to apply under the final regulations.

The third initial requirement for interpreting physicians, § 900.12(a)(1)(i)(C), is 60 hours of documented medical education in mammography, including instruction in the interpretation of mammograms and education in basic breast anatomy, pathology, physiology, technical aspects of mammography, and quality assurance and QC. Unlike the proposed rule, the final regulation requires that all 60 of these credits be Category I CME. At least 15 of these 60 Category I CME hours must have been acquired within the 3 years immediately prior to qualifying as an interpreting physician. Hours spent in residency specifically devoted to mammography will be considered as equivalent to Category I CME and will be accepted if documented in writing by an appropriate representative of the training institution. The specific mammographic modality training requirement that was included in the proposed rule (61 FR 14907) has been deleted from this part of the final regulations because it is duplicated in § 900.12(a)(ii)(C).

(Comment 205). Several comments agreed with § 900.12(a)(1)(I)(C) as originally proposed, while others, including NMQAAC, maintained that all 60 hours of credit should be Category I in order to provide consistency in the quality of the training. Several comments recommended that the number of hours spent in each subject be specified. Many comments said that the 40 hours already required by the interim regulations are sufficient and that raising the number to 60 would have a negative impact on cost and the availability of mammography services. Several stated that Category II credit is just as educational as Category I and should be allowed. One comment questioned the value of CME requirements generally, stating that most of what is said at conferences and courses is repetitive.

FDA disagrees with the comment questioning the usefulness of CME. The agency believes that 60 hours of training is in keeping with current trends in training and the emergence of new technologies. Because this expanded requirement will apply only to new interpreting physicians and time spent in residency specifically devoted to mammography will be accepted toward meeting this requirement, FDA does not believe that the number of hours required will have a negative impact on availability of services. FDA has been persuaded by the comments and its experience under the interim regulations that all 60 hours should be Category I. Category I CME credits are generally those that offer more formal training and provide a solid basis for the ongoing maintenance and growth of the interpretive skills of the physician. While Category II hours may be useful, the variability of such education and the difficulty in documenting such training convinced FDA to strengthen the requirement by making all 60 hours Category I. FDA has not specified the number of hours required to be spent in each subject because the agency believes that this would be too restrictive and would limit the ability of physicians and programs to individualize training.

(Comment 206). Three comments recommended that FDA clarify that the persons providing this training be in active practice and individually fulfill these qualifications.

FDA disagrees with these comments. It is not necessary for all of the persons providing the training to meet the qualifications of interpreting physicians. For example, those teaching basic breast anatomy, pathology, or physiology do not have to be interpreting physicians to provide expert instruction in those subjects.

(Comment 207). One comment asserted that 40 or 60 hours of training does not qualify someone to read a mammogram.

In response to this comment and others that questioned the clinical value of any particular requirement, FDA agrees that 60 hours of training alone does not qualify a physician to read a mammogram. However, this is only one of a series of requirements; the combination of requirements relating to training, experience, and continuing education is intended to provide assurance that those interpreting mammograms meet baseline quality standards.

The final initial qualification relates to experience reading mammograms. Section 900.12(a)(1)(I)(D) requires the qualifying physician to interpret or multi-read at least 240 mammographic examinations within the 6 months immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician. The intent of this requirement is to demonstrate recent supervised experience before the physician begins to interpret mammograms independently. Although the language has been clarified, this requirement is essentially unchanged from the proposal.

(Comment 208). Several comments misinterpreted the proposed requirement to mean that interpreting physicians would have to interpret 240 studies under direct supervision any time he or she changed facilities.

That interpretation is incorrect. This is an initial requirement for the individual prior to beginning practice as a new interpreting physician and is independent of the number of facilities at which the physician works.

(Comment 209). Two comments suggested that the requirement to interpret 240 mammograms under direct supervision should be revised to be 240 within the last 2 years of training prior to qualification as an interpreting physician. The comments stated that the requirement of 240 mammograms in the last 6 months of training is virtually impossible for any residency program with more than 6 residents in any postgraduate year.

FDA agrees. Both the proposal and the final rule include a provision that allows residents to meet this requirement in the last 2 years of their radiology residency programs if they become appropriately board certified at the ''first allowable time.'' See discussion of § 900.12(a)(1)(iii)(B) that follows.

(Comment 210). One comment asked for clarification concerning the 240 mammograms that a physician must interpret for initial training. The comment wanted to know if two

readings of a mammogram can be counted as two interpretations.

Multi-reading, as defined in § 900.2(ff), allows two or more physicians to read the same mammogram and each may count it as one interpretation. However, one physician may not read the same mammogram twice and count it as two separate interpretations.

(Comment 211). Several comments stated that physicians should be given a document stating the number of mammograms read after completing residency training. This would assist the facility in making sure physician requirements are met.

FDA agrees that this is a good idea and has and will continue to inform residency programs of the benefits of such a policy. However, FDA does not regulate residency programs and cannot require that such programs provide this documentation.

(Comment 212). Several comments recommended that the supervised interpretation required for initial qualification be performed under someone qualified to teach interpretation. NMQAAC recommended that this training be obtained in a radiology residency program.

While the majority of interpreting physicians will receive this training in their residency program, FDA believes that restricting such training to only those in radiology residency programs would unnecessarily limit the availability of adequate training opportunities. As previously discussed, FDA's experience under the interim regulations has led the agency to conclude that adequate training opportunities exist outside of radiology residency programs.

Section 900.12(a)(1)(ii)(A) is the first of the requirements established to ensure that interpreting physicians, who have met initial requirements, maintain their qualifications as they practice mammography. Under this requirement, in order to continue to qualify under the MQSA rules, interpreting physicians are required to have interpreted or multi-read at least 960 mammographic studies in the previous 24 months. Although the wording has changed somewhat from the interim and the proposed final rules, there has not been a substantial change in this requirement. The proposal has been amended so that a total of 960 examinations have to be interpreted in the previous 24 months instead of the previous formulation of an average of 40 examinations per month over 24 months. This requirement continues to provide flexibility to physicians who find they need or want to interrupt their practice for periods of time for personal or professional reasons (e.g., maternity, illness, sabbaticals). The wording has also been revised to clarify that the 24 months can be measured in any of the following ways: From the date of the annual inspection of the facility at which the interpreting physician works; from the last day of the calendar quarter immediately preceding the annual inspection date; or from any date in between the two. These options will ease the paperwork burden on the facility and allow the facility to gather and monitor this information in a more efficient manner. For example, rather than tabulate daily or monthly totals, the facility may wish to tabulate this data only at the end of the quarter prior to the next expected annual inspection. FDA strongly recommends that facilities use the same tabulation method and the same option for determining the 24-month period for all of their personnel for simplicity and to help achieve consistency within the facility. However, this is not required.

(Comment 213). Ten comments stated that diagnostic radiology graduates who pursue a fellowship in a field other than mammography face a difficult situation and will unnecessarily burden supervising physicians when they resume mammographic interpretation at the end of these fellowships. The comments stated that interpreting physicians who meet the requirements for 2 months training during residency and pass the certifying board exams have been adequately educated, and their interpretations do not need to be supervised when they resume reading mammograms.

FDA disagrees and has received advice from many groups, including NMQAAC, that continuing experience is a necessary requirement to help ensure the accuracy of mammographic interpretation. FDA believes that it is in the best interest of the patient for physicians who have not interpreted the required number of studies in the previous 24 months to be supervised prior to independent interpretation. This requirement applies equally to radiology fellows who have been outside the practice of mammography as well as to interpreting physicians who stop practicing for a significant period of time.

(Comment 214). FDA received 17 comments addressing the issue of interpreting an average of 40 mammographic examinations per month. Of these, 7 agreed with the proposal or recommended a higher number of examinations, while 10 asserted that the requirement was unnecessary, or that the number was too high and would adversely effect low volume or rural facilities.

FDA believes that all women, including those in rural areas, are entitled to the same quality of care. The agency cannot support lower standards for particular facilities. The agency also believes that it will not be difficult for most physicians to meet this continuing qualification, even for those in rural areas. The agency also wants to clarify that this is a physician requirement, not a facility requirement. Interpreting physicians who provide services to low volume facilities can interpret films at more than one facility to attain the required number of examinations. Multi-reading of images previously interpreted by another physician is also accepted as a way of meeting this requirement. However, the physician may not count interpretation of the same mammogram more than once. Currently, under the interim regulations, multi-reading is being used successfully by some interpreting physicians to meet this requirement. For all of these reasons, the agency believes this requirement will not cause a mammography access problem.

FDA recognizes that numbers alone cannot guarantee competency, but believes that the experience a radiologist accumulates through interpreting a certain minimum number of studies is a necessary aspect of the qualification process. In § 900.12(f), FDA has issued requirements for the establishment and implementation of a medical outcomes audit for individual physicians. When used properly, this type of monitoring can further improve the reliability, clarity, and accuracy of interpretation of mammograms.

(Comment 215). One comment stated that FDA should not set a maximum number of films that can be read by an interpreting physician.

FDA agrees. There is nothing in the MQSA or the regulations that establishes such a limit.

Section 900.12(a)(1)(ii)(B) requires interpreting physicians to further maintain their skills by teaching or completing at least 15 Category I CME credits in mammography in the previous 36 months. This training must include at least six Category I continuing education credits in each mammographic modality used by the physician. As with the continuing experience requirement, FDA has modified the language of the proposal to allow facilities greater flexibility and efficiency in tabulating this data for interpreting physicians working at the facility.

(Comment 216). Seventeen comments raised questions about CME in

technologies that do not fall within the scope of the MQSA, such as ultrasound or MRI. These comments asked whether 6 hours of CME in each of these breast imaging applications is required and, if not, can such continuing education in these technologies nevertheless be used to satisfy the CME requirements. Two comments suggested further clarification of what activities are acceptable as CME.

Because these technologies are outside the scope of the MQSA, there is no requirement for a physician to have continuing education in them in order to qualify under the MQSA. CME in such technologies may, however, be applied to fulfill a portion of the continuing education requirement if that continuing education is likely to aid the physician in the understanding of mammographic breast cancer detection. CME in ultrasound and MRI of the breast would fall into this category and could be used to fulfill a portion of the continuing education requirement.

(Comment 217). Several comments supported the requirement for interpreting physicians to obtain at least 15 Category I CME every 3 years. Others asserted that there was no clear basis for the requirement. One comment stated that the interim rule requirements regarding completion of CME are unnecessarily bureaucratic because one's knowledge does not suddenly expire with an arbitrary deadline. Two comments maintained that the cost and number of man-hours required by these regulations is a serious burden, particularly considering that there is no scientific evidence that these efforts will result in improved medical care. Another comment indicated that training in each mammographic modality is already part of training programs and, for the vast majority of individuals, training is unnecessary because they have been providing services in these modalities for many years. This comment and others asserted that requirements for additional documentation of continuing education is unnecessarily burdensome for physicians who can demonstrate that they have completed an accredited program and have appropriate certification.

FDA has been advised by NMQAAC and professional organizations, such as ACR, that continuing education is necessary in order to maintain skills in an ever changing field of medicine. The agency agrees and notes that the statute, 42 U.S.C. 263b(f)(1)(D)(ii), establishes a general requirement for continuing education. FDA has required that the credits be Category I CME in order to ensure that continuing education is more formal, can be documented, and contributes to the development of the professional skills of the physician. FDA believes that there are many avenues for obtaining this education and that the cost and man-hours required will not be overly burdensome on physicians. This requirement, as it relates to timeframes for monitoring compliance, has been modified from the proposal in a manner similar to that for continuing experience. This change will clarify that facilities need not update CME for physicians on a daily or monthly basis. FDA has evaluated many different scenarios for use as averaging periods and reviewed this particular issue with NMQAAC.

(Comment 218). Several comments recommended that CME be averaged over a fixed 3-year period rather than on any given day. FDA notes that under a fixed 3-year period, physicians could acquire CME credits at the beginning of one period and at the end of the next, resulting in a span of almost 6 years in which the physician had not received any CME.

FDA has concluded that the present floating 36-month period is more likely to contribute to quality mammography. A floating 36-month period eliminates the possibility that physicians will go for extended periods of time without continuing education. At the same time, it still permits physicians to devote their time to longer courses, when they are available, and to update their CME when the best opportunities for training arise, regardless of when that offering is made within the 36-month period.

(Comment 219). One comment recommended that interpreting physicians be tested every 2 years to keep up to date with all changes in the discipline.

FDA believes that, at the present time, there is no adequate proficiency test to judge the continuing competency of interpreting physicians. For the foreseeable future, continuing experience and education requirements appear to offer the most satisfactory method for establishing compliance with these personnel standards.

(Comment 220). One comment requested stricter control over acceptable ways for an interpreting physician to obtain continuing education units in mammography. The comment claimed that interpreting physicians who do not attend actual view box classes, but get their CME from a syllabus, have higher call back rates on films that they interpret. The comment recommended that all interpreting physicians be required to attend actual hands-on training seminars.

FDA disagrees with this comment. After discussion with NMQAAC, the agency believes that limiting continuing education to hands-on training would greatly restrict the ability of many interpreting physicians to obtain such training, without providing a documented corresponding benefit. FDA believes that syllabi and other types of training can be as beneficial as hands-on training.

(Comment 221). Several comments, including some from NMQAAC, indicated that a better definition of modality was needed. In order to reduce any confusion, the term ''modality'' has been changed to ''mammographic modality'' to emphasize that the term does not refer to nonmammographic techniques, such as ultrasound or MRI, that may be used to examine the breast.

Several comments stated that the requirement for six Category I CME credits in each mammographic modality is impractical and recommended that the continuing education qualification be left at 15 Category I credits in breast imaging, as required under the interim regulations. The comments went on to say that radiologists do more than just breast imaging and that, in any case, breast imaging courses do not list their credits by mammographic modality.

FDA believes that the requirement for six Category I CME credits in each mammographic modality used by the interpreting physician is consistent with the goal of maintaining expertise. At the present time, there are only two mammographic modalities available, film screen and xeromammography. More than 99.5 percent of facilities are using only one mammographic modality, namely film screen. Currently, because there is only one mammographic modality generally used, this requirement would not create an additional burden for the vast majority of physicians. When digital mammography becomes available, those physicians using both film screen and digital modalities would have to acquire at least six category I CME credits in each of these mammographic modalities over a 3-year period. If three different mammographic modalities become available and all three were used by an interpreting physician, that physician would have to accumulate at least 18 Category I credits in the previous 36-month period, 6 in each mammographic modality. It is true that designation of CME credits in mammographic modalities other than film screen is not commonplace at the present time. However, as courses become available in digital mammography, the number of

hours devoted to the new mammographic modality can be documented by the course sponsors. In the meantime, keeping a copy of the program outline listing the lecture titles will serve as adequate documentation for the MQSA inspectors.

Section 900.12(a)(1)(ii)(C) requires that, before using a new mammographic modality in his or her practice, the interpreting physician must have at least 8 hours of training with that mammographic modality.

(Comment 222). Several comments, including those from NMQAAC, supported this requirement, while many others wanted additional clarification or stated that 8 hours was excessive because similar skills are used in all mammographic modalities. Several comments asked how this training could be obtained and documented in light of the fact that CME courses do not presently provide such training or give certificates in such detail.

FDA believes that 8 hours of training in a new mammographic modality is an appropriate baseline. FDA agrees that there is overlap in the skills necessary to interpret studies done by different mammographic modalities. However, there are enough differences to justify this additional education. Before a physician begins to interpret images produced by a particular mammographic modality, the agency believes that the physician should have specific training in the interpretation of such images. Until new mammographic modalities become widely available, there may be a paucity of formal CME courses giving such instruction. FDA recognizes this and, therefore, has not required that this be Category I CME. This will allow other entities, such as equipment manufacturers, to supply the initial training. In this way, physicians and other personnel will be able to obtain the required 8 hours of training from sources intimately associated with the new equipment they will be using. Formal category I CME courses will also be accepted. As mentioned previously, for those courses that do not list the CME by mammographic modality, the program outline can serve as documentation of how much time was spent in the new mammographic modality.

(Comment 223). Many comments interpreted this requirement to mean that physicians must receive 8 hours of CME credit in xeromammography, which is now used very infrequently. These comments misinterpreted this requirement, which applies only when a physician begins using a mammographic modality in which he or she has not been previously trained.

Because xeromammography is seldom used today, it would be extremely unlikely for an interpreting physician to begin using this mammographic modality for the first time. It would only be in this unlikely circumstance that the interpreting physician would have to obtain 8 hours of xeromammographic training.

(Comment 224). One comment suggested that, in addition to this requirement, the physician should also be required to interpret a specified number of mammograms from the new modality under the supervision of a qualified interpreting physician before independent interpretation.

FDA does not support this additional requirement. While supervised interpretation might benefit interpreting physicians who begin using a new modality, the agency does not believe this qualification needs to be mandated for physicians who are already experienced in interpreting mammograms through another mammographic modality. Such a requirement could hinder the introduction of new mammographic modalities by raising the cost of initial training and significantly reducing access.

With the concurrence of NMQAAC, § 900.12(a)(1)(ii)(D) was added to the final regulations to clarify that CME earned by teaching a particular course could be counted only once towards the 15 credits for an interpreting physician under § 900.12(a)(1)(ii)(B).

Section 900.12(a)(1)(iii) establishes exemptions from certain personnel requirements for interpreting physicians in specific cases. Section 900.12(a)(1)(iii)(A) exempts physicians who qualified under the interim regulations from the new and additional initial requirements in § 900.12(a)(1)(i): The additional month of training for physicians using the alternative pathway; the additional 20 hours of CME; and the requirement that 15 Category I CME credits must have been acquired in the 3 years immediately before qualifying as an interpreting physician.gi11(Comment 225). One comment opposed ''grand parenting'' of interpreting physicians who qualified under the interim regulations because of the ''minimal standards'' required under the interim regulations. Another comment agreed with the regulation as written.

In order to ensure continuing and uninterrupted availability of mammographic services and because FDA's inspections over the past 2 years do not demonstrate problems with these physicians, FDA is permitting those interpreting physicians who qualified under the interim regulations to continue to interpret mammograms, provided that they maintain the continuing experience and education requirements in § 900.12(a)(1)(ii). As discussed in connection with other personnel requirements, the agency has determined that qualifying standards should be raised as new personnel qualify in the future because of increasingly complex and changing technologies. The agency has also concluded that the need for continued availability of services, fairness to practicing personnel, and the compliance record of facilities with the MQSA over the past years justify permitting personnel who qualified under the interim regulations to continue to practice. FDA believes the final rule strikes the proper balance among these considerations and is in the best interest of the public health.

Section 900.12(a)(1)(iii)(B) establishes another exemption in response to concerns raised by members of NMQAAC and others that the initial experience requirement in § 900.12(a)(1)(i)(D) may pose a problem for residency programs that schedule mammography rotations earlier than the final 6 months in the residency program. Instead of requiring the initial reading experience to be completed in the last 6 months prior to initial qualification, this provision has been amended to permit some residents to satisfy the requirement by having interpreted at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of the residency. This exemption is available only to those residents who successfully become board certified at the ''first allowable time,'' which means the earliest opportunity provided by an eligible certifying board. The physician who qualifies for this exemption would become responsible for fulfilling the continuing education and experience requirements of § 900.12(a)(1)(ii) beginning on the date of that physician's board certification in diagnostic radiology, provided the other initial requirements are satisfied. If the physician does not become board certified at the first allowable time by the certifying board, the exemption does not apply and the physician must interpret 240 mammographic examinations under the direct supervision of an interpreting physician within a period of 6 months immediately prior to initial qualification as an interpreting physician.

(Comment 226). Several comments said that this exemption was still too restrictive and recommended that the

requirement be expanded to allow reading at any time during the residency, rather than within the final 2 years. Some believed the requirement was too stringent because the exemption was available only to those residents who became board certified at the ''first allowable time.'' One comment asserted that residents who did not pass the boards at the first allowable time were no less qualified to perform mammography than the resident who successfully completed the boards, unless the physician failed the mammography section.

After considering these comments, FDA has concluded that the final regulations provide sufficient flexibility. The exemption permits residents to interpret the required number of mammograms in any 6-month period during the last 2 years of their residency program, as long as they become board certified the first time they are eligible. This allows residency programs flexibility in scheduling their residents and prevents the scenario of having all senior residents doing their mammography rotation during the same 6-month period. FDA believes that mammography interpretations performed more than 2 years before completion of a residency program are not recent enough to qualify as initial experience, even in the situation where residents become board certified at the first allowable time. FDA expects that the 2-year time period will allow participants in virtually all residency programs to comply with the regulation. A baseline standard in general radiology would be ensured by the fact that residents qualifying for this exemption would have passed their certification boards, including the mammography section. Those residents not successfully completing their board certification at the first allowable time would not be eligible for this exemption.

(Comment 227). Several comments stated that this exemption should be revised to allow an individual completing a radiology residency program and progressing on to a 1-year fellowship to qualify under § 900.12(a)(1)(iii)(B).

FDA disagrees and believes that meeting the initial requirements and qualifying for this exemption is independent of any additional training the individual may obtain. As discussed previously in connection with continuing experience requirements, FDA believes it is in the best interest of public health that interpreting physicians, including radiology fellows who have been outside the field of mammography, have relatively recent experience before beginning or resuming independent interpretation.

Section 900.12(a)(1)(iv) provides a method for physicians to reestablish their qualifications as interpreting physicians in the event they do not maintain the continuing experience or education requirements. Section 900.12(a)(1)(iv)(A) requires the physician who has failed to meet the continuing experience requirement to interpret or multi-read either 240 mammographic examinations or enough mammographic examinations to bring the physician's total up to 960 for the prior 24 months, whichever is less. These interpretations shall be under the direct supervision of an interpreting physician and occur within the 6 months immediately prior to resuming independent interpretation. This section was modified from the original proposal to be consistent with policies that have been successfully implemented under the interim regulations to deal with physicians who need to reestablish their qualifications.

Section 900.12(a)(1)(iv)(B) requires physicians who have not maintained the continuing education requirement to obtain a sufficient number of Category I CME credits in mammography to bring their total up to the required 15 credits in the previous 36 months. A physician who fails to maintain continuing experience or education requirements may not serve as an interpreting physician until he or she reestablishes those qualifications.

(Comment 228). Two comments stated that there should be a penalty for physicians who do not meet the requirements in the appropriate timeframe.

FDA believes that temporary disqualification from independent interpretation is the most effective and appropriate penalty in these situations. The purpose of the regulations is to ensure that personnel meet baseline standards. Under the final regulations, physicians who do not maintain the required number of interpretations or earn the necessary CME credits must cease independent interpretation of mammograms until such time as they complete a sufficient number of supervised interpretations or CME to meet the requirements. This is the best way to protect the public health. FDA disagrees with the comment that the physician should be penalized in some additional manner for not having maintained the continuing requirements.

c. *Radiologic technologists § 900.12(a)(2)*

FDA's interim and final regulations for radiologic technologists performing mammography both seek to ensure that technologists: (1) Possess adequate general qualifications for performing radiologic examinations; (2) possess adequate specific qualifications for performing mammography examinations; and (3) maintain these qualifications over time. The changes from the interim regulations to the final regulations were primarily clarifications with some additional requirements to address concerns that became apparent as the interim regulations were implemented. In response to comments on the proposed rule, a number of changes have been made. A ''grand parenting'' provision has been added to qualify those technologists who met the interim requirements as fulfilling the initial training and experience requirements of the final regulations. The final regulations also relax the requirements that had been proposed for training specific to imaging patients with implants and reduce the number of supervised examinations that have to be performed as part of the initial requirements and to ''requalify'' in cases where the continuing experience requirement has not been met. The following changes are discussed in connection with the specific provisions.

The general issue that drew the most comments was the question of whether a ''grand parenting'' clause should be added for presently practicing technologists.

(Comment 229). Over 30 comments urged that technologists who met the qualification requirements of the interim regulations should be deemed to meet those of the final regulations. An additional six comments urged that technologists who have earned the advanced certificate in mammography from the American Registry of Radiologic Technologists (the ARRT(M)) should be accepted as meeting the final regulations.

(Comment 230). Three comments recommended that either 40 hours of training or 20 hours and the ARRT(M) be the basis for grand parenting, while another comment urged that ''years of experience'' be the basis for grand parenting. Members of NMQAAC also recommended the addition of a limited grand parenting provision. Specifically, NMQAAC recommended limiting grand parenting to technologists who met the initial training requirements of the interim regulations by receiving 40 hours of training or earning the ARRT(M) (two of the several options that FDA had accepted under the interim regulations) and who had also performed at least 100 examinations.

Many comments expressed concern that, without grand parenting of present

technologists, there would be no one qualified to practice under the final regulations without more training. The comments asserted that these training demands would be expensive, disrupt facility routine, and overwhelm the training resources available to technologists. Some of the comments further argued that there would be no one qualified to provide this training.

The agency has been persuaded by the comments it received and the advice of NMQAAC that ''grand parenting'' provisions should be added to the technologist requirements. Under the final regulations technologists who have met the requirements of § 900.12(a)(2) of the interim regulations by the effective date of the final regulations will be considered to have met the initial mammography training and experience requirements in the new regulations. Section 900.12(a)(2)(ii) of the final regulations has been revised to reflect this. This change will achieve consistency with grand parenting provisions already existing for the other personnel groups. Although FDA believes that there are many technologists presently practicing who will meet the requirements of the final rule, this change will ensure that there will be an adequate number of qualified personnel to perform examinations and teach new technologists after the final regulations become effective.

FDA did not extend this grand parenting to the continuing education and experience requirements of § 900.12(a)(2)(iii) and (iv). Because these are ongoing requirements intended to ensure that technologists keep their skills sharp and their knowledge up-to-date, past qualifications can not be used to meet these requirements. Similarly, FDA did not include the general licensing or certification requirement established by § 900.12(a)(2)(i) as a qualification that could be grand parented. Because the license or certificate has to be renewed on a periodic basis, fulfilling this requirement in the past cannot justify exempting technologists from the need for future renewal.

On the other hand, FDA has declined to adopt the limitations on grand parenting proposed by NMQAAC. Under the interim regulations, FDA has accepted a number of ways for technologists to meet the initial mammography qualifications. Successful completion of 40 hours of training or the ARRT(M), the exclusive methods recommended by NMQAAC, are only two of these ways. Other ways technologists have been accepted as meeting the initial training requirement include obtaining a mammography certificate from the States of California, Arizona, and Nevada and successfully passing a comprehensive training course that is less than 40 hours in length but meets other rigorous criteria. Still other technologists have been accepted as qualified after a case-by-case evaluation of their qualifications. FDA estimates that as many as several thousand technologists might be disqualified if the NMQAAC recommendation was accepted, creating a potentially serious impact on access to mammography, and individual hardship. FDA has no evidence to indicate that these technologists as a group are performing inadequately and, therefore, has retained them within the scope of the grand parenting provision.

The requirements of § 900.12(a)(2)(i) are intended to provide some assurance that the radiologic technologist is qualified to perform radiologic examinations.

(Comment 231). Two comments supported this requirement as written, but others suggested various changes.

Over 20 comments stated that technologists should be required to be licensed in ''the'' State in which they were practicing or, at least, if they met § 900.12(a)(2)(i) through a State license, that it should be a license in ''the'' State of practice. A related comment suggested that FDA require technologists to meet State requirements that are as stringent as FDA's.

FDA has not accepted the suggestions made by these comments for a number of reasons. First, the statute provides that technologists be given a choice between State licensure or certification by a professional body (42 U.S.C. 263b(f)(1)(C)(i)) and the law also requires that the license be from a State, not ''the'' State of practice. FDA can not limit the choices established by the statute and notes, in addition, that some States do not have technologist licensure. FDA also believes it to be beyond the authority conferred upon it by the MQSA to stipulate State licensure requirements.

(Comment 232). One comment recommended that there should be national licensing of mammography technologists.

FDA does not believe that the MQSA contemplated the establishment of a national licensing requirement to replace State standards and procedures. The statute's specific reference to State licensing as an alternative requirement supports this conclusion (42 U.S.C. 263b(f)(1)(C)(i)(I)).

(Comment 233). With respect to certification, one comment urged that the general certification be limited by regulation to that of ARRT.

FDA agrees that ARRT general certification meets the requirements of § 900.12(a)(2)(I) and, in fact, this is presently the only certification accepted by the agency for this purpose. However, as discussed in the proposal, FDA does not want to codify a list of eligible certifying bodies because that will restrict its ability to add or delete organizations in a timely manner (See 61 FR 14900).

(Comment 234). Two comments suggested that FDA require certification bodies to establish a special mammography certification program based upon 6 months of training as an alternative to the general certification or licensing requirement.

FDA does not believe that this is necessary. Certification bodies are free to establish alternative programs and expand existing ones and FDA will evaluate such programs on a case by case basis. However, the increased level of training contemplated by this suggestion may not justify the cost. Similarly, although FDA believes that the suggestion in another comment that technologists be required to watch radiologists read films 8 hours every 6 months to improve ''rapport'' may be useful training, FDA has no evidence that the expected benefit would warrant mandating such a requirement.

The provisions of § 900.12(a)(2)(ii) are intended to provide some assurance that technologists possess adequate qualifications specific to mammography before beginning to perform mammography examinations.

(Comment 235). One issue related to these requirements drew several hundred comments, the largest number received on any part of the proposed regulations. This issue was the value of earning the ARRT(M) in meeting the specific mammography requirements for radiologic technologists. Unfortunately, over 80 percent of these comments, consisting primarily of multiple copies of 8 or 10 similar form letters, were based on a misunderstanding conveyed by an article in a journal that is widely distributed to mammography facilities. Many comments were based on an impression gained from this article that, because the ARRT(M) was not mentioned specifically in the regulations, it would have no weight in meeting the requirements. Some comments even indicated a belief that FDA would somehow ''take away'' the certification that the authors of the comments had worked so hard to obtain.

The authors of these comments unfortunately did not understand that the ARRT(M) has been given great weight under the interim regulations as

evidence that the technologist is adequately qualified, even though it is not mentioned explicitly in those regulations. In fact, none of the large number of certificates or training programs that FDA has accepted to meet part or all of the personnel training requirements are mentioned in the interim regulations. FDA, moreover, stressed in the proposed regulations that the agency has ''recognized the value of training hours required for ARRT special certification'' and intends to continue to do so (61 FR 14094). Specific mention of a credential in the regulations is not necessary for acceptance and, as discussed earlier, the agency has concluded that codifying particular organizations or programs will hamper the agency's ability to evaluate training programs on a case-by-case basis and to make timely changes in the acceptance of such training (61 FR 14900, 14904).

FDA regrets the distress this misunderstanding has caused many technologists and has contacted as many of the authors of these comments as possible to ease their concerns over the issue. The agency also has offered to work with the journal and the author of the article to ensure greater accuracy in future articles on the MQSA requirements. The journal has published the FDA correction of the article in an attempt to dispel this misunderstanding.

(Comment 236). Some of the comments received about the ARRT(M) made specific suggestions as to what type of recognition it should receive. Nearly 150 comments expressed the opinion that the ARRT(M) should be required of all technologists doing mammography, while over 40 more stated that it should be required in association with other training.

While FDA recognizes the great value of the ARRT(M) and intends to continue to accept it towards meeting the 40-hour requirement for radiologic technologists, the agency will not designate that particular certificate as a required or exclusive standard. FDA has no basis for establishing the ARRT(M) as the only way of demonstrating training in mammography. Furthermore, before a technologist can earn the ARRT(M), she or he must first earn general certification from the ARRT. The MQSA establishes that technologists have two alternative routes for general radiologic training: Either State licensure or certification by an approved professional group (42 U.S.C. 263b(f)(1)(C)(i)). If FDA were to require the ARRT(M), it would effectively eliminate the State licensure route to general qualification, in contradiction to the statuary provisions.

(Comment 237). Over 50 comments urged that the ARRT(M) be accepted as an alternative to the 40 hours of training required by § 900.12(a)(2)(ii). This also was the recommendation of NMQAAC members at the January 1997 meeting, although at earlier meetings NMQAAC had recommended that the ARRT(M) be accepted as equivalent to only 20 hours of training. One comment questioned the value of the ARRT(M), based on the opinion that the examination that must be passed to receive the ARRT(M) was not sufficiently specific to mammography.

FDA will not accept the ARRT(M) in lieu of the 40 hours of training required by § 900.12(a)(ii). The ARRT itself has recognized earning the ARRT(M) as equivalent to 24 hours of training. FDA does not have a basis for disagreeing with this evaluation by the sponsoring organization and, in most circumstances, intends to evaluate the ARRT(M) as equivalent to 24 training hours. FDA also notes that the performance of clinical examinations is a required component of the 40 hours of training required under § 900.12(a)(2)(ii) of the final rules. FDA has been informed by members of NMQAAC and others that technologists can and do pass the test for receiving the ARRT(M) without having performed any mammography examinations. For these reasons, although FDA did accept the ARRT(M) as meeting the interim regulation requirement to have training ''specific to mammography,'' and will continue to do so until the effective date of the final regulations, the ARRT(M) will not be considered equivalent to the final requirement of 40 hours of training, which must include the performance of examinations.

(Comment 238). Over 100 comments urged that the ARRT(M) be accepted as meeting at least part of the 40-hour training requirement of § 900.12(a)(2)(ii). Another 27 comments made suggestions for the number of hours for which it should be accepted, with the numbers varying from 5 to 30 hours.

FDA agrees that the ARRT(M) is acceptable for meeting part of the training requirement. Also, as already noted, the agency intends to accept the ARRT's estimate of the amount of training represented by its approved programs, unless there is evidence, now or in the future, that such acceptance is not warranted. Thus, the ARRT(M) ordinarily will be accepted as meeting 24 hours of the 40-hour training requirement and the agency reiterates that the fact that the ARRT(M) is not specifically mentioned in the regulations does not preclude this acceptance.

(Comment 239). A number of other comments addressed whether 40 hours of training was an adequate and appropriate amount to provide reasonable assurance of quality mammography. Twenty comments stated that it was a reasonable amount. Three comments asserted that the amount of training was excessive or even that training in mammography was not needed. An additional comment was concerned about the impact of the requirement on small facilities.

In response to these comments, the agency notes that training for radiologic technologists specific to mammography is required by the statute. The agency also notes that nearly all technologists who have met the interim regulations, whether at small or large facilities, have already obtained 40 hours of training or close to it without a noticeable adverse impact on the facilities. Some portion of these comments, and seven others, may have been based on the mistaken belief that the 40 hours was required to be in addition to any previous training in mammography. The grand parenting provision, which provides that meeting the interim regulations will qualify individuals as meeting the initial training requirements under the final regulations, should alleviate some of these concerns.

On the other hand, 14 comments stated that 40 hours of training was inadequate. Several of these made suggestions for higher levels of training, ranging up to 480 hours and including the performance of 200 examinations. The preponderance of the comments, however, seemed to support the figure of 40 hours of training. This amount was originally recommended, and is still supported, by NMQAAC. In the absence of any current evidence that 40 hours of training are insufficient, FDA believes that no change needs to be made in this number of hours.

(Comment 240). A number of comments addressed instructor qualifications. Concerns mentioned earlier, namely, that there would be no qualified instructors, have been addressed in part by the grand parenting provision. Thirteen other comments asked for more clarification as to who would be a qualified instructor or suggested listing specific categories of individuals who would be qualified.

FDA believes that the new definition of qualified instructor in § 900.2(oo) will address these concerns. Because of the wide variety of individuals who have expertise to provide the various segments of the technologist training, the agency wrote this definition with

the goal of describing certain groups that can be identified as qualified at this time, while retaining the flexibility to accept other individuals on a case-by-case basis.

(Comment 241). Three comments urged that the training be required to be Category A, but another comment said that such a requirement would make it difficult for a facility to find courses to qualify new technologists.

NMQAAC also did not reach a consensus on this issue. Although FDA has decided to accept only Category I training as meeting the interpreting physician requirements, the agency does not believe that a similar step is needed in the technologist area. In contrast to the situation with physician Category I and II training, the distinction between Category A and B is based upon whether or not prior approval by a recognized group has been obtained, not on the type of training. Thus, the concerns that led the agency to restrict physician training to Category I do not apply in the technologist situation.

Similarly, FDA does not believe that it is necessary to require the 40 hours of training to be ''graduate'' training that is taken after the technologist meets the requirements of § 900.12(a)(2)(i), as suggested by one comment. FDA is unaware of any reason to believe that the mammography training received as part of the technologist's basic training curriculum is unacceptable.

(Comment 242). Four comments were critical of the concept of continuing education courses, stating that students ''sleep through them'' and that they are only ''money-makers'' for the training providers.

While abuses of these types may exist, FDA believes that the great majority of training providers are sincerely interested in providing training that will improve medical care and that the great majority of students are equally interested in learning as much as possible from their training.

(Comment 243). Another large group of comments addressed the specific requirements included in § 900.12(a)(2)(ii). Nine comments suggested the addition of more subjects to those required to be included in the 40 hours of training. Specific suggestions included technical factors, film evaluation and critique, pathology, mammography of disabled women, and communication with patients. Three other comments supported the proposed inclusion of the topics of positioning and quality assurance.

FDA agrees that the topics suggested, and probably many others, could be valuable components of technologist training. Some, in fact, are subsumed under the topics proposed and finalized under § 900.12(a)(2)(ii)(A). However, the agency's intention was to limit this list in the regulation to only the subject areas most central to the quality performance of mammography examinations in order to maximize flexible and individualized training. FDA has added only imaging of patients with breast implants to the list of required topics, for reasons discussed below. The final regulation includes the words ''but not necessarily limited to'' to clarify that training in other areas also could be included in the 40 hours as long as the basic areas are covered. The agency intends to make additional information available on training programs and subjects that can satisfy this requirement.

At its January 1997 meeting, NMQAAC reconsidered a recommendation it made earlier and advised that FDA amend the proposed regulations to require the initial experience requirement of § 900.12(a)(2)(ii)(B) to be in addition to the 40 hours of training instead of part of the training, as was proposed. FDA did not receive any other comments making this recommendation. After considering the advice of NMQAAC, the agency has decided to retain the proposed requirement without amendment. FDA's experience in implementing the MQSA over the past years has not provided evidence that the significant increase in the training hours (approximately 50 percent over the proposal) that would result from NMQAAC's recommendation is warranted.

(Comment 244). Several other comments asked for clarification about whether previous training could be counted towards the mammography requirement or expressed concern about current technologists having to repeat their training. As explained previously, under the grand parenting provision that has been added, radiologic technologists who have previously qualified under the interim regulations will be deemed to have met the initial personnel requirements and will not have to repeat training for that purpose.

Section 900.12(a)(2)(ii)(B) requires that performance of clinical examinations under direct supervision of a qualified individual be part of the initial training. This requirement was intended to be parallel to the requirement that existed for interpreting physicians under the interim regulations and was continued for them in the final regulations.

(Comment 245). Eight comments supported this provision, noting that competency comes about by combining didactic training with actual experience and that such a requirement has worked well in the State of Iowa for several years.

A much larger number of comments opposed such a requirement. Eight of those opposing the requirement mistakenly believed that the supervision would have to be done by a radiologist and such supervision was not available in their situation.

Supervision of radiologic technologist examinations by a physician is not required; the new definition of a qualified instructor (§ 900.2(oo)) should help correct this misunderstanding.

(Comment 246). Twenty comments expressed concerns about having qualified supervision, especially in small and rural facilities. The new grand parenting provision that has been added to the final rule for radiologic technologists should solve this problem in areas where a shortage might have occurred.

(Comment 247). Nineteen other comments raised concerns about requiring supervised mammography examinations that related to issues of cost, liability, and patient privacy.

FDA notes that these are all issues that have been faced and successfully resolved by technologist schools nationwide in connection with the clinical training that they provide their students. FDA believes that they are manageable concerns and that any difficulties they raise are outweighed by the benefit of clinical training for radiologic technologists. The agency also notes that the addition of the grand parenting provision will limit this requirement to new technologists wishing to enter the field and that the number of examinations has been decreased, as discussed below.

(Comment 248). Six comments took the position that practical training was not needed. Their authors apparently believed that technologists could learn to adequately perform mammography examinations with only classroom training.

FDA disagrees. In view of the difficulty of performing adequate mammography examination, the agency believes that some clinical experience is vital for initial qualification.

(Comment 249). A number of comments expressed conflicting views on the appropriate number of examinations that should be done as part of the initial training. Twenty-two of these comments expressed the opinion that 50 examinations was too many, due to cost or difficulty of completing that number, or because of a belief that fewer examinations would serve the same purpose. Ten comments,

however, suggested higher numbers, ranging up to 200 examinations.

The question of the number of initial examinations was raised at the January 1997 NMQAAC meeting, but no recommendation was made on the issue. After considering these comments, FDA concluded that reducing the required number to 25 examinations would give the technologist adequate initial experience, while at the same time ease burdens relating to cost and availability of the training.

(Comment 250). A relatively large number of comments were also received on the requirements proposed in § 900.12(a)(2)(ii)(C). These comments focused primarily upon the proposal that all technologists doing mammography should receive at least 5 hours of training in the imaging of patients with breast implants as part of their 40 hours of initial training. Several different issues were brought up with respect to this requirement.

The first issue was whether it was at all necessary to require training in breast implant imaging. Over 30 comments supported this requirement. These comments noted that the training was necessary to perform adequate examinations of women with implants and that having the training would remove the need to have a physician present during the examination. About half of these comments recommended that no specific amount of training be required. Eighteen comments opposed any requirement relating to implant imaging, arguing that technologists were already obtaining such training as part of their initial curriculum, that imaging of women of breast implants did not require special training, and that their facilities conducted so few examinations that such a requirement would be ''overkill.''

A second issue was whether the training should be required of all technologists, as proposed, or just those who perform examinations of women with implants. One comment supported requiring it of all technologists in order to ensure that no matter what facility a woman with breast implants chose for an examination, she would be examined by a technologist with this training. The NMQAAC took this same position for the same reason. Ten other comments, however, urged that this requirement be limited in some way, with suggestions varying from limiting it to technologists who perform such examinations, to new technologists, or to technologists at facilities that perform a minimum number of examinations of patients with implants per year.

A third issue was whether there was sufficient training available in this area. Approximately 25 comments stated that there would not be sufficient training opportunities available to meet this requirement. A few of these comments supported this position with data from their own experience or surveys of training providers in their area. This position is in contrast with the comments mentioned earlier, which stated that this requirement was not needed because training of patients with breast implants was already routinely being received. The position is also somewhat inconsistent with the 15 comments FDA received from technologists who said that they had received the required training in the past, but might have difficulty providing documentation because their certificates do not specifically state the content of the training.

A fourth issue addressed in the comments was the proper mixture of classroom, video, and practical training. Eight comments stated that video training would have to be permitted because there would not be enough patients available to meet this requirement through clinical training. An additional 5 comments stated that it would probably not be possible to include clinical training. On the other hand, 20 comments emphasized the importance of clinical training and another 12 stated that it should be possible to receive this training in a clinical seminar. However, another comment pointed out that models would be reluctant to undergo the compression required by such training.

The final issue was the amount of training that should be required in imaging patients with implants. Nearly 30 comments expressed the opinion that 5 hours was too much for reasons that included cost and the belief that the necessary knowledge could be conveyed in less than 5 hours. Over 50 additional comments suggested specific and lesser amounts of training. About 80 percent of these comments supported a requirement for 2 hours of training, although some of those supporting 2 hours would also require an additional number of examinations under direct supervision. Several comments also suggested stating the requirement in a different way, for example, as part of a larger number of hours devoted to positioning or in terms of a minimum number of patients.

There were also a number of comments based on misunderstandings of the proposed requirement. Thirteen comments, for example, urged that the 5 hours be part of the general 40-hour training requirement, apparently not realizing that was already proposed. Seven other comments were based on the mistaken belief that implant imaging was a ''mammographic modality'' and that training in this area would also be required as part of their continuing education.

The training required for imaging patients with implants is part of, and not in addition to, the 40 hours of initial training and that the definition of mammography modality does not include breast implants. The agency expects to issue educational materials to help interpret the final regulations and will further clarify these and similar misunderstandings.

In response to the comments on the five major issues, FDA first notes that the statute requires the agency to establish standards relating to special techniques for mammography of patients with implants (42 U.S.C. 263b(f)(1)(H)). Requiring technologists to be trained in examining such patients is consistent with the statutory requirements. In addition, FDA has received many comments, including advice from NMQAAC, which underscore the necessity for performing such examinations with trained personnel.

The agency also notes that the grand parenting requirement will relieve technologists who met the interim regulations from the need to obtain additional training in the imaging of patients with breast implants. This should alleviate much of the concern that was expressed in comments about availability of training and the overloading of limited training resources. The grand parenting provision also eliminates the possibility that technologists who have been performing such examinations successfully for years but were not formally trained, or who do not have documentation of their training, would have to obtain this training. At the same time, all technologists newly entering the field will have to receive training in imaging of patients with breast implants. FDA believes this requirement strikes the proper balance to ensure that patients are properly examined.

Further, after consultation with NMQAAC, FDA concluded that this training should not be established as a separate requirement, but instead should be included under § 900.12(a)(2)(ii)(A) as one of the topics required to be covered during the 40 hours of training related to mammography. By including imaging of patients with breast implants among these required subjects, FDA ensures that all radiologic technologists being trained for the field of mammography will receive education in this important technique, as required by the MQSA. At

the same time, by eliminating any particular hourly requirement, the agency permits maximum flexibility in the amount and type of training received, plus some degree of assurance that the student will be evaluated in this area as part of the formal training process. Radiologic technologists who expect to examine patients with implants on a more frequent basis or facilities that have large numbers of such patients among their clients can increase the training hours in this subject. Conversely, radiologic technologists and facilities with few such examinations can devote training hours to other subjects that seem more beneficial to their practice, as long as the basics of imaging women with implants have been covered adequately. Because the hours devoted to such training are required to be documented contact hours under the supervision of a qualified instructor, a variety of types of training similar to those suggested in the comments could be suitable as long as they meet the criteria of § 900.12(a)(2)(ii)(A).

The second part of proposed § 900.12(a)(2)(ii)(C), which was that at least 8 of the 40 hours must be training with each mammographic modality used by the technologist, received far fewer comments.

(Comment 251). Five comments supported the requirement, although some concern about problems of documentation was expressed. Two comments opposed the requirement, one due to a mistaken impression about the number of modalities for which training would be required, the other because of a desire to leave the facility the flexibility to decide how much training was needed. Fourteen comments wanted the number of hours required per mammographic modality to be reduced.

FDA believes that much of the opposition to this requirement as proposed arises from a misunderstanding of what is meant by mammographic modality. Presently, there are only two mammographic modalities, screen-film and xeromammography, as defined in the regulations. Most technologists use only one or the other and, thus, this requirement has no great impact on them. For those technologists who do, or will, work with more than one mammographic modality, FDA does not believe it is excessive to have at least 20 percent of the total amount of initial training related to each mammographic modality used. Therefore, this part of the proposal has been retained in the final regulations.

The continuing education requirement, § 900.12(a)(2)(iii), was the first of two, along with continuing experience, intended to ensure that the technologists keep their skills and knowledge base up-to-date. The basic requirement proposed was that radiologic technologists have continuing education equivalent to 15 continuing education units in a 3-year period. The amount proposed was unchanged from that established under the interim regulations, but the proposed wording puts the emphasis on the total to be earned in a 3-year period instead of a yearly average.

(Comment 252). Five comments supported the requirement as being flexible and adequate to keep ''technologists on top of changes.'' Three comments opposed it on the grounds that the continuing education requirements of the ARRT were sufficient or that earning the ARRT(M) should excuse technologists from earning continuing education credits.

FDA is aware that the ARRT requires earning 12 credits per year while the proposed regulations require an average of only 15 per 3-year period. However, the 12 per year required by the ARRT continuing education standards can be from any area of radiology and will not necessarily be training in mammography. If the radiologic technologist takes mammography training to fulfill ongoing ARRT requirements, that training can be counted towards satisfaction of the MQSA continuing education standards. Similarly, while earning the ARRT(M) is evidence of a high level of knowledge at the time the test was taken, it does not ensure that the technologist will keep up with changes after that date, which is the primary purpose of continuing education. Thus, FDA cannot excuse technologists from this requirement on the basis that they have met the ARRT continuing education standard or have earned the ARRT(M).

Two additional comments supported the idea of looking back 3 years for the averaging period. Ten identical comments suggested changing the requirement to earning 10 hours every 2 years while two others urged that technologists be required to earn 5 hours of continuing education credit each year.

FDA established the longer time period for averaging continuing education credits to permit and encourage the technologists to take longer and more comprehensive courses as they became available. The agency believes such training may be more valuable than several short uncoordinated courses. Shortening the averaging period to 1 or 2 years would not prevent technologists from taking 15 credit courses, but it might discourage them from doing so due to a reluctance to pay for hours of training that would be beyond those necessary to meet the requirements. Use of a 3-year averaging period also provides greater flexibility in selecting courses that best meet individual needs and minimizes the possibility that a technologist will sign up for a course simply because it was available and the end of the year was approaching.

(Comment 253). Two comments urged that continuing education in implant imaging be specifically required as part of the continuing education for technologists.

In view of the many comments discussed earlier concerning the appropriate amount and type of training needed to successfully image patients with implants and the availability of that training, FDA has concluded that such a specific requirement would be too restrictive.

(Comment 254). A number of comments were received about the number of continuing education units being required. Eight comments asserted that the requirement of an average of 5 units per year would be too great a burden on technologists in rural facilities. On the other hand, one comment suggested increasing the number of credits required to 12 per year and provided further suggestions on the type of training, while another urged the requirement be raised to 10 credits per year.

After considering these comments, FDA has concluded that the 5 unit per year average is reasonable. Twelve units of continuing education per year are required to maintain the ARRT credentials and, at this time, the majority of radiologic technologists practicing mammography have ARRT certification. Because the 5 units required by these regulations can be part of those 12, the final regulation does not establish an excessive requirement. The agency also believes that, in association with the requirement in § 900.12(a)(2)(iii)(D) for extra training if the technologist begins working with a new mammographic modality, an average of 5 credits per year is adequate to ensure that the technologist keeps up-to-date.

(Comment 255). Five comments urged that only Category A training be accepted, while a sixth asked for clarification on that point and a seventh would restrict the training to certain types without reference to category.

For the reasons previously discussed, FDA does not believe that it is necessary

to restrict continuing education credits for radiologic technologists to Category A courses.

(Comment 256). One comment stated that a limit should be placed on the number of times credit could be earned for teaching the same course. NMQAAC, when discussing this issue, recommended that no credit should be given for teaching. FDA recognizes, however, that a great amount of study and learning is required to successfully teach a course, especially the first time it is given. The agency will continue to permit personnel to earn credit towards the continuing education requirement by teaching, but has added a new provision that limits the times a particular course can be counted towards this requirement to once in any 3-year period (see § 900.12(a)(2)(iii)(B)). This is consistent with similar provisions for interpreting physicians and medical physicists.

(Comment 257). A number of comments on this section were based on misunderstandings. One comment expressed the belief that this requirement actually meant that an individual would have to earn 15 units every 2 calendar years in order to meet this requirement. Another comment, incorrectly assuming that implant imaging was a mammographic modality, assumed that 6 hours of implant imaging training would be required every 3 years. Other comments mistakenly concluded that 5 credits on implant imaging would be required every year, that the requirement to average 5 credits a year was being increased to 6, or that 5 credits were being required each and every year.

All of these comments opposed the requirement based on their misunderstandings. As FDA develops educational materials to help personnel understand how they may comply with the new regulations, special attention will be focused on correcting such misunderstandings. Changes in the wording of § 900.12(a)(2)(iii)(A) from the proposal are intended to emphasize that the basic continuing education requirement is to earn 15 credits over 3 years and to clarify options for calculating the time period to be used to demonstrate compliance with that requirement. The agency hopes that these changes will eliminate confusion about whether 5 units must be averaged per year or earned per year (the unit requirement is an average) and provide radiologic technologists and the facilities that employ them with some flexibility in maintaining and documenting compliance with this requirement. Both of the changes parallel similar changes made in the wording to the interpreting physician and medical physicist requirements.

Only two comments were received on proposed § 900.12(a)(2)(iii)(B) (now § 900.12(a)(2)(iii)(C)), which requires a technologist to have some continuing education for all modalities used by that technologist. One comment stated this was a ''great revision.'' The other expressed concerns about the availability of the training.

FDA believes that if a new mammographic modality is introduced, training will be available initially from the originators of the mammographic modality because those originators will have a high interest in ensuring that the mammographic modality is used properly. FDA acknowledges that training with a disappearing mammographic modality, like xeromammography, may be more difficult to obtain. However, FDA has concluded that the possibility of detriment to the public health that could result from personnel not maintaining their skills must override this concern.

(Comment 258). FDA received four comments on proposed § 900.12(a)(2)(iii)(C) (now § 900.12(a)(2)(iii)(D)), which describes requalification procedures for technologists who failed to meet continuing education requirements. One comment agreed with the provision and two comments went further to suggest that there should be some sort of penalty for not meeting the requirement on time. The authors apparently did not realize that the penalty was not being able to perform mammography except under direct supervision until the requalification was completed (see previous discussion related to interpreting physician). The fourth comment supported the requirement, but expressed concern about who would approve the training and keep the records of completion.

FDA has found the mechanisms used under the interim regulations for approving training, which involve the participation of professional groups, are adequate. These same professional groups ordinarily provide documentation of completion. Under the interim regulations, it has been the responsibility of the facility to obtain and maintain such records and this will continue under the final regulations.

(Comment 259). The three comments received on proposed § 900.12(a)(2)(iii)(D) (now § 900.12(a)(2)(iii)(E)) opposed the requirement that a technologist receive training in use of a mammographic modality for which she was not previously trained before using that modality. One comment stated that the requirement would be an undue hardship and two stated that it will be difficult to obtain the training. FDA believes that the value of being trained in the use of a mammographic modality before beginning to use it on patients overrides the hardship concern. As discussed earlier, FDA also believes that availability of training will not be a problem and that the definition of qualified instructor (§ 900.2(oo)) provides for an adequate number of teachers. The proposed requirement has been retained unchanged.

Continuing experience is the second of the general requirements intended to ensure that the technologists maintain their skills. As proposed, § 900.12(a)(2)(iv) required that technologists perform a minimum of 100 examinations during a 12-month period. This requirement was intended to parallel the continuing experience requirement for physicians.

(Comment 260). Eight comments supported a continuing experience requirement for technologists, explaining that a technologist's positioning skills improve with additional mammography examinations. Nine comments opposed the requirement. Several of these suggested alternative measures, such as a ''lengthy appraisal (at least 3 days * * *) * * *'' by the chief technologist and radiologists or a certification program similar to that used by the American Heart Association for CPR certification.

While these suggestions have merit, they are a form of proficiency testing and, as discussed elsewhere, large numbers of comments provided valid reasons to conclude that it is premature to require such testing.

(Comment 261). Another comment opposed the requirement on the grounds that ''if you can do a mammogram, you can do it, period.'' The author's basic assumption seems to be that you never forget how to perform mammography. FDA notes that the purpose of continuing experience requirements is to ensure that technologist skills are maintained at a level that is likely to produce accurate and reliable mammograms. In view of the complexity of the examination and changes in technology, FDA believes that the optimism expressed by this last comment is unwarranted.

(Comment 262). Proposed § 900.12(a)(2)(iv)(A) set the continuing experience requirement at the performance of at least 100 mammography examinations in a 12-month period. One comment stated that this was a ''very acceptable requirement,'' but two believed that it

should be higher. One of these recommended that the number should be the same as the 480 interpretations a year required of radiologists. Four comments supported the level of the requirement, but asked that the averaging period be longer than a year to allow technologists to be absent for longer periods and still be able to meet the requirement. Two of these comments noted that physicians are allowed a 24-month averaging period for their continuing experience. Ten other comments suggested that the number be lowered, with 50 or 75 a year being the most common suggestions.

FDA has concluded that the number of 100 per year, which was first suggested by NMQAAC in February 1994, and supported by them at their January 1997 meeting, is the most reasonable compromise between the need to establish a requirement sufficiently high to maintain skills and the need to avoid disqualifying large numbers of competent technologists. The agency notes that as few as two examinations per week will be sufficient to meet this requirement.

FDA does agree with the suggestion that the averaging period be lengthened to 24 months and the wording of the regulation has been changed to require the performance of 200 examinations in a 24-month period. A clarification of how to determine the 24-month period was also added, which parallels similar provisions for calculating such time periods for interpreting physicians and medical physicists.

(Comment 262a). Seventeen comments identified specific groups that they believed would have difficulty meeting this requirement. These included individuals, such as mammography supervisors, instructors, and technologists in sales, who had made career choices that would make it difficult for them to meet this requirement.

FDA understands the desire of these individuals to keep their options open in case they wish to return to the performance of examinations, but the agency believes that higher priority must be given to maintaining technologist proficiency. FDA also notes, as discussed later, that a requalification procedure has been provided for technologists in this situation.

(Comment 263). A related concern was expressed in the 13 comments that indicated technologists in rural hospitals would have difficulty meeting this experience requirement. As explained previously, FDA recognizes that rural facilities face special challenges but believes that it would be contrary to the MQSA goal of assuring women a uniform minimum level of quality of mammography nationwide to establish lesser standards for technologists practicing in rural areas.

As proposed, § 900.12(a)(2)(iv)(B) stated that technologists who fail to meet the continuing experience requirement can re-establish this qualification through the performance of 50 mammography examinations under direct supervision.

(Comment 264). Ten comments stated that this number of examinations was too many and suggested that it be reduced, with 30, 25, and 20 examinations all being proposed. Another comment urged that there be a penalty for failing to meet this requirement, apparently not realizing that the penalty was not being able to work independently until requalification was completed. One comment urged that proficiency testing be used instead of an experience requirement, while another was concerned about how the performance of these examinations would be documented.

As discussed above, FDA has reduced the number of examinations that have to be performed under direct supervision as part of the initial training from 50 to 25. The agency has no reason to require the requalification figure to be higher than the number of examinations for initial qualification. Accordingly, the agency has similarly reduced the requalification requirement from 50 to 25 examinations.

d. *Medical physicist (§ 900.12(a)(3))*

Section 900.12(a)(3) establishes the requirements that must be met by medical physicists who conduct surveys of mammography facilities and provide oversight of the facility quality assurance program. Initial qualifications, alternative initial qualifications, continuing qualifications, and the reestablishment of qualifications are all covered. No major changes have been made in the final regulations from what was proposed. Some changes have been made in the survey experience requirement and in the averaging time for the continuing qualifications requirement. The comments received on the final regulations in each of these areas are discussed in below in connection with the specific provisions.

(Comment 265). One comment stated that the proposed rule is very positive, ensuring that only properly trained and adequately qualified professionals perform medical physics surveys. Another comment concluded that the medical physicist qualifications were appropriate and reasonable.

The initial qualification requirements for medical physicists include board certifications or State licensure or approval; masters degree or higher in physical science with 20 semester hours in college or graduate level physics; 20 contact hours of training in mammography; and survey experience.

The proposed initial qualifications requirements generated a wide spectrum of comments. Views varied greatly on the value of State approval or licensure in ensuring that physicists were properly qualified to perform mammography services.

(Comment 266). Ten comments expressed doubt that State approval/licensure provided a sound basis for establishing competence. One comment recommended that the State approval option be deleted, while another suggested that State approval be accepted only after FDA investigation. One comment stated that State approval/licensure should be part of alternative criteria with additional appropriate training and experience requirements. Three comments argued that State approval or licensure should be specific to the State where the professional practice will occur, unless a State reciprocity mechanism is in place. One comment stated that the proposal was unclear as to whether State approval was sufficient or additional requirements would need to be met after October 1997. On the other hand, seven comments stated that State approval, like board certification, was adequate by itself and that additional requirements were not needed.

Five comments stated that board certification should be required for all medical physicists. Several other comments urged FDA not to accept board certification without requiring a special certificate for mammography. Two comments recommended deleting the master's degree requirement and argued that course work in college level physics and supervised experience should be adequate. One comment contended that the issues of degree, training, and curricula are unnecessarily complicated in the proposed regulation. Another comment stated that the requirement of board certification or State licensure unfairly excludes physicists who are otherwise well qualified to test mammography equipment on the basis of their actual experience in this field. One comment stated that these requirements are appropriate.

FDA considered all of the comments received concerning initial qualifications requirements for medical physicists. Because the MQSA expressly establishes State approval or licensure

as an alternative pathway (42 U.S.C. 263b(f)(1)(E)(i)), FDA could not eliminate this route for initial qualification, even if the agency believed it was desirable to do so. The agency is aware that not all States have adequate minimum qualifications standards. Concern has also been expressed that some board certified physicists do not have adequate experience with mammography equipment. Therefore, as proposed, FDA added additional educational and experience requirements for all physicists, regardless of which initial route they follow to become qualified under the MQSA. These additional requirements are: (1) For initial qualification, masters degree or higher in physical science, with a minimum 20 semester hours or equivalent in college or graduate level physics, 20 contact hours of training in mammography, and experience of surveying 1 facility and 10 units; and (2) for alternative initial qualification, bachelors degree or higher in physical science, with a minimum 40 semester hours or equivalent in college or graduate level physics, 40 contact hours of training in mammography, and experience of surveying 1 facility and 20 units.

(Comment 267). A number of comments suggested that additional subjects, such as mathematics, biology, nuclear physics, and radiologic technology should be added as acceptable fields in which the degree may be obtained. Some comments wanted the reference to physical science to be changed to medical physics. One comment stated that physicists who are not board certified should be required to demonstrate a stronger educational background than currently required. In response to the agency's discussions in the preamble section of the proposal about the possibility of requiring all 20 semester hours in imaging physics (61 FR 14905), two comments stated that such a requirement would not be appropriate because the mammography equipment evaluation would require more than training in imaging and limiting 20 semester hours to imaging physics would not provide the physicist with the education needed to adapt to constant changes in technology.

The agency has decided to keep the requirement of physical science as the field in which the degree must be obtained and believes that its definition of physical science (§ 900.2(jj)) sufficiently covers the wide range of subfields that can provide adequate initial training to enable an individual with 20 semester hours of physics to understand the basics of mammography physics. The agency believes that this would not be the case if other fields, such as biology, were added to the definition.

(Comment 268). Sixteen comments stated that board-certified physicists should not have to demonstrate compliance with the additional educational requirements of § 900.12(a)(3)(i)(B)(*1*) in the proposed regulations, but should demonstrate experience conducting mammography surveys. Because the MQSA establishes board certification and State licensure/approval as equivalent pathways for qualifying medical physicists, FDA has not issued different additional qualifications for each of these groups. Accordingly, the agency has retained this requirement as proposed. However, if a designated board confirms that its certification in an accepted speciality always requires the minimum of a masters degree in physical science with at least 20 semester hours in physics, the agency may not have to verify the degree and semester hour requirements during annual inspections for those physicists certified by that board.

Another initial requirement is that physicists have 20 contact hours of documented training in mammography. Several comments requested further clarification of contact hours. Some comments urged FDA to accept self attestations of contact hours for experienced physicists who have worked in the field for a long time but do not have any documented contact hours. Ten comments stated that, if the medical physicist is board certified, the contact hours requirement should not apply.

After considering these comments and consulting with NMQAAC, FDA has retained contact hour requirements for all physicists, regardless of which initial route they followed to become qualified. FDA will accept self attestation of any contact hours received before October 1994. The agency has also provided a more detailed description of contact hours in § 900.2(m).

Under the proposal, an additional initial requirement was that medical physicists shall have the experience of surveying at least 5 facilities and 10 units.

(Comment 269). About one hundred comments opposed the requirement for multiple facility surveys for in-house physicists and stated that in-house physicists who are employed by hospitals and medical schools are often contractually prohibited from performing surveys at outside facilities. Several of these comments suggested that FDA should instead base its requirement on number of unit surveys.

In response to these comments, the agency has revised this requirement so that physicists qualified under § 900.12(a)(3)(I) will be required to have initial experience of one facility and ten unit surveys. FDA did not eliminate the facility requirement entirely because the agency strongly believes that having experience with complete surveys of facilities, including oversight of all QC records, is necessary. Evaluations of units only cannot provide a medical physicist with the same experience and knowledge as the survey of a facility. Although the amended regulation does not mandate survey experience with more than one facility, the agency encourages all physicists to perform additional facility surveys when possible to expand their experience. FDA believes that it is also advisable to gain familiarity with a number of different mammography units because much of the educational benefit is lost if the same unit is surveyed repeatedly to meet the experience requirement. In order to address this concern to some degree, the regulation now provides that no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

The initial experience requirement also stated that, after the effective date of these regulations, the initial survey experience must be acquired under the direct supervision of a qualified medical physicist.

(Comment 270). One comment stated that direct supervision would be very difficult to arrange. Another suggested requiring two surveys under direct supervision and the rest under indirect supervision. The comment stated that indirect supervision with telephone consultation and advice is more valuable than the direct supervision.

FDA has retained this requirement because the agency and NMQAAC consider it important that new physicists entering the field acquire initial experience in conducting mammography surveys under the direct supervision of a qualified medical physicist, who can correct any mistakes made during the learning process before they pose to a threat to patients. Because this provision does not take effect until the effective date of the regulations, the agency believes that it will not disrupt the availability of experienced medical physicists.

Alternative initial qualifications were established in § 900.12(a)(3)(ii) to provide a way to permit medical physicists who have been successfully providing mammography physics services for some time, but who lack a masters degree, to continue to practice

without lowering quality standards in any manner that would jeopardize public health. In general, in order to qualify by this alternative qualification route, an individual must have qualified under § 900.12(a)(3) of the interim regulations and maintained his or her licensure, approval, or certification requirement as required under the interim regulations. The physicist using this alternative route is also required to have a bachelors degree or higher in physical science, with at least 10 semester hours or equivalent in college level physics, 40 contact hours of training in mammography, and survey experience of 10 facilities and 20 units.

(Comment 271). Several comments opposed the alternative pathway for initial qualifications and considered the proposed educational requirements for these medical physicists to be inadequate. On the other hand, a larger number of comments shared FDA's concern for existing medical physics service providers and the facilities they serve. These comments supported this alternative qualifications route and recommended that experienced individuals who have previously qualified and who meet continuing education and experience qualifications should be allowed to continue to practice. Five comments stated that the alternative initial qualifications should be a permanent option. One comment claimed that the proposed alternative qualifications criteria were too restrictive to permit many State licensed physicists to qualify.

A number of comments suggested increasing the requirement of semester hours of college level physics for this alternative route from the proposed number of 10. Some comments suggested that the credit hours requirement for this alternative route be increased from 10 to 15 or 20 hours by including subjects such as biology, radiation biology, radiation science, and chemistry. Other comments expressed concern that this college level physics requirement would bar a number of presently qualified physicists from continuing to provide mammography services. Two comments stated that the requirement for semester hours in physics should be removed, and that physicists qualified under the current interim regulations by the State licensure or approval process should not have to meet additional educational requirements. One comment stated that 10 hours of physics is reasonable. Another comment stressed that formal training in physical science is necessary and stated that this standard should not be weakened.

In the preamble to the final regulations, the agency explained its reasons for proposing the alternative initial qualifications route for physicists with bachelors degrees who are currently performing mammography physics services under the interim rule (62 FR 14905). Based upon discussions with NMQAAC and the Conference of Radiation Control Program Director's Task Force on Medical Physics Criteria, the agency proposed the requirements for course work in physics, contact hours, and experience included in this alternative route. The agency believes that the combination of all these requirements provides adequate protection for the public health, while permitting most practicing physicists to continue to provide mammography services under the final rule.

Moreover, the agency considered it to be unfair to individual physicists and potentially detrimental to facilities and the public to exclude many currently practicing physicists by withdrawing the alternative initial qualifications route or by increasing the educational credit hours requirement for these individuals in the absence of evidence that such physicists are providing inadequate services. The agency was concerned that such an exclusion could cause a possible shortage in the availability of physics services for some period of time.

Several comments supported the views expressed in the preamble to the proposed rule. In addition, the agency's experience and data gathered from its inspection data base affirm that many currently practicing medical physicists with bachelors degrees, adequate course work in physics, and substantial experience are performing quality medical physics surveys in mammography facilities with care and competence.

The agency continues to believe that it is very important to have at least 10 semester hours in college or graduate level physics. The other subjects, suggested by some comments, will not necessarily provide an individual with the necessary background and training to understand the basics of mammography physics. However, because at least a bachelors degree in physical science is also part of the educational requirement, the credit hours in other related subjects, suggested by the comments, may be associated with fulfilling the degree requirement. Although the agency believes that a minimum of 10 hours of course work in physics is necessary to gain proper physics background, it also believes that requiring more credit hours in physics, as some comments and some members of NMQAAC suggested, will exclude individuals other than physics minors or majors or those with graduate degrees. For these reasons and those previously stated in the proposed rule (61 FR 14905), the agency has retained, as proposed, the minimum requirement of a bachelors degree with no less than 10 semester hours or equivalent courses in physics in its final rule on alternative initial qualifications.

The agency agrees, however, that enhanced educational qualifications are necessary in order for physicists entering the field in the future to have the required background to understand the technology of the future as it becomes increasingly intricate. As previously proposed, therefore, FDA is limiting the use of this alternative pathway to only those physicists who have met its requirements by the effective date of the final regulations.

(Comment 272). Several comments opposed the contact hours requirement, while some supported it.

The agency has previously stated its justification for retaining this requirement for initial qualification route. For the same reason, the agency will retain the requirement for the alternative route.

(Comment 272a). A large number of comments stated that the proposed initial experience requirement of 10 facilities and 20 unit surveys for the alternative route in § 900.12(a)(3)(ii)(B)(*3*) would be impossible to achieve for many in-house physicists and suggested eliminating the reference to the number of facilities.

In order to be consistent with the initial requirements for physicists under § 900.12(a)(3)(i)(B)(*3*), the agency has revised § 900.12(a)(3)(ii)(B)(*3*) to change the required initial experience from conducting surveys of at least 10 mammography facilities and 20 units to conducting one facility and 20 unit surveys. Again, no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(Comment 272b). Two comments stated that the experience component under the alternative initial requirement should have to be fulfilled under the direct supervision of a qualified medical physicist, as required under § 900.12(a)(3)(i)(B)(*3*). Another comment suggested changing the effective date of this regulation to the effective date of this section because there is more than one effective date in these regulations.

The agency points out that § 900.12(a)(3)(i)(B)(*3*), which will take effect 18 months after these regulations

are published, will affect only new medical physicists entering the field. Because § 900.12(a)(3)(ii)(B) establishes that the alternative pathway is only available until the effective date of the final rules, the direct supervision requirement does not apply to the individuals qualified through the alternative pathway, because no one will enter the field through that pathway following the effective date of the rules. In response to the comments about varying effective dates in the proposed rule, FDA points out that, except for some of the equipment standards and equipment QC tests, all sections of the final rule will be effective 18 months after publication. This is clearly stated in the final rule.

The continuing qualifications requirements for medical physicists have two components: § 900.12(a)(3)(iii)(A) continuing education, which requires the physicist to earn 15 units over 3 years; and § 900.12(a)(3)(iii)(B) continuing experience, which requires the physicist to survey 2 facilities and 6 units over 24 months.

(Comment 273). One comment questioned FDA's authority to require continuing education at all.

In response, FDA observes that the MQSA is designed to provide the government with authority to issue and enforce standards to ensure safety and accuracy of mammography in the United States. The section of the statute relating to quality standards lists a variety of requirements for each group of personnel associated with mammography practice. Although only the requirements relating to interpreting physicians expressly includes a reference to continuing education, these requirements are not an exclusive or limited list of standards to be established by the agency. They represent only the minimum requirements that Congress mandated that the Secretary must ''include'' among those issued to ensure safety and effectiveness of mammography (42 U.S.C. 263b(f)(1)). Just as FDA has determined that continuing education is necessary to maintain the skills and expertise of radiological technologists, the agency has concluded that continuing education requirements are also essential for medical physicists, who play a critical role in guaranteeing the safe operation of equipment and effective quality assurance systems.

(Comment 274). One comment stated that these requirements are appropriate. Two comments asserted that self training by reading and studying should qualify. Other comments asked that continuing education units be better defined. Another comment stated that the language was too prescriptive. One comment stated that most medical physicists would have completed rather than taught continuing education units and another opposed giving repeated credit for a course taught several times. One comment maintained that no CME has been available for those who have tested Xerox systems for the last 5 years, and that such courses are unlikely to be available in the future.

FDA notes that the final rule establishes that the units earned through teaching of a specific course can only be counted once towards the 15 education units requirement. A new definition for continuing education unit or credit has been added in § 900.2(l). The agency will accept only the continuing education credits offered by professional organizations whose training is shown to be relevant and acceptable for medical physicists. Language clarifying the options for calculating the 3-year period has also been added. The agency understands that sufficient training opportunities may not be available in xeroxmammography. However, because only 0.5 percent or less of the facilities use xeromammography, the agency believes that the majority of physicists, if not all, will need only continuing education related to screen-film mammography. When other mammographic modalities, such as digital mammography, become available, medical physicists will need continuing education in those areas. The agency believes that such training will be increasingly more available as the technologies develop. The agency advises the facilities that use xeromammography to contact the manufacturer of this system to provide or arrange for training in xeromammography.

(Comment 275). One comment recommended that the second and subsequent 3-year periods begin to run from the original date that the physicist was required to meet the continuing experience qualification.

FDA decided to use a floating 3-year period for all mammography personnel, instead of a fixed 3-year period as suggested by the comment, for two reasons. First, as explained previously, a fixed period actually allows an individual to go much longer without continuing education than the length of the period itself. With a 3-year fixed period, for example, if an individual received training near the beginning of one period and near the end of the next period, he or she would go nearly 6 years without continuing education, which is entirely too long in a changing field such as mammography. Second, because inspections are annual, if an inspector found that an individual had not met the continuing education requirement during the previous fixed period, that individual might have provided services to the facility for almost a year before the failure was discovered. Depending upon the circumstances, the actions needed to correct the consequences of using the services of a noncompliant individual could require a considerable amount of time and money on the part of the facility.

(Comment 276). Two comments stated that persons providing continuing education should meet the qualifications of a medical physicist as described in the proposed regulations and that the instructors should be in active practice.

FDA disagrees. The agency believes that many scientists, university professors, and equipment manufacturers can provide training in different aspects of mammography physics.

(Comment 277). Another comment claimed that it is excessively bureaucratic to require that a physicist send a copy of his or her CME to include in the operating manuals, as was insisted upon by an inspector at their facility.

FDA believes that the author of the comment misunderstood the reason why the information on CME was required to be sent to the facility. The reason was not for inclusion in the facility's operating manual but to enable the facility to demonstrate that its medical physicist met the continuing education requirement. All interpreting physicians, radiologic technologists, and medical physicists providing services to mammography facilities have to document that they meet the continuing education requirement.

(Comment 278). One comment stated that there should be some penalty for failing to meet the continuing education requirements.

The consequences of failure to maintain these requirements is the inability to work independently as a medical physicist. As stated with respect to other mammography personnel, the agency believes this penalty is the most effective means to guarantee that physicists maintain qualifications and to protect the public health.

Under the proposal, FDA would require medical physicists to maintain their skills through the survey of at least 3 mammography facilities a year.

(Comment 279). More than 50 comments opposed this requirement. As

expressed in related comments, in-house physicists may be contractually prohibited from surveying outside facilities. Many of these comments suggested deleting the reference to the number of facilities.

In response to these comments and in order to establish consistency with revisions to the initial experience requirement discussed above, FDA has revised the proposed continuing experience requirement. The requirement will be for surveys of two facilities and six units in a 24-month period. The same facility can be surveyed twice. However, as with the initial experience requirement, no more than one evaluation of a specific unit within a period of 60 days may be counted towards the requirement. In addition, while the same facility may be surveyed twice within this 24-month period by an individual physicist in order to meet this requirement, the two surveys by this physicist must be at least 10 months apart. This restriction does not prohibit the facility from having surveys more frequently than once every 10 months, if it wishes to do so out of quality concerns or for other reasons. The restriction only limits the number of surveys of that facility that an individual physicist can use to meet his or her continuing experience requirement. The reduction in the number of facilities will address the concerns that were raised about in-house physicists.

In order to be consistent with the equivalent physician and technologist requirements, the continuing experience requirement for physicists is now based upon a 24-month period. This will now make it more feasible for physicists who are out of the field for a time, e.g., on maternity or sabbatical leave, to maintain their qualifications. The requirement has also been amended to explain options for identifying the 24 months that will be used to determine compliance. This change parallels similar changes in the requirements for radiological technologists and interpreting physicians and is intended to provide personnel and facilities with additional flexibility for monitoring compliance with these standards.

Section 900.12(a)(3)(iii)(C) requires physicists to be trained to do surveys of a mammographic modality for which they have not previously received training before independently doing surveys of such units.

(Comment 280). A number of comments correctly pointed out that the reference to mammographic ''examinations'' should actually be to mammographic ''surveys'' or ''evaluations.''

FDA has corrected this error by replacing the word examination with survey.

(Comment 281). Several comments opposed the requirement for 8 hours of training in a new mammographic modality prior to doing a survey of such a modality. One comment expressed concern that this will keep physicists from surveying new modalities. Another comment suggested that length and degree of training be commensurate with the specifics of the new modality. Two comments stated that the requirement overestimated the complexity of new modalities and undervalues the physicist's capability of adapting to new modalities in medical imaging. One comment stated that this rule is unnecessary because a qualified physicist will be able follow guidelines developed by ACR and AAPM when a new modality, such as digital mammography, begins to be used by the facilities. One comment stated that 8 hours of training in a nonscreen-film modality would be difficult to complete, while another comment stated that only expert instrument manufacturers would be qualified to provide such training.

The agency continues to believe that the proposed requirement of 8 hours of training in a new mammographic modality before a medical physicist may begin performing surveys independently in that type of modality is reasonable and necessary. Training prior to practice using a new mammographic modality is required for all critical personnel (interpreting physicians, radiologic technologists, and medical physicists) because FDA has determined that the benefits to patients from such prior training outweighs the cost to individuals and facilities. The agency recognizes that training in a new modality may not be widely available and agrees with comments that have observed that equipment manufacturers would and should be able provide such training. The agency will encourage manufacturers of a new mammographic modality, such as digital mammography, to provide or arrange for such training when the modality is commercially marketed.

Section 900.12(a)(3)(iv) describes measures medical physicists may take to reestablish their qualifications if they have failed to meet their continuing qualifications requirements.

(Comment 282). Two comments stated that the surveys of facilities and units required for reestablishing qualifications should be consistent with the experience requirement for initial qualifications. The authors believed that, if a medical physicist is not actively involved in mammography facility surveys for an extended period of time, performing the proposed three surveys may not be enough to regain the required expertise. They recommended that the requirement for requalifying be increased to five supervised surveys. One comment supported the qualification's supervision requirements. Another comment questioned why physicists are not allowed to perform surveys without the supervision of a qualified physicist, while such supervision is not required for physicians and technologists.

The agency notes that this provision has been amended to be consistent with similar provisions relating to physicians and technologists. In order to reestablish qualifications, physicists must perform facility and unit surveys to bring their total up to the required survey of 2 facilities and 6 units in the previous 2 years. This change also makes the requirements for continuing experience qualification more consistent with the experience requirements for initial qualification, as suggested by some comments. Any survey performed by a physicist to bring his or her total up to the requirement must be under the direct supervision of a qualified medical physicist. Contrary to the assumption in one of the comments, physicians and technologists who fail to meet their continuing experience requirement are also required to reestablish their qualifications under direct supervision and cannot resume working independently until the requalification is complete.

e. *Retention of personnel records (§ 900.12(a)(4))*

The provision on retention of personnel records § 900.12(a)(4) is intended to describe the personnel records that must be kept by the facility to establish that their personnel meet the MQSA requirements and to indicate how long such records should be kept.

(Comment 283). Ten comments disagreed with the proposal by FDA to allow records to be discarded following the next annual inspection and the resolution of any personnel problems discovered during that inspection. These comments urged that records be required to be kept for longer periods, with ''as long as the person is employed at the facility'' being the maximum suggestion. Four more comments suggested that FDA also establish requirements for how long records of staff members who have left the facility should be kept. One comment noted that the list of the people for whom records were required in the proposal included darkroom personnel and pointed out there were no specified qualifications for such individuals. Two

comments suggested that, if mammography is performed at various sites under the same ownership, the records be kept only at one site and be sent to the separate facilities as needed. Finally, one comment expressed the opinion that keeping personnel records was an unnecessary burden, but made no suggestions as to how personnel qualifications could be verified without documentation.

FDA has made a number of changes in this requirement in response to the comments. First, to address the concern about inclusion of darkroom personnel, the list of activities performed at a facility has been replaced with a reference to those personnel for whom quality standards have been issued. The wording was further changed to clarify that, as long as an individual is employed at a facility in one of these capacities, records must be available to show that the individual meets all qualifications. Records for individuals who have left the facility may be discarded after the next inspection has occurred and FDA has determined if the individual met the requirements. Although nothing in the MQSA or these final regulations precludes the facility from retaining these records for longer periods of time, FDA does not expect to have further need to review such records following the subsequent inspection. In response to comments suggesting that multi-site facilities retain personnel records in a central location, FDA notes that such a practice would be permitted but is not required under the final rule. Because the MQSA inspections are typically announced in advance, a facility could store its records at one site and bring them to the other sites as needed for review during the inspections there.

2. Equipment (§ 900.12(b))

The requirements were intended to establish specifications to ensure that each facility would have equipment that is capable of producing quality mammograms. FDA made a number of significant changes in the equipment requirements that were proposed. These changes include removing several of the requirements proposed for phase-in 5 and 10 years after the publication of the final rule and moving several requirements from § 900.12(b) to the quality assurance paragraph in § 900.12(e). Most of the test procedures that would have been required under the proposal have also been deleted. Each of these changes will be discussed below.

a. *General comments on equipment*

(Comment 284). A number of comments raised issues that did not address specific provisions proposed under § 900.12(b), but were directed generally toward the entire package of regulations governing equipment. These included two comments that expressed a blanket support for the regulations proposed under § 900.12(b).

One comment stated that it would be useful to have a better delineation of responsibility for ensuring that units meet particular standards under the MQSA. The comment recommended that the facility medical physicist be designated as the individual responsible to ensure that a facility's equipment is in compliance.

FDA believes responsibility for compliance with all the MQSA requirements rests ultimately with the facility. Within the scope of each facility's individual operations, responsibility can be apportioned as the facility wishes, so long as this is consistent with the regulations. The suggestion made by the comment is not inconsistent with the regulations. Under § 900.12(d)(1)(iv), the medical physicist is designated as the individual responsible to oversee the QC requirements, though no provisions specifically require routine QC testing to be performed by the medical physicist.

(Comment 285). Three comments suggested that FDA cannot anticipate future changes in mammographic equipment technology sufficiently well to be able to determine all appropriate requirements in this area over this extended timeframe. One of these recommended that FDA review the equipment requirements on a continuing basis to recommend and propose modifications that are recognized to promote quality mammography. One comment suggested that FDA simply require all mammography X-ray units to be replaced every 8 to 10 years in order to keep facilities upgraded with standardized equipment.

FDA agrees that it cannot anticipate all changes in mammography equipment over the next 10 years and has not attempted to do so. In the proposed regulations, FDA simply incorporated specifications of current equipment that experts had deemed desirable for quality mammography systems. The goal of the proposal was to ensure that, 10 years in the future, each facility would be using equipment that was considered state-of-the-art in today's market. FDA approached this goal by phasing-in the requirements over various time periods. Equipment requirements considered most fundamental to the delivery of quality mammography would be required first, followed by those specifications considered useful but which, because of cost impact, could be delayed for a period of 5 years. The third phase under the proposal included ''nice to have'' features that are not absolutely necessary to the production of quality mammograms and would not be required until the end of a 10-year period. However, based on the uncertainty surrounding the need for the phase three requirements, consultation with NMQAAC and industry representatives, assessment of the costs associated with some of the proposed 5-year phase-in requirements, and consideration of the public comments, FDA has determined that this goal is inconsistent with efforts to keep the costs associated with the delivery of mammography services at a manageable level. The agency has, therefore, decided to eliminate many of the requirements that had been proposed for both 5- and 10-year phase-in. FDA has previously stated that it plans to periodically review the regulations for necessary revisions in response to new technology and remains committed to that effort. The agency intends to and will revisit these areas in the future to reassess the need for additional regulations.

Although the revised equipment standards do not mandate that each facility have all the equipment features the agency originally had proposed, FDA believes the final regulations establish basic requirements that ensure that every facility meets the baseline equipment standards necessary to perform safe and accurate mammography. In response to the comment that recommended requiring new equipment every 8 to 10 years, FDA does not believe that the costs associated with the arbitrary replacement of mammography equipment every 8 years to 10 years is justifiable. In addition, the agency notes, too, that the alternate standards provisions, included in the regulations under § 900.18, provide the flexibility needed to ensure that new and innovative advancements reach the market without unnecessary delay.

(Comment 286). Two comments recommended that all detailed testing procedures be eliminated from § 900.12(b) to allow flexibility for qualified medical physicists to determine the appropriate testing methodology.

FDA has, in large part, adopted this approach in the final regulations. In doing so, the agency has placed responsibility on the medical physicists to be able to justify the procedures that they utilize to perform testing of equipment in any particular facility.

(Comment 287). One comment suggested that the X-ray tube companies are ''planning for early tube retirement so they can replace the tubes frequently at high cost to the facilities.'' The comment asked FDA to address this issue immediately in an effort to keep mammography costs down.

FDA does not control the pricing of equipment in the marketplace. The agency is, however, interested in equipment problems that may indicate a unit does not meet its specifications and/or aspects of compliance that it is certified as meeting. Specific information about manufacturers should be submitted to the Office of Compliance in FDA's Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

(Comment 288). One comment suggested that there should be a lock-out and/or alarm mechanism preventing a mammography technologist from exposing the patient to radiation without placing film in the equipment. Another comment suggested a requirement for an interlock to prevent a second exposure until the cassette is changed, and two more comments recommended a requirement for an interlock to ensure the presence of a cassette in the bucky/film holder. These comments noted that such incidents have occurred, needlessly exposing patients to radiation multiple times because the technologist forgot to insert or change the film.

Although FDA is aware that some manufacturers include interlocks that ensure the presence of a cassette or that cassettes are changed after each exposure on their equipment, FDA is not considering such requirements at this time. FDA believes that, unlike equipment performance, this is an aspect of the mammography process that is within the complete control of the technologist and that the technologist must assume responsibility for preparing the system for each exposure. In facilities where more than one technologist uses the equipment, a check list of items should be followed and this should most certainly be one of the items on the list. If the technologists adequately follow standard procedures, incidents such as those described in the comments can be prevented without incurring the considerable expense involved in requiring the suggested interlocks.

(Comment 289). One comment asked the agency to consider requiring special grounding devices to protect operators and patients. The comment also suggested a prohibition against carpeting in the mammography room, and a requirement for the use of static mats around the mammography machine.

Although these items might be desirable they do not impact the quality of the mammography image and are beyond the scope of these regulations.

(Comment 290). One comment suggested that a requirement establishing a maximum distance from the surface of the patient support to the sensitive part of the image receptor should be incorporated in § 900.12(b).

FDA is not aware, and the comment did not offer evidence to show, that this represents a problem for current mammography systems. Accordingly, the agency is not planning to regulate this aspect of equipment performance.

(Comment 291). One comment suggested that the maximum allowable photo-timed exposure for mammography applications should be specified. The comment stated that the backup limit of 2,000 mA's (from 21 CFR 1020.31(a)(3)(iii) in the *Performance Standards for Diagnostic X-ray systems and their major components*) was clearly selected based on prior technology, i.e., much slower screen-film systems or, perhaps, industrial X-ray film where exposures were typically on the order of 5,000 milli Roentgen (mR) for an average breast.

FDA notes that the regulations under 21 CFR 1020.31 presently set a limit of 2,000 mA's for automatic exposure control equipment when operating with a peak tube potential under 51 kVp. This regulation is not specific to mammography, but applies to any diagnostic X-ray equipment operating with a peak tube potential under 51 kVp. In previous draft regulations presented to NMQAAC, a lower value of 600 mA's was proposed for mammography systems. The committee was of the opinion that 600 mA's was too low and FDA planned to increase the value to 800 mA's. In the meantime, FDA received comments from industry pointing out that some systems have variable SID capability. This variability in current equipment undermines an approach that relies on the maximum mA's concept because the mA's required at a longer SID may be significantly greater than that required at a shorter SID, although the dose delivered might remain constant. Because FDA was faced with setting dose limits for the termination of the exposure or unnecessarily limiting equipment SID, the agency decided that the maximum allowable photo-timed exposure should not be prescribed in the regulations at this time. This decision was presented to NMQAAC, which had no comment. FDA may revisit this area in future proposals.

(Comment 292). One comment noted that the time between exposure of the film and photographic processing is critical because the latent image on all film decays with time.

FDA had considered this aspect of the imaging process for regulation but, based on comments from the public and NMQAAC, decided not to propose requirements at this time. This area may be revisited in the future when more is understood about the requirements and practices in the mobile mammography community, where film processing often must be delayed for a significant period of time after exposure.

(Comment 293). Several comments recommended that FDA set standards for batch variability of film, stating that this variability is often greater than that proposed for the equipment standards.

FDA recognizes that the variability of film may be a potential problem but believes that facilities can control this, to a significant degree, through their purchasing specifications and selection of suppliers. FDA will monitor this problem closely to determine if future regulation is required.

(Comment 294). Twenty-five comments recommended that FDA include requirements for the viewbox and/or the viewing conditions for the physician and technologist.

FDA agrees such standards would be beneficial, but does not believe that enough is known, at this time, to set appropriate specifications for viewing conditions. The guidelines recommended by ACR are excellent and the agency encourages facilities to follow them. FDA will consider this subject for future regulation and all relevant comments will be reconsidered at that time.

(Comment 295). Thirty-nine comments expressed concern that the cost of some or all of the equipment regulations would cause facilities to close and thereby restrict access for patients. Many of these comments urged that the equipment requirements should be made to apply to manufacturers of equipment for items manufactured after the specified effective date of the regulations. A related comment suggested that the current interim rule, which requires only that equipment be specifically designed for mammography, is working well and that further regulation proposed under § 900.12(b) will serve only to stifle invention, add cost, and ''overly rigidify'' this important aspect of providing the highest quality mammography services at the lowest cost to the public.

FDA can understand why the last comment believes the interim regulations are far less extensive than what was proposed. The interim regulations address the equipment aspect of mammography quality directly by listing four criteria that all X-ray systems used for mammography must satisfy: (1) The X-ray equipment must be specifically designed for mammography; (2) it must be certified to meet the performance standards in 21 CFR 1020.30; (3) it must have a removable grid; and (4) it must have a compression device. In addition, however, the interim regulations required each facility to undergo an annual survey in accordance with the standards specified in the 1992 or 1994 ACR QC manuals (see § 900.12(d) and (e) of the interim regulations). These manuals outline extensive requirements for the equipment associated with the mammography process. In the final regulations, FDA has not referenced these manuals although NMQAAC strongly advised their continued use and has instead included specific requirements that were part of the ACR standards under final regulations at § 900.12(b) and (e). Although they appear as new regulations, many of these new provisions merely restate requirements that previously had been referenced through the ACR manuals but are now reformatted as regulation.

FDA is also concerned about all costs associated with the regulations under the MQSA, including those incurred by the purchase, upgrade, and repair of equipment. However, FDA's authority under the MQSA relates to the user of the equipment rather than the manufacturer. Under authority granted to FDA by provisions of the act (which incorporates the Radiation Control for Health and Safety Act of 1968), FDA is pursuing a parallel path to generate standards for new equipment under § 1020.30. This process will take some time and regulations on new equipment only gradually affect the installed base. The agency concluded that regulations directed at new equipment only, and not the installed base, would have inappropriately delayed the benefits of the improvements provided by the new equipment for millions of women for a number of years.

For these reasons, FDA determined that equipment standards implementing the MQSA should be directed to the installed base to ensure that all women, not just those that utilize facilities with new equipment, receive an adequate and equal baseline of care. Based on facility inspection experience with the interim regulations, FDA does not expect a large reduction in providers and anticipates no access problems solely as a result of the equipment regulations. In addition, FDA has provided mechanisms for alternate standards in § 900.18 to allow for innovation and flexibility under the final rule. The agency has no reason to believe that the regulations will cause stagnation in the market for new and useful equipment.

(Comment 296). One comment asked if it was necessary to attempt to codify and regulate equipment standards that, in the respondent's opinion, will evolve anyway through competition in the market.

Again, the agency responds that the introduction of new products into the market place can be a slow process and waiting for manufacturers to manufacture and market and for users to purchase would not produce the change in minimum national standards that FDA perceives is needed. Additionally, in FDA's experience, certain segments of any market are often driven by price concerns rather than features or performance. FDA believes that regulations are the only mechanism that will provide the impetus to achieve the desired baseline of care in a reasonable time.

(Comment 297). One comment supported phasing in the equipment standards over the next 1 to 10 years, as discussed in the preamble to the proposal (61 FR 14909). Two comments stated that 5 years is not a sufficient amount of time to require the purchasing of new equipment and maintained that it would be more appropriate to allow a longer phase-in period, for example, 10 years.

Five comments offered a contrary point of view, suggesting that the majority of the mammography equipment presently in use meets most of the proposed standards in § 900.12(b) and that many of the timeframes proposed in § 900.12(b) are excessively long. One of these comments expressed concern that there are some facilities where the machine limits the ability to do adequate imaging and the facility will not get newer equipment if not forced by law to do so.

FDA appreciates these comments and recognizes that some facilities will not upgrade their equipment until the last possible moment, thereby using equipment that has become inadequate by current standards. The agency must balance these concerns with cost concerns that facilities, patients, and FDA all share. The decision to require certain equipment standards to be phased in relatively quickly and postpone others represents the agency's efforts to balance these competing concerns.

(Comment 298). One comment suggested that there should be regulations for needle biopsy systems in § 900.12, including provisions that address misalignment of the biopsy cross-hair. The comment stated that the cross-hair assembly, if not accurately aligned, may lead to inaccurate localization of lesions during needle localization, increasing the possibility of morbidity. FDA recognizes the need for regulation in this area and has raised the issue with NMQAAC in the past. As a result of discussions with NMQAAC and opinions offered by the ACR, the decision was made to delay regulations for this aspect of breast radiography until community consensus can be reached on all aspects of the process. As discussed earlier, FDA is currently working internally on possible regulations for interventional mammography, while awaiting the results of collaborative efforts between the ACR and the American College of Surgeons to reach consensus on recommendations for standards in this area.

(Comment 299). One comment recommended that the equipment specifications proposed under § 900.12(b) should not be included in the final regulations and that the entire section should be issued as guidance rather than a binding regulation.

FDA has considered this approach, but has determined that, because the guidelines would not have the force of law, they would not achieve the widespread results necessary to meet the goals of the MQSA.

(Comment 300). Nine comments expressed concern that the proposed regulations under § 900.12(b) were not specific as to whether all equipment in a facility must comply and one of these comments questioned if existing mammography units must be redesigned and/or upgraded to all the standards by the effective dates.

FDA intends that all facilities performing mammography shall meet each of the final regulations by the effective date of each requirement. In the case of equipment, all equipment used for covered mammography procedures must meet the requirements in effect at any given time. If equipment must be repaired, replaced, or upgraded to achieve this result, then such actions must be completed by the effective date or the facility must discontinue offering mammography services with the nonconforming equipment until compliance is achieved.

(Comment 301). One comment stated that the equipment standards sometimes

give very specific descriptions of testing equipment and procedures. For example, in proposed § 900.12(b)(4)(iv), FDA specifically described a 12 cm diameter acrylic disc 1.5 cm thick. The respondent was unsure why 12 cm was specified instead of 10, and why 1.5 cm was specified instead of 1 or 2.

FDA notes that in each case where test procedures and/or test objects are specified in these final regulations, the objects or procedures are usually based on established test protocols. In some cases where the test object itself could be variable, the specifications are identical to an object used in another required test in order to reduce the number of items required for the entire survey or inspection. In cases where the test or the test object is new, the details of its design are beyond the scope of this document. FDA intends, whenever possible, to issue guidance documents that will address the use of such new procedures and equipment. The particular example cited in the comment has been deleted from the final regulations.

(Comment 302). One comment stated that the proposed rules are not entirely consistent with the guidance document developed by ACR and CDC. The comment recommended that every effort should be made to ensure consistency with the ACR guidance document.

FDA is, of course, aware of the ACR/CDC document and, in fact, adopted many of its requirements for these final regulations. However, the ACR/CDC document was written as a guideline for new equipment and not as a regulation for installed equipment. As a guideline, its wording would not readily transfer to regulation and, as a specification for new equipment, its scope was not sufficiently broad to address the range of the installed base or the cost concerns associated with upgrade and replacement of equipment. The agency also notes that the recommendations in the ACR/CDC guidance represent an attempt to describe an optimal system. NMQAAC and members of the public have stated that some of the features, while desirable, would generate costs not justified by the expected benefit, especially when applied to the installed base. In those cases where the agency believes the benefit does not warrant the cost, FDA has not made particular features regulatory requirements. Within these limitations, FDA has generally made efforts to remain consistent with the ACR/CDC guidance where doing so is appropriate.

(Comment 303). One comment suggested that a section in § 900.12(b) or (e) should address the issue of screen placement in the cassette. The comment noted that, because the screen is sometimes not positioned with its edge in contact with the inside wall of the cassette at the chest wall, the film edge is underexposed or unexposed. The comment suggested that ''such cassettes should be rejected and the screens remounted.''

FDA agrees that such conditions should not exist, but believes the annual survey and normal QC procedures will identify and correct such problems and is not considering regulations to address this concern at this time.

(Comment 304). One comment recommended that the proposed equipment regulations in § 900.12(b) be rewritten to correspond more closely with existing international standards.

In certain aspects of equipment related requirements, FDA has attempted to conform to both national and international precedent. However, in some cases, those guidelines are inappropriate or do not address the specific concern being considered under the MQSA.

(Comment 305). One comment suggested that the proposed requirements of § 900.12(b)(17) through (21), which do not relate to X-ray equipment or film processors, should be included as part of the annual physics survey and need not be specified by regulation. FDA believes that this respondent misunderstood these provisions because the core of the annual physics survey is, in fact, set forth in these regulations. Some of these regulations have been modified and/or transferred to the quality assurance section of the final regulations, while others have been deleted. The remaining requirements may be checked as survey or inspection items, verified by documentation provided by the manufacturers, or established through normal QC procedures performed by the facility. Although the agency has not expressly prescribed how these requirements should be met in all cases, FDA has determined that the facility is responsible for establishing compliance with these standards rather than trusting that they would be included in all medical physicists routine surveys.

b. *Prohibited equipment (§ 900.12(b)(1))*

This paragraph prohibited the use for mammography of general purpose equipment or equipment designed for special nonmammography procedures.

(Comment 306). Seven respondents recommended that the use of xeromammographic equipment should be prohibited or phased out.

FDA considered taking this action but believes that the unique characteristics of the xeroradiographic process may provide a valuable tool in the diagnosis of some cases. Records obtained during the first year of facility inspections under the interim regulations indicate that there are an extremely small number of these units in service and it is believed that the number will continue to decrease as their use falls out of favor with the community. FDA has concluded, therefore, not to ban their use.

c. *General (§ 900.12(b)(2))*

This paragraph, as proposed, required that all equipment be designed for mammography and certified under § 1020.30.

(Comment 307). One respondent suggested that a definition of ''specifically designed for mammography'' be included because some units may be used for imaging of extremities.

FDA does not believe that this is necessary because the manufacturer's labeling, along with the FDA device approval process, ensures that the design is appropriate for mammography. FDA recognizes the fact that the characteristics of mammography radiographic equipment make it useful for other radiological examinations and does not intend to restrict such applications if the product has also been approved for that use.

d. *Motion of the tube-image receptor assembly (§ 900.12(b)(3))*

This paragraph proposed that the gantry be capable of specific rotation, that the angle of the gantry be indicated, and that the tube-image receptor assembly remain rigidly fixed in any position where it was designed to operate.

(Comment 308). Two comments noted a citation error in the proposed regulations. One comment recommended the deletion of the entire section, with the possible exception of requiring the system to remain fixed when placed in an operating position. Three other comments supported the proposed requirements, although one suggested that only one unit at each facility need meet the requirements. NMQAAC supported the proposed requirements, with the recommendation that they be applicable only to equipment acquired 5 or more years after the publication of the final regulations.

FDA has determined that NMQAAC's recommendation to require compliance only on equipment acquired 5 or more years after publication of the final regulations presents major problems with respect to enforcement. Such an approach would produce a situation where two distinct levels of quality would be in place for different facilities

and often within the same facility, based on when equipment was acquired. After reviewing the public comments and assessing the possible cost impact of the requirements, FDA decided to remove the provisions detailing the range of gantry motion and angle indication. If this area is considered for future regulation, all comments submitted on these sections will be reconsidered in the process. FDA has reworded the provision that requires the tube-image receptor assembly to remain fixed in its designed operating positions and this requirement remains under § 900.12(b)(3) in the final regulations. The citation error has been corrected.

e. *Image receptor sizes (§ 900.12(b)(4))*

This paragraph requires that all mammography systems have, at a minimum, both a 18 X 24 cm and 24 X 30 cm screen-film receptor and matching grids, and that the grids should be removable. This section also proposed that grid motion should not be impeded when a breast is subjected to compression in the system.

(Comment 309). Seven comments supported the proposal regarding the image receptor sizes and matching grid requirements proposed in § 900.12(b)(4)(i). Two comments opposed the specification requiring both a large and a small image receptor system in the regulations. One of these misread the proposal as being applicable to xeromammographic equipment and suggested that the regulation might prohibit the use of such equipment because such systems may not provide multiple image receptor sizes. The other comment supported the concept of requiring a large and small image receptor combination, but opposed a provision specifying the actual dimensions of these receptors. A related comment, while not actually opposing the proposal, expressed concern that requiring multiple image receptor sizes for screen-film systems might establish difficult precedents for future technology.

FDA believes that, for the present and foreseeable future, the dominant film sizes used in screen-film mammography will remain 18 X 24 and 24 X 30 cm and has not been persuaded to revise the provision that requires systems to have both sizes with corresponding grids. The agency believes that the last comment is concerned with digital systems currently under development and the concern that large or multiple sized image receptors would be prohibitively expensive with such systems. FDA has not formulated an opinion in this area and will wait to see what final technology and configurations evolve for digital systems before addressing this issue in regulation.

(Comment 310). One comment, while neither agreeing nor disagreeing with the requirement for multiple size image receptors, stated that the use of smaller image receptors, even on large breasts, results in clearer, sharper images and noted that larger areas compressed all at once do not provide the sharpness and detail needed to pick up very small cancers. The comment stated that, even though more films are taken when a smaller film size is used to image a large breast, the benefits of finding a life-threatening cancer far outweigh the minimal increase in radiation exposure to the patient.

FDA recognizes this practice as essentially the ''spot compression'' of the entire breast in multiple exposures. Although ''spot compression'' can yield improved images, it is not a recognized or accepted procedure in screening mammography. Interpreting physicians who deem such studies necessary will order them to be performed, but it is not standard practice for routine screening. The agency also notes that the regulation merely requires that the two-image receptor sizes be available; their use in any particular case is left to the judgment of the mammography personnel involved.

(Comment 311). One comment proposed that the requirement for multiple image receptor sizes be restated to require at least one unit at the facility to provide the multiple sizes, rather than requiring each unit to have both receptors. Experts on NMQAAC recommended that the requirements of § 900.12(b)(4)(i) not be weakened by permitting a facility to satisfy this equipment standard by having only one system with the multiple cassette sizes. The rest of the committee agreed. FDA has accepted this advice and retained this requirement under § 900.12(b)(4)(i).

Section 900.12(b)(4)(ii) requires facilities to have systems with moving grids matched to all image receptor sizes provided.

(Comment 312). One comment commended FDA for requiring both an 18 x 24 and a 24 x 30 bucky for each unit. Another recommended that the regulation read: ''Systems using screen-film image receptors shall be equipped with separate moving grids matched to all image receptor sizes provided.'' FDA does not believe that the suggestion was a significant improvement and did not make the change.

(Comment 313). One comment recommended the inclusion of a requirement in § 900.12(b) that specifies the image receptor support device shall match the cassette size.

The agency does not believe this additional requirement is necessary. By requiring the system to have both a large and small image receptor and corresponding sized grid assemblies, FDA is confident that most technologists will select the appropriate receptor and cassette size for each patient.

Section 900.12(b)(4)(iii) requires the grid to be removable for systems used for magnification.

(Comment 314). Three comments requested clarification regarding applicability and intent of this provision.

FDA notes that the final regulation was drafted to clarify the interim rule. Section 900.12(b)(4)(iii) simply states that the system must be operable with the grid removed from between the source and the image receptor when the technologist is performing magnification procedures. This could be accomplished in various ways, including actually removing the grid mechanism, substituting a nongrid film holder for the grid film holder assembly, or any other mechanism that ensures that the grid does not interfere with the image or the automatic exposure control, if one is used.

Under § 900.12(b)(4)(iv), FDA proposed that the grid motion not be impeded when the breast is compressed and also proposed detailed requirements for verifying compliance.

(Comment 315). Seven comments supported the proposed requirements for assessment of grid related artifacts, while 14 comments supported the concept of evaluating grid related artifacts, but opposed both listing the requirement in regulation and the test procedure outlined in the proposal on the basis that the test method was unproven and objective standards for evaluation of the seriousness of the problem were lacking. In April 1996, and again in January 1997, NMQAAC recommended removing § 900.12(b)(4)(iv) regarding the grid related artifacts.

FDA has accepted NMQAAC's recommendation and removed this paragraph.

(Comment 316). Twelve comments requested justification, clarification, or suggested modifications for the test procedure proposed under § 900.12(b)(iv). If the issue is revisited for future regulation, the comments to this section will be reconsidered at that time.

f. *Beam limitation and light fields (§ 900.12(b)(5))*

This paragraph covers devices for limitation of the X-ray field and specifies light localizer characteristics.

Under § 900.12(b)(5)(i), FDA proposed that all systems ensure that the X-ray field can extend to or beyond the chest wall edge of the image receptor.

(Comment 317). Two comments interpreted this as a requirement that the collimator must provide separate adjustability on the chest wall edge and suggested that such adjustability is unnecessary.

FDA accepted these comments and reworded § 900.12(b)(5)(i) to clarify that the intent is not that the collimator be adjustable, but that the collimator allow complete coverage of the image receptor at the chest wall edge unless it is the intent of the operator to not do so. This requirement has been moved to the quality assurance section and appears in § 900.12(e)(5)(vii).

Section 900.12(b)(5)(ii) proposed that any system with a light field that appears to approximate the X-ray field must approximate the X-ray field to a specified tolerance and that the light must produce a minimum specified brightness. Four comments supported the alignment recommendations with the observation that, in the respondents' opinions, the alignment was more important on the chest wall edge.

(Comment 318). Two comments expressed disagreement with this requirement. In § 900.12(b)(5)(ii), FDA also proposed a definition for the mammographic source to image receptor distance (SID) that was changed slightly from the definition used for more general purpose radiographic systems in order to be more consistent with the actual usage in mammography. Two comments supported this change, two opposed it, and one respondent expressed concern that the definition of SID in this section might be confusing.

After reviewing the comments, FDA has determined that the requirements for the alignment of the light field and X-ray field and the definition of SID are adequately addressed by existing regulations in § 1020.31, and has deleted the proposed requirements from this standard. A QC test to verify alignment now appears in the quality assurance section at § 900.12(e)(5)(vii).

With respect to the proposal that the light provide a minimum illuminance, two comments supported the requirement and four comments opposed it.

FDA notes that this proposed requirement is the same as that currently required for general purpose systems covered by § 1020.31. Thus, it already applies to such collimators using such light localizers on mammography systems. FDA has chosen to restate the specification here to eliminate any confusion and to clarify that the general requirement also applies to mammography equipment. The restatement now appears under § 900.12(b)(5)(ii) in the final regulations.

Under § 900.12(b)(5)(iii), (iv), and (v), FDA proposed a phase-in of additional requirements. The first stage required all mammography systems to incorporate such a light localizer 5 years after publication. The second stage required that 10 years after publication, all mammography systems were to prevent X-ray production unless the correct combinations of field size and image receptor were selected and to prevent any exposure with an X-ray field exceeding the size of the image receptor support device.

(Comment 319). Three comments supported the requirement for the light field as proposed, with one of these urging that it be instituted at the earliest date the regulations become effective. One comment agreed that a light field, as proposed, may be a desirable feature but thought properly trained personnel are able to position the breast correctly without a light and suggested that the requirement should be deleted because, in the respondent's opinion, the cost would be too high to justify. NMQAAC supported the requirement for a light field, as proposed. Four comments supported the proposed requirements in § 900.12(b)(5)(iv) and (v) but one of these suggested that a means to override the interlocks should be provided. One comment opposed both proposals.

FDA has reevaluated these proposals and concluded that they raise safety concerns related to X-ray systems in general rather than image quality concerns. For this reason, and the cost concerns discussed previously, the agency has decided to delete both § 900.12(b)(5)(iv) and (v) from these regulations and to develop such requirements under the authority provided in the act for regulatory products subject to the Radiation Control for Health and Safety Act of 1968. Accordingly, FDA is discussing relevant changes to part 1020 with its Technical Electronic Product Radiation Safety Standards Committee.

After the revisions to the proposal were completed, there remained only two paragraphs in this provision: § 900.12(b)(5)(i), requiring beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor; and § 900.12(b)(5)(ii), which establishes the illuminance requirement.

g. *Source-image receptor distance (SID) (proposed § 900.12(b)(6))*

FDA proposed requirements for a minimum SID for mammography systems and specified that the SID must be displayed. The agency also proposed an accuracy specification for that display. In § 900.12(b)(6)(i), FDA proposed that all mammography systems have a minimum SID of at least 55 cm.

(Comment 320). One comment recommended that FDA include a definition of ''contact mammography'' as used in § 900.12(b)(6)(i) to eliminate confusion about its meaning. Another comment supported the minimum SID as proposed, and six comments supported the concept but recommended that the minimum SID be reduced to 50 cm; NMQAAC supported the proposal as published.

In considering these comments and other more general comments relating to avoidance of unnecessary specifications that may limit future technology, FDA has decided that other requirements in the final regulations (dose, resolution/focal spot condition, and system output) make issuing this requirement unnecessary. Therefore, the limitation on the SID has been removed from the final regulations. In the future, if the agency determines that regulations covering this area are required, all relevant comments will be reconsidered at that time.

In § 900.12(b)(6)(ii), FDA proposed that each system should provide a visual indication of the SID, accurate to within 2 percent.

(Comment 321). One comment stated that the actual SID needs definition or that there should be specification of an acceptable method of verifying the SID or location of the focal spot. Other comments were concerned with uncertainties in determining the end points of the SID. One comment noted that the indication of the SID proposed in § 900.12(b)(6)(ii) might differ between systems because of differences in interpretation of the location of the image receptor. Conversely, another comment suggested that the concept of an indication of the SID, as proposed in § 900.12(b)(6)(ii), is ambiguous for those systems having multiple focal spots and anode tracks because all focal spots are not at the same location on the anode. The comment further suggested that the ''source'' be defined as the average location of all focal spots.

Another comment noted that the standards in IEC 601–1–3(point 29.203.2) specify a tolerance of 5 percent for the SID indicator and requested that FDA consider adopting that specification rather than the 2 percent proposed. One comment suggested that FDA might wish to

consider recasting the proposal of § 900.12(b)(6) as an outcomes specification. Another comment recommended that the proposed requirement in § 900.12(b)(6)(ii) for indication of SID be restated to require the indication only for variable SID units. NMQAAC recommended that the section be deleted because they believed that it would add to the equipment costs with little benefit to the quality of mammography.

FDA has accepted the NMQAAC recommendation and deleted § 900.12(b)(6)(ii). If this issue is revisited, all comments will be reconsidered at that time.

h. *Magnification (§ 900.12(b)(6) (proposed § 900.12(b)(7)))*

As proposed, this paragraph required that systems used for procedures beyond basic screening mammography have magnification capability available to the user.

(Comment 322). One comment suggested that the proposal was unclear as to the intent of ''available to the user.'' One comment incorrectly assumed that, because there was no implementation date for the requirement, all diagnostic equipment installed presently have magnification capability and will meet the requirement. One comment expressed concern that this requirement made his facility's equipment obsolete and stated that most diagnostic mammography does not require magnification.

The radiologists on NMQAAC stated that magnification is needed for noninterventional problem solving mammography. The committee debated whether to recommend to delete or change these provisions and decided not to recommend such actions.

FDA has retained the provision, but reworded parts of the proposal to clarify the intent. The changes include replacing the term ''diagnostic mammography'' with ''noninterventional problem solving mammography.'' This change was necessary because there is no general consensus as to the definition of ''diagnostic mammography.'' ''Problem solving mammography'' refers to mammography requiring techniques beyond those utilized in standard mammography of asymptomatic patients and ''noninterventional'' indicates that the procedures are noninvasive in nature. The term ''available to the user'' simply means that any attachments or accessories necessary to allow the X-ray system to perform magnification procedures must be present with the system and available to the technologist to encourage and facilitate the use of the feature.

(Comment 323). Four comments recommended that the specification be reworded to require the facility to have the capability to provide magnification instead of requiring that each system provide the feature. However, the experts on NMQAAC stressed the importance of requiring the feature in each system used for such procedures and FDA has retained the requirement.

In § 900.12(b)(7)(ii) of the proposal, FDA specified that at least one magnification setting should be in the range of 1.4 to 2.0. One comment suggested that the use of magnification greater than 1.5 is questionable and that limits for the image quality and average glandular dose should be set for these conditions.

FDA agrees, in principle, with this comment. Generally, magnification for these procedures is accepted within the range specified by the requirement and most sources seem to agree that magnification at approximately 1.5 is optimal. FDA believes that by requiring the equipment to provide magnification in the optimum range the facility will then be able to adequately perform the procedure. Some systems currently used for magnification will not meet this standard. This will not, in itself, however, force the replacement of the equipment because the unit may still be used for the general population ''screening'' of asymptomatic patients so long as it meets the other requirements.

(Comment 324). One comment noted that ''magnification setting'' as used in the proposal was not defined. Another comment stated that the method of determining the magnification, along with acceptable limits, should be specified or referenced. FDA has removed the word ''settings'' from the requirement because it might be confusing but has not added a definition of ''magnification'' to § 900.2; FDA believes that the term is generally understood to be the ratio of the source-to-image receptor distance to the source-to-object distance.

Because the proposed SID requirements were moved, proposed § 900.12(b)(7) *Magnification* has been codified as § 900.12(b)(6).

i. *System resolution (proposed § 900.12(b)(8))*

This paragraph proposed requirements for the system resolution for both contact mode and magnification mode mammography.

(Comment 325). Nine comments requested that a test procedure be specified for the contact mode requirement proposed in § 900.12(b)(8)(i). One comment suggested that a specification of the appropriate resolution target should be included along with a specification of its position in the test plane, and a requirement for an absorber in the beam to lengthen the exposure times, because very short exposures may introduce interference from gridlines.

FDA agrees with these comments and has included a description of the test conditions in the final regulations.

(Comment 326). One comment correctly noted that the requirements in proposed § 900.12(b)(8)(i) and (ii) attribute failure to meet resolution requirement to problems with the focal spot when, in fact, the cause of observed low resolution values may be some other component in the imaging chain.

FDA agrees with this comment and has rephrased the requirement.

Based on recommendations from NMQAAC, FDA has removed this requirement from the equipment standard and established a QC requirement for system resolution that is codified under § 900.12(e)(5)(iii).

In § 900.12(b)(8)(ii), FDA proposed regulating the system resolution in the magnification mode. Based on guidance received from NMQAAC, FDA has moved this requirement to the quality assurance provisions in § 900.12(e)(5)(iii), and has designated it for phase-in after 5 years. If, in that time, other values are determined to be more appropriate, the regulations will be modified accordingly.

Thus, proposed § 900.12(b)(8) *System resolution*, no longer appears among the equipment requirements.

j. *Focal spot selection (§ 900.12(b)(7) (proposed § 900.12(b)(9)))*

As proposed, this provision included several requirements for indication of the focal spot selected for use in examinations, interlocking of the focal spot with selected kVp, and alignment of the focal spot with the image receptor. FDA also proposed that the system indicate which focal spot and, where applicable, which focal spot material is selected prior to exposure. The proposal also recognized that some systems may automatically select the focal spot during the exposure and required a post exposure indication of the focal spot used during such exposures.

(Comment 327). Three comments, including that of NMQAAC, recommended that the requirements proposed in § 900.12(b)(9)(ii) and (iii), concerning indication of the target material, be linked with an ''or.''

FDA did not accept this recommendation because it would essentially eliminate the requirement for post-exposure indication of the machine selected focal spot. The agency believes that the change would modify the

requirement in a way the agency does not intend or desire because it would permit the equipment to display only the initial preselected focal spot and never indicate the actual focal spot used.

(Comment 328). Two comments supported the proposal in § 900.12(b)(9)(iv) that the system be interlocked to prevent exposure with improper or incompatible combinations of kVp and target material. One comment opposed this requirement, two requested clarification, and one requested a test procedure. NMQAAC recommended that the initial clause in the proposal be deleted.

After further consideration of this requirement, FDA concluded that the requirement was already adequately covered by requirements relating to diagnostic X-ray systems in § 1020.30(m) and has deleted proposed § 900.12(b)(9)(iv).

k. *Focal spot location (proposed § 900.12(b)(10))*

This paragraph proposed a requirement that the focal spot be located in a specific geometric relationship to the image receptor.

(Comment 329). One comment supported the requirement, five (including NMQAAC) opposed it, believing that it was unnecessary, three requested clarification on its testing, and one, recognizing its relationship to the compression paddle alignment, recommended that the provision be moved to the section on compression paddle alignment.

FDA accepted the NMQAAC recommendation and deleted this requirement from the final rule.

l. *Filtration (proposed § 900.12(b)(11))*

This proposed paragraph contained a statement requiring mammography systems to comply with the beam quality standards for half-value-layer (HVL) codified at § 1020.30(m)(1).

NMQAAC recommended that the section specifying the HVL requirements should be moved to the QC section. FDA accepted this recommendation and codified the requirements for filtration under § 900.12(e)(5)(iv).

(Comment 330). One comment suggested that the proposed rule in § 900.12(b)(11)(i) was too vague and subject to arbitrary interpretations. Another comment recommended that more precise rules be used to determine the required HVL and suggested that existing dose tables could be used to determine the desired limits. The respondent based this position on the fact that § 1020.30(m)(1) requires the interpolation or extrapolation of HVL values in the mammographic range. One comment noted that filtration is not the same as HVL; the HVL measure indicates the filtration that is in the X-ray system, but it is not an actual measurement of filtration. Two comments noted that the proposed regulations refer to § 1020.30(m)(1) for the minimum filtration requirement and incorrectly interpreted this as a lack of specification for kVp's not listed. They asked what FDA is planning to do concerning the perceived lack of regulation of filtration for kVp's below 30 kV since the table of HVL specifications does not list any values below 30 kV. One comment stated that some realistic values for expected HVL at ranges of 25 to 30 kVp should be given. One comment stated that § 900.12(b)(11)(i) seems less specific than current requirements for filtration and another comment suggested that the requirement in § 900.12(b)(11)(i) should be referenced to the most recent ACR physics manual instead of § 1020.30(m)(1).

FDA believes that the comments indicate that relationship between filtration and half-value-layer (HVL) in the mammographic energy range and the concept of mathematical extrapolation and interpolation may not be fully understood by some members of the mammography community. It is generally understood that the first HVL is an indirect measurement of the filtration in the X-ray beam. In the kVp range up to 50 kVp, the values specified in § 1020.30(m)(1) represent a beam with an inherent filtration equivalent to 0.5 mm of type 1100 aluminum. FDA notes that, although the standard relates the HVL in terms of type 1100 aluminum, it does not specify that the same alloy be used to measure the HVL. Therefore, the measurement of the first HVL and the comparison of the result to the specification indicate whether the system has sufficient filtration in the beam; if the first HVL is less than the number specified in the table, there is insufficient filtration because the HVL is a function of the filtration and the energy of the X-ray beam (kVp).

In response to the comments, FDA has provided a table of the extrapolated values of HVL in the mammography kVp range under the quality assurance provisions in § 900.12(e)(5)(iv). Values not shown may be derived by interpolation. FDA believes that providing these values, which are derived from the Federal performance standard at 21 CFR 1020.30(m)(1) and are serendipitiously identical to the ACR recommended values when the paddle is not in the beam, makes it unnecessary to reference the ACR manuals or any other external source of HVL values.

(Comment 331). Five comments supported a specification of a maximum filtration requirement in § 900.12(b)(11)(i) and another comment recommended that a maximum HVL, specified as a function of kVp, be added for each known combination of anode and filter materials. One comment noted and agreed with the deletion of the upper limits for HVL that had been proposed in previous drafts of the proposed regulations.

FDA deleted those upper limits because it had concluded that other aspects of performance and image acceptability will serve to limit the maximum filtration. Comments to the proposal have not persuaded the agency to reverse that position.

(Comment 332). One comment noted that § 900.12(b)(11)(i) references § 1020.30 and questioned the need to repeat the requirement. The comment also found the proposal ''redundant with § 900.12(b)(2),'' which requires equipment to be specifically designed for mammography. FDA does not agree that the references are redundant and has concluded that the restatement in this regulation serves to clarify and reinforce the § 1020.30 specification.

One comment suggested that the regulation be recast in terms of desired outcomes and offered this example: ''The type and quantity of filtration interposed between the source and the breast entrance surface shall be such as to provide the maximum subject and image contrast consistent with limitations on dose (§ 900.12(c) of the interim regulations) and minimum half-value layer (§ 1020.30(m)(1)).''

FDA believes this suggestion would introduce an unacceptable level of subjectivity into the evaluation process without eliminating the need to reference the specification in § 1020.30(m)(1).

FDA also reconsidered the requirements in § 900.12(b)(11)(ii) for variable filtration systems, which proposed interlocking the filtration with the target material. Upon further review, the agency concludes that requiring equipment to meet standards that ensure that the minimum filtration required in § 1020.30(m)(1) is in the beam during each exposure is sufficient to ensure proper filtration and has deleted § 900.12(b)(11)(ii) from the final regulation.

m. *Compression (§ 900.12(b)(8) (proposed § 900.12(b)(12)))*

This paragraph proposed a number of requirements concerning the application of compression. The basic proposal was

that each mammography unit should have a compression device.

(Comment 333). Five comments and several members of NMQAAC supported the proposed requirement. One comment suggested that FDA should go further and require the use of the compression device.

If the compression device is present, most technologists will use it responsibly and also recognizes that the use of an item is difficult to enforce. FDA, therefore, has rejected this suggestion.

Under § 900.12(b)(12)(i) FDA proposed that, 5 years after publication, each system would be required to be equipped with an initial, foot controlled, power driven compression and also be required to allow the user to control additional ''fine adjustment'' of the compression. The proposal required that both controls be operable from each side of the patient.

(Comment 334). Two comments stated that power-driven compression by foot control is unreasonable or unnecessary. One comment stated that FDA should delete the requirement for fine adjustment controls and the specifications on how the compression controls should operate because they will increase the cost of new equipment while providing little benefit. Another comment stated that no requirement beyond one that the system ''be capable of maintaining a force of 25 pounds for 15 seconds and have a maximum force no greater than 40 pounds when used in automatic or power driven mode'' is necessary.

In contrast, twenty-eight comments agreed that ''automatic'' power driven compression should be required of all facilities but stated that it should be put in effect immediately, not 5 years from now, as proposed. Several of these comments expressed the opinion that the technologist needs to have both hands free to optimize the breast position. Five comments stated that manual and power compression controls, as called for, are essential for quality mammography. The comments further noted that manual controls are needed for finer adjustment and that the two controls complement each other, although one comment expressed the respondent's belief that the fine adjustment should be a manual control because that type of control was reassuring to some patients. One comment recommended that the reference to ''foot controls'' be deleted since the goal of ''hands-free'' application of compression may be achievable by some mechanism other than a foot operated control.

FDA has accepted the last comment and modified the requirement accordingly. However, FDA believes that this ''hands free'' application of power compression and the fine adjustment control are basic to the delivery of quality mammography care and is retaining the requirements in the final regulations. FDA appreciates that this will have a cost impact on the installed base; however, the agency believes that the benefit to public health outweighs this cost and also notes that most of the current equipment can be brought into compliance with modifications that are far less costly than total replacement.

(Comment 335). One comment suggested that FDA might wish to recast the proposal in terms of the desired outcomes, for example:

> Means of applying compression to the breast shall be provided that; (i) allow the technologist to use both hands to position the breast while applying compression, (ii) facilitate positioning from both sides of the patient without removing hands from the patient, (and) (iii) allow a slow, final adjustment of compression.

While FDA appreciates this suggestion, the agency believes that such terms as ''allow'' and ''facilitate'' require too much subjective evaluation in the interpretation of compliance. Under some design and use conditions, certain technologists may be able to demonstrate that the equipment meets these requirements, while others may not. FDA believes that establishing reasonable standards for the equipment allows the majority of technologist the greatest opportunity to achieve optimal positioning for even the most challenging patients.

(Comment 336). One comment stated that a number of different types of mammography systems in use either do not offer automatic compression or have only automatic compression with no manual compression knob. The comment suggested it would be worthwhile to retain maximum flexibility in the final regulation to allow evaluation of this type of retrofit system, so long as the intent and specifications of the final regulations were met. A second comment stated that the ''fine adjustment compression,'' as proposed, would place a costly burden on some facilities that do not have manual compression. Another comment indicated that when requiring all units to have a power driven compression paddle activated by foot controls, as proposed, it is also necessary to have a manual compression mode as well. One comment suggested that final compression should always be done using a hand control knob, which the technologist can easily control with direct tactile feedback. One comment agreed that it is necessary to have power driven compression, as proposed, but noted that it was not necessary that the fine adjustment control be power driven. One comment noted that the proposed requirements do not preclude the equipment from having a manual compression provision.

Many of these comments resulted from misreading the proposed regulations. The proposal does not require the fine adjustment compression be a manual operation. The fine adjustment is usually a ''manual'' adjustment in that it is applied by a hand operated (''manually operated'') control. This does not imply or require the provision of a direct linked drive dependent only on the input force provided by the operator. Many of the ''manual'' knobs are actually servo-driven power compression devices that are under a more closely controlled incremental advance than that provided by the foot control and, in these cases, the ''tactile'' feed-back sensed by the technologist is not necessarily related to the force applied to the patient. As the regulations are written, the design of the equipment can provide a truly ''manual'' control for the fine adjustment, or can provide a slower power driven application that may be adjusted by a hand control or other suitable means. FDA believes that most equipment with power-driven compression already provides a fine adjustment control and that the cost impact on those facilities not presently meeting this requirement will be outweighed by the advantages to positioning and improved image quality.

(Comment 337). Five comments suggested that a requirement for maintaining compression for a specified period of time should be added and one suggested that this specification should be established for both automatic and fine adjustment compression.

FDA proposed the criteria for application of compression without stating a specified time for maintaining the compression. This means that FDA expects the compression to meet the criteria in the regulations until the compression is terminated, either by an automatic release at the end of the exposure or by operator intervention during or after the exposure. Therefore, it is not necessary to expressly establish a time limit for maintenance of compression.

NMQAAC discussed these provisions at some length and several committee members spoke about the importance of compression to the overall quality of

mammography. The committee recommended that the requirements for power driven and fine adjustment compression become effective immediately but that the requirements for the maximum force in the initial power drive remain a 5-year phase-in requirement. The agency considered the recommendation to move forward the effective date for the power driven and fine adjustment controls, but has determined that the cost considerations associated with accelerating the implementation of these requirements cannot be justified based on the expected improvements. Therefore, FDA has reworded these requirements to address some of the above comments, and has retained the effective date that was proposed.

Section 900.12(b)(12(i)(C) proposed limits on the compression force required for the automatic power compression mode.

(Comment 338). Two comments stated that the proposed requirement for 25 to 40 pounds under power driven compression was excessive and may result in patient injury.

Based on input from NMQAAC, ACR, and the general comments provided by manufacturers, FDA believes that 25 to 45 pounds is an appropriate range and presents little risk of injury to patients when applied by trained technologists.

(Comment 339). One comment observed that the proposal only limits the compression under power driven control and recommended that an upper limit be set for the maximum compression under manual control.

Although FDA had considered such an upper limit, the idea was opposed by NMQAAC because they felt that it was unnecessary. FDA is not proposing such a limit at this time.

(Comment 340). One respondent was concerned that there may be units designed to achieve the proposed compression forces but that have user adjustable controls that allow adjustment to values below the minimum proposed specification.

FDA agrees that such equipment may exist or be introduced into the market place. The agency notes that under the regulations, as codified, the requirement is for values attainable by the user. If the user has direct control over any such system adjustment, then this adjustment must be used in testing the system. If such adjustment is only available through service or installation configuration, then the unit should be tested only to the limits adjustable by the operator. Under these circumstances, the respondent's concerns are adequately addressed because any user adjustable controls must be utilized in determining the compliance of the system with the standards. FDA has moved the requirement for the range of acceptable power driven compression to the quality assurance section under § 900.12(e)(4)(iii).

Under § 900.12(b)(12(ii)(B), FDA proposed that each system have a means for manual compression release in the event of failure of other decompression mechanisms.

(Comment 341). One comment questioned if the wording meant that compression must be maintained in the event of power failure and, if so, must the required display of override status also be maintained after power failure.

FDA intends that the compression be maintained after a power interruption. However, the display of override need not continue in such circumstance because the fact that the patient is still under compression would serve as adequate indication that manual release is required.

(Comment 342). One comment noted that there were many designs currently on the market that allowed for the manual release of the compression without the presence of a specific device as called for in § 900.12(b)(12)(ii)(B). The comment requested that the proposal be reworded to emphasize the desired outcomes rather than a specific means of obtaining those outcomes.

FDA believes that the wording in the proposal does address outcomes and does not intend the provision to require any specific release design. Any mechanism that allows the manual release of compression would meet the requirement. The requirements for the compression forces and decompression have been moved, as recommended by NMQAAC, to the quality assurance section of the regulations and are addressed in § 900.12(e)(4)(iii) and (e)(5)(xi).

In § 900.12(b)(12)(iii)(A), FDA proposed that systems be equipped with different sized compression paddles matching the sizes of all full-sized image receptors provided and that compression paddles for special purposes, including those smaller than the full size of the image receptor (for 'spot compression') could be provided. FDA did not require that these special paddles be provided but included the reference to clarify that these paddles could be included in the system and are exempt from certain parts of the requirements applicable to the full size paddles.

(Comment 343). Three comments supported the requirement in § 900.12(b)(12)(iii)(A) as written. One comment recommended that the proposed requirement be expanded to require that facilities have the ''spot compression paddles'' available. NMQAAC supported the proposal as published.

FDA has done some minor rewording in this paragraph and renumbered it in the final regulations under § 900.12(b)(8)(ii)(A).

In § 900.12(b)(12)(iii)(B), FDA proposed that the compression paddle be flat and parallel to the patient support and not deflect from parallel by more than 1.0 cm at any point when under compression.

(Comment 344). Nine comments opposed the proposed requirement. Three of these suggested that this is not the best way to compress the breast because it ignores the anterior tissues and the often thicker tail of the breast. One comment stated that nonparallel paddles are useful for compression of very large breasts in the MLO view. Another comment noted that one manufacturer's equipment does not meet the proposed requirement, suggested that the subject does not need regulation, and recommended that the section be deleted. This comment maintained that the exemptions available for alternate devices would be ''much too difficult to use to allow possible improvements.'' One comment responded to FDA's request for comments on the nonparallel ''alternate design'' compression paddle by supporting the concept of allowing such a configuration under the proposed regulations. The comment further noted that some manufacturers are investigating the use of compression paddles that apply compression in nonparallel geometry and that these paddles would have difficulty complying with the regulation as proposed. One comment suggested that the proposed requirement was too restrictive, stating that several manufacturers have measured the paddle deflection on their units and found that the requirement may be difficult to meet on the 24 x 30 cm paddles. One comment suggested that the proposed specification could be improved if the tolerance were loosened, if the measured compression force were reduced, or if the allowable flex were expressed as a function of the applied force.

Two comments asserted that the proposed regulation in § 900.12(b)(12)(iii)(B) places too great an emphasis on the position of the compression paddle, but does not address the position of the film in the patient support. These comments recommended that the regulations

address the film location with respect to the edge of the patient support and relax the requirements for the compression plate. Three comments suggested that the description of the test method as proposed in § 900.12(b)(12(iii)(B) should be deleted and that testing procedures should be left to the medical physicist to determine, or be included in a companion manual prepared by FDA. Fifteen comments neither supported nor objected to the proposed requirement, but were concerned with the test procedure as proposed and suggested modifications or requested clarification of the procedure.

NMQAAC discussed this section at some length. Some members and consultants were concerned that the specifications in the proposal would limit the introduction of new equipment and, even though the regulations provide procedures for obtaining approval for alternate standards, wanted to modify the requirement. Experts on the committee stressed that the purpose of this regulation was to eliminate those worn and faulty compression devices that were intended to be flat and parallel by design but which, through use, now flex unacceptably. After consideration, the committee recommended that the requirement remain but that a new provision be added that addressed those paddles that by design were not intended to remain straight and parallel under compression. They also recommended that the test procedure described in this section be deleted as a requirement because it could be determined by the physicist during the survey.

In response to the public comments and NMQAAC recommendations, FDA has made changes as outlined below. FDA is deleting the provision that established a test procedure for this section. The requirements have been modified and renumbered as § 900.12(b)(8)(ii)(B) and a new § 900.12(b)(8)(ii)(C) requires that all paddles intended by the manufacturer's design not to be flat and parallel under compression must meet the manufacturer's design specification and maintenance requirements. The agency will revisit and modify its proposal for the test procedure for this section in the future and all comments regarding the procedure will be considered again in that process.

Under § 900.12(b)(12)(iii)(C) and (D), FDA proposed that the chest wall edge of the compression paddle should be straight and parallel to the edge of the image receptor and that the chest wall edge of the compression paddle should not interfere with the chest wall edge of the image.

(Comment 345). Two comments requested clarification on how straight and how parallel the requirement intended the chest wall edge of the paddle to be. One comment agreed with the intent of the proposed regulation, but expressed concern that varying interpretations of the written regulation will lead to confusion in enforcement. This comment recommended that, if such specifications are included in the final regulations, there should be some tolerance specified that is both affordable and effective in the improvement of mammography.

FDA notes that the intent of this section is to eliminate the older style compression paddle that had a curved chest wall edge. The agency believes that the words straight and parallel are well understood but will address concerns raised by the comments through issuance of a guidance on this paragraph that contains a test procedure facilities may utilize. The description of this procedure should also clarify any confusion regarding FDA's interpretation of the regulation.

In § 900.12(b)(12)(iii)(D), FDA had proposed that the chest wall edge of the compression paddle should be bent upward.

(Comment 346). One comment recommended that the proposed regulation include a requirement that the chest wall edge of the paddle be perpendicular to the surface of the compression plate. Another comment stated that the use of ''should'' in § 900.12(b)(12(iii)(D) has little meaning and is unenforceable.

NMQAAC discussed both paragraphs and did not recommend any changes. FDA notes that this provision was not intended to establish a mandatory requirement but to clarify that such a design, intended to enhance patient comfort, was permissible. This requirement has been codified under § 900.12(b)(8)(ii)(E) in the final regulations. The word ''should'' has been replaced with ''may'' in the final rule. FDA does not agree that it is advisable to require the chest wall edge to be perpendicular to the surface of the compression paddle since this could lead to sharp edges that might cause patient discomfort.

Under § 900.12(b)(12)(iv)(A), FDA proposed that, 5 years after the publication date of the final regulations, the edge of the compression paddle shall align with the chest wall edge of the image receptor to within 1 percent. Proposed § 900.12(b)(12)(iv)(B) further restricted the alignment to within 2 millimeters 10 years after publication and § 900.12(b)(12)(iv)(C) proposed a test procedure for the requirement.

NMQAAC recommended that the § 900.12(e)(12)(iv)(A) be moved to the QC section of the final regulations and that the requirements should go into effect at the earliest opportunity. NMQAAC also recommended that the requirement under § 900.12(b)(12)(iv)(B) and (C) be deleted because the committee believed the proposed 2-millimeter requirement was too stringent. The proposed 2-millimeter requirement and the test procedure have been deleted and the final regulation regarding compression paddle-image receptor alignment was moved to the quality assurance section and is codified under § 900.12(e)(5)(vii)(C) where it will become effective at the earliest effective date.

(Comment 347). One comment recommended caution in specifying these alignment requirements because they might limit design in some areas of new technology. The comment recognized that these proposed specifications are only applicable to film-screen systems, but expressed concern that the concepts might carry over into new technology areas.

FDA assumes that this comment was directed toward the issue of image receptor size for digital systems, but does not anticipate any conflict.

(Comment 348). Eleven comments agreed with tightening the tolerance for alignment as proposed in § 900.12(b)(12)(iv) but suggested that only a positive misalignment should be allowed.

FDA agrees and accepts these comments.

(Comment 349). Eight comments noted a typographical error in § 900.12(b)(12)(iv)(A). FDA has corrected this.

(Comment 350). Three comments recommended that the ''October 1, 2000'' effective date be deleted and that the requirement go into effect in the earliest phase because, in the respondents' opinions, the vast majority of systems already meet this requirement.

FDA agrees with these comments and has accepted this recommendation to move the effective date forward.

(Comment 351). Six comments expressed concern regarding the test for this paragraph.

These comments will be reconsidered when FDA publishes its guidelines for the QC test.

Under § 900.12(b)(12)(iv)(D), FDA proposed that the alignment criteria for the contact mode should also be applicable to the magnification mode 10 years after the publication of the final regulations and proposed a test procedure.

(Comment 352). Five comments suggested that the requirement was unnecessarily restrictive and should be dropped. Four comments supported the proposed requirement, believing it serves to ensure the accuracy of the alignment of the edge of the compression paddle with the edge of the image receptor. One comment recommended a rewording for the requirement. Two respondents expressed concern regarding the test procedure. NMQAAC suggested that the requirement in the magnification mode was unnecessary and should be deleted.

After reviewing the comments, FDA has accepted the NMQAAC recommendation and deleted the requirement for paddle alignment in the magnification mode.

Under § 900.12(b)(12)(v), FDA proposed that, 5 years after publication of the final regulations, all systems should display the compressed breast thickness. The proposal also established a test procedure for the requirement.

(Comment 353). One comment pointed out that current indicators of compressed breast thickness are grossly inaccurate for a number of reasons, including paddle and compression arm flex, lack of uniformity across the breast, and differences in the location at which various manufacturers determine the breast thickness (since there is no agreement where the breast thickness is to be measured). Two comments recommended that the word ''correct'' be inserted between ''the'' and ''compressed'' in § 900.12(b)(12)(v). One manufacturer requested an exception for its product because the measured breast thickness read out could be off by 0.6 to 1.0 cm for their paddle. One comment expressed concern that there was no clear specification to the accuracy of the indicated value proposed in § 900.12(b)(12)(v)(A). NMQAAC discussed this provision at its April 1996 meeting and recommended that the requirement for a display remain but that no accuracy specification be associated with the display. NMQAAC revisited the issue at its January 1997 meeting but did not change its recommendation. Another comment suggested that the proposed requirement should apply only to equipment that uses the compressed breast thickness in an algorithm to determine technique factors. One comment supported the proposed requirement in § 900.12(b)(12)(v)(A) because it is especially important for implant patients, but recommended that it go into effect 5 years after the effective date of the regulations rather than 10 years after, as proposed.

FDA has reviewed the comments and reassessed the need for this requirement. The practical application of the information provided by the display to the mammography process appears to be questionable and the concept of having a display that has no associated accuracy is of debatable value. FDA has decided to remove § 900.12(b)(12)(v) from the final regulations in accordance with the agency's desire to minimize costs, as discussed previously. All comments requesting clarification or suggesting modification to the test procedure will be considered again if FDA revisits this requirement.

The portions of proposed § 900.12(b)(12) that have been retained in the equipment provisions were codified under § 900.12(b)(8).

n. *Technique factor selection and display (§ 900.12(b)(9) (proposed § 900.12(b)(13)))*

In this paragraph, FDA proposed requirements for the selection and display of technique factors.

FDA proposed in § 900.12(b)(13)(i) that every system shall have the capability for manual selection of mA's or, at least, of mA or time. No public comments addressed this issue. NMQAAC discussed the proposal at both the April 1996 and the January 1997 meeting and supported the proposal. FDA reworded the requirement slightly before codification to clarify its intent. Because of the deletion of paragraphs listed earlier in the proposal, paragraph § 900.12(b)(13) has been codified as § 900.12(b)(9), and this paragraph became § 900.12(b)(9)(i) in the final rule.

Under § 900.12(b)(13)(ii), FDA proposed that all technique factors be clearly displayed at the control panel prior to exposure. At § 900.12(b)(13)(iii), the agency proposed that such factors be preindicated in the AEC mode.

(Comment 354). One comment recommended FDA clarify that the specification in § 900.12(b)(13)(ii) applies only to the manual mode of operation. A comment on § 900.12(b)(13)(iii) requested clarification of which technique factors were intended to be covered by this requirement. At its April 1996 meeting, NMQAAC also expressed some confusion regarding the same issue. Another comment recommended that the requirements of § 900.12(b)(13)(iii) and (iv) be combined.

FDA believes that requirements for preindication and postindication of the technique factors should be presented under separate paragraphs and has not accepted this last comment. FDA did clarify § 900.12(b)(13)(ii) and (iii) and combined them into a single provision at § 900.12(b)(9)(ii).

Under § 900.12(b)(13)(iv), FDA proposed that, after AEC exposure, the system should indicate the actual kV and mA's used during the exposure.

(Comment 355). Two comments recommended that this requirement be deleted or its implementation date be delayed because the replacement or retrofit of many older units might be costly. Another comment stated that a mA's readout, as proposed in § 900.12(b)(13)(iv), has not been proven necessary. NMQAAC discussed this issue and the cost concerns related to retrofits to provide the postexposure mA's indication. The committee supported the requirement but requested some wording changes to clarify the meaning of mA's indication.

FDA has retained this provision because it concluded that the costs associated with the possible retrofits are not significant enough to outweigh the benefits and has included it in the final regulations under § 900.12(b)(9)(iii).

Under § 900.12(b)(13)(v), FDA had proposed that each unit provide an indication of kVp that was accurate to within + 5.0 percent of the actual kVp.

(Comment 356). Five comments agreed with the proposed five percent accuracy specification, but another comment suggested that the requirement for kVp accuracy of + 5.0 percent was not justified because there was no definition of what kVp really means and no calibration available for kVp meters. Another comment stated that ''5 percent of the actual kVp as proposed in (b)(13)(v), is a very large discrepancy,'' noting that 5 percent of 30 kVp allows 31.5 kVp, which, in the respondent's opinion, presently is considered to be unacceptable. The comment further suggested that § 900.12(b)(13)(v) be changed to read: ''All indications of kVp shall be within 1 kV of the actual kVp.''

In § 1020.30 FDA defines kVp to mean the maximum value of the potential difference across the X-ray tube during an exposure. FDA agrees with the comment that the + 5.0 percent accuracy is a large discrepancy and notes that it is the same specification currently established by the most recent revision of the ACR manuals. The agency intends to provide additional information regarding compliance with this requirement.

(Comment 357). Three comments, including one from NMQAAC, noted that there was a conflict between the kVp accuracy specification at § 900.12(b)(13)(v) and at § 900.12(e)(5)(ii)(A). NMQAAC also recommended that the requirement be moved to the quality assurance section

and that the + 5.0 percent accuracy specification be retained. FDA has accepted these recommendation and the requirement now appears in the final regulations under § 900.12(e)(5)(ii) and includes the + 5 percent accuracy specification.

In § 900.12(b)(13)(vi), FDA proposed that, 10 years after the publication of the final regulations, each X-ray unit used for mammography would be required to have a specific range of kVp and mA's selection and that adjacent selections of the kV selection and adjacent selections of the mA's should not vary by more than a prescribed amount. The public comments regarding this section were overwhelmingly against including these proposals in the final regulations. NMQAAC supported the proposals but only marginally so, with many opposing opinions. FDA has reconsidered the advisability of including these specifications in the final regulations, based in part on the public comments and in part on the difficulty in predicting the necessity for these limitations 10 years in the future and has deleted all requirements proposed under § 900.12(b)(13)(vi) from the final regulations.

o. *Radiation output (proposed § 900.12(b)(14))*

This paragraph proposed setting a minimum value for radiation output per second of mammography X-ray equipment, with an increase in that minimum value to occur 5 years after publication. This section has been codified in the quality assurance section of the final regulations.

(Comment 358). Two comments agreed with the requirement proposed in § 900.12(b)(14)(i), with one urging that the requirement be fully implemented at the earliest possible date rather than being phased-in. One comment suggested that the proposed requirements in § 900.12(b)(14)(i) and (ii) might actually be in conflict with each other. FDA reviewed these provisions and does not see a conflict because clause (i) specified an exposure rate and (ii) specified a time over which that rate must be met. However, in response to other concerns, as outlined in the preamble to the quality assurance section, FDA has modified the requirement to clarify that the specification is to be an average over three seconds and not an instantaneous rate measurement.

(Comment 359). One comment suggested that the proposed requirement in paragraph (b)(14)(i) be replaced by the equivalent air kerma expressed in milligray (mGy). The guidelines followed by FDA in the writing of regulations specify that all numerical limits, where applicable, be expressed in terms of the International System (SI) of Units, the internationally accepted standard, followed by the more common equivalent in parentheses.

In the proposed regulations, FDA had represented radiation limits in terms of exposure expressed in the SI unit of coulomb per kilogram (C/kg). Although C/kg is the correct SI unit for exposure, it is an awkward unit for the actual operating ranges of exposure (10–4 C/kg) of mammography systems. FDA believes now that it would be more advantageous to specify radiation limits in terms of the alternate quantity air kerma expressed in the SI base unit of gray (Gy). Air kerma, which is defined at § 900.2(d), is the sum (per unit mass of air) of the initial kinetic energies of all the charged ionizing particles liberated by the X-rays. At the X-ray energies typically used in diagnostic radiology and mammography, values for air kerma are practically indistinguishable from values of absorbed dose in air. Air kerma is increasingly accepted in the international community as the quantity preferred in the specification of radiation delivered, and it is being proposed to replace exposure in amendments in 21 CFR part 1020. Because amendments to those standards are not final, the units were not used in the proposal. However, FDA is replacing the quantity exposure with the quantity air kerma in these final MQSA regulations because it anticipates that parallel changes will be made in the international standards and part 1020.

(Comment 360). One comment suggested that FDA recast proposed § 900.12(b)(14)(i) as a performance objective, such as: ''The radiation output, in terms of exposure rate, at clinically useful kVp's shall be sufficiently high to avoid exposure times of such duration that loss of resolution due to motion or excessive dose due to film reciprocity failure is expected to occur.''

FDA appreciates the benefits of adopting performance standards when appropriate but believes that in this case the suggested wording introduces an unacceptable level of subjectivity into determining compliance.

(Comment 361). One comment recommended that the test procedure proposed to measure radiation output in § 900.12(b)(14)(iii) specify the position of the compression paddle during the measurement.

FDA assumes this comment is expressing concern regarding the scatter contribution to the reading and its variability depending on the distance the paddle is located from the detector. FDA recognizes the possible effects of scatter on this measurement but does not believe the contribution is of sufficient concern to warrant the prescription of paddle position relative to the detector. In clinical use, the paddle is obviously in contact with the breast. If a facility wishes to test with the paddle in a similar position, FDA has no objection. Similarly, if the paddle is moved nearer to the focal spot, FDA would find this acceptable. FDA does, however, require the compression paddle to be in the X-ray beam between the source and the detector as was specified in § 900.12(b)(14)(iii).

(Comment 362). One comment suggested that FDA require that compliance with § 900.12(b)(14) be determined ''with the phantom in the beam and that the exposure be completed within 2.5 seconds.''

FDA believes that placing any phantom in the beam during this test would not improve this test and that the three second exposure proposed is both reasonable and appropriate for this requirement.

(Comment 363). Two comments suggested that compliance with § 900.12(b)(14)(i) should be determined at a routine clinical kVp instead of the proposed 28 kVp. FDA notes that 28 kVp is used clinically for mammography, although not as frequently as other kVp values. It was selected first by the American Association of Physicists in Medicine and then by the ACR/CDC Imaging System Focus Group as the standard kVp to be used in association with their radiation output specifications. These specifications were utilized by FDA in establishing this radiation output requirement. If a different kVp were selected, the radiation output would likely have to be modified; however, professional consensus on what modifications would be appropriate is presently lacking. The agency, therefore, does not accept these comments.

(Comment 364). One comment recommended that the proposed requirements under § 900.12(b)(14) should be made part of § 1020.31 so that uniform requirements would be ensured nationwide. FDA reiterates its previous position that this would not achieve the desired impact on the installed base of mammography equipment. FDA believes that most modern mammography systems can meet this requirement. However, the agency is considering parallel requirements under § 1020.31 to ensure that future production is compliant.

(Comment 365). One comment supported the test procedure specified in § 900.12(b)(14)(iii) as being an

improvement over the current specification. Another comment suggested that the requirement in § 900.12(b)(14)(i), as written, should only apply to a molybdenum/molybdenum Mo/Mo anode/filter combination because other target-filter combinations may not need to meet the requirement to deliver adequate imaging.

NMQAAC supported the proposed requirements, but suggested that the specifications should be limited to Mo/Mo target-filter units only. They also recommended that all of § 900.12(b)(14) be moved to the quality assurance section.

FDA has accepted NMQAAC recommendations to limit the requirements to Mo/Mo target-filter units and to codify the requirement with the QC requirements.

(Comment 366). One comment noted that xeromammography equipment might not meet these proposed requirements.

FDA believes that xeromammography units should be able to meet the requirement, as proposed, but with the acceptance of the Mo/Mo limitation discussed above, the requirement would no longer be applicable to xerox systems, which incorporate tungsten targets.

(Comment 367). One comment suggested that the proposed requirements of § 900.12(b)(14)(i) and (iii) need to be linked in order to explain where the output is to be measured.

FDA does not agree with this comment although it has reworded the proposed § 900.12(b)(14) for clarification. The provision has been codified as § 900.12(e)(5)(x).

p. *Automatic exposure control (§ 900.12(b)(10) (proposed § 900.12(b)(15)))*

As proposed, this paragraph required that each mammography system have an automatic exposure control (AEC) for mA's, established a specification for the AEC reproducibility, and set requirements for the indication of the AEC detector positions and selected location.

(Comment 368). One comment suggested that the requirements proposed in § 900.12(b)(15) should be prefaced with a statement that they are intended to apply only to film-screen modalities. A related comment reported that xeromammography systems do not have AEC controls as required in § 900.12(b)(15) and that this would bar their use.

FDA agrees with these comments and has rewritten this requirement to limit it to screen-film mammography systems.

Under § 900.12(b)(15)(i), the proposal required all AEC devices to be operable in each equipment configuration provided and gave examples of common configurations.

(Comment 369). Several comments sought to limit the applicability of this requirement in different ways. One comment supported the proposed requirements in § 900.12(b)(15)(iv)(A) and (B) as a means to ensure appropriate detector location and thereby avoid repeat exposures and reduce patient dose. One respondent did not believe that the automatic exposure control photo-timing proposed in § 900.12(b)(15)(i) is significant in obtaining satisfactory diagnostic mammograms. Three comments recommended modifying § 900.12(b)(15)(i) by replacing ''of equipment configuration provided'' with ''where applicable.'' The comments further suggested that the examples of equipment configurations in § 900.12(b)(15)(i) be deleted. One comment agreed with the April 1996 NMQAAC recommendation that the requirements proposed in § 900.12(b)(15)(i) should be limited to clinically used configurations.

FDA remains convinced that the use of AEC devices on mammography equipment is an aid to quality mammography and believes that requiring it for ''all combinations of equipment configuration provided'' is appropriate and necessary. The agency notes that the requirement applies to the configuration of the individual unit. For example, if the unit is not provided with magnification capability, then it would not be required to have a functioning AEC in a nonexistent magnification mode. The agency also notes that NMQAAC reversed its April 1996 position during its January 1997 meeting and concurred with the requirement as proposed.

Under § 900.12(b)(15)(ii), FDA proposed that the AEC be capable of providing automatic mA's selection.

(Comment 370). One comment recommended deleting this requirement, stating ''that it is the purpose of AEC to provide automatic mA's selection'' and, therefore, the requirement was redundant. One comment requested clarification of the phrase ''automatic mA's selection.'' Another comment asked whether § 900.12(b)(15)(ii) required automatic termination of exposure or automatic display of mA's and questioned why the AEC should be able to automatically select mA's.

FDA defines an automatic exposure control as a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a preselected location. Such a device would automatically terminate the exposure when the selected quantity of radiation had been delivered. This definition does not restrict the technique factor(s) that may be selected; the control of target material, focal spot, filtration, time, mA, and/or kVp are all viable options for such a device. Because the mA's is the product of time (in seconds) and mA, the control of time and/or mA represents control of the mA's; therefore, AEC's generally function by controlling mA's and/or kVp. FDA was initially concerned that an AEC that controlled kVp alone, without capability to control mA's, could not adequately ensure the small incremental changes in radiation that are often necessary in mammography. FDA has reconsidered this position because it has concluded that any such device that reaches the marketplace would provide the necessary ranges of adjustment in order to have been approved under the FDCA's requirements for safety and efficacy of new devices. Therefore, FDA is removing the requirement proposed in § 900.12(b)(15)(ii) that all AEC devices provide automatic mA's selection.

Under § 900.12(b)(15)(iii), FDA proposed a limit on the reproducibility of the AEC.

(Comment 371). One comment suggested the wording be changed to include ''for each target/filter combination.''

FDA believes the change is not needed; because no target-filter combinations were specified in the regulation, all combinations are subject to the requirement.

NMQAAC recommended that this requirement be moved to the quality assurance section. FDA has accepted this recommendation and the specification for the evaluation of the AEC reproducibility is codified in § 900.12(e)(5)(i).

Under § 900.12(b)(15)(iv), FDA proposed requirements regarding the positioning flexibility of the AEC detector, visual location of the available detector positions, and indication of which AEC detector location was selected.

(Comment 372). Two comments recommended that the proposal be expanded to require increased flexibility in placement of the AEC detector. One comment commended the proposed requirement for AEC positions to be indicated at the input surface of the breast compression paddle. The comment believed that this requirement would improve the quality of imaging and prevent repeat images. Two

comments suggested that FDA add a requirement specifying the necessary accuracy of the indication of both the size and available position of the AEC detectors. The respondents' suggested the indication might depend on magnification of the indication resulting from various breast thicknesses.

FDA interprets these comments to mean that a projected indication on the input surface of the breast might vary in size and location depending on the magnification induced by the displacement of the input surface caused by various breast thicknesses. FDA agrees that this might occur and notes that such a system would be a design that might not be able to meet the requirements.

FDA intends the indications of the size and location represented on the compression paddle to be representative of the actual size and location of the detectors as they would appear if marked on the breast support device. The agency anticipates no confusion will be caused by varying displacement of the paddle from the patient support since the indication of size and position will remain constant.

(Comment 373). One comment suggested that the indicators should not ''give rise to artifacts in the image.''

FDA believes that any such artifacts will be detected and corrected during the normal QC process and, therefore, modification of this requirement is unnecessary.

(Comment 374). One comment stated that this requirement leaves too much room for interpretation and would be very difficult to inspect against. The comment suggested one could argue that merely knowing the position via the handle that moves the detector would be adequate for proper detector positioning. The comment further stated that all current units do provide clear indication of detector position, which is visible from both sides of the patient, and that the requirement should be removed.

FDA does not agree that the requirement is subject to conflicting interpretation or would be difficult to inspect, but does agree that the location of the position selector would be an adequate indication of which detector position had been selected (although it would not indicate the detector position itself). FDA also does not agree that the installed base of systems all provide such flexibility or indications and remains persuaded that the requirement will provide useful tools for the technologist.

NMQAAC recommended that FDA delete the proposal that the selected detector position be visible from both sides of the patient because they did not consider it of sufficient importance to require in the regulations. FDA has adopted this recommendation and the requirement has been amended accordingly.

Under § 900.12(b)(15)(v), FDA proposed that the operator be able to vary the optical density from the normal density setting. No specific comments were received on this proposal and FDA codified this requirement without change.

Under § 900.12(b)(15)(vi), FDA proposed that, 10 years after the publication of the final regulations, each unit would be required to provide four steps above and four steps below the normal optical density setting and proposed limits for the acceptable variability between adjacent settings on this control.

(Comment 375). FDA received a large number of comments on this section. The overwhelming majority were opposed to the requirement because of concerns regarding the wording of the provision, the perceived cost to facilities, the range of control to be provided, the incremental difference between adjacent settings, and the necessity for the requirement. In response to these comments and because of agency concerns regarding costs, FDA concluded that the proposal should be deleted from the final regulations and that further study should be undertaken to determine if future requirements in this area are warranted. If regulations or guidelines are proposed later, the individual comments will be reconsidered at that time.

Under § 900.12(b)(15)(vii), FDA proposed requirements for the optical density variation permitted with a screen-film mammography system under AEC.

(Comment 376). Three comments supported the proposed requirement in paragraph (b)(15)(vii) because it evaluates the equipment performance when used on breasts of various size and density. Two comments indicated that § 900.12(b)(15)(vii) was not stringent enough and one of these recommended that an initial value of 0.15 OD should be specified.

FDA disagrees with this comment because it believes that the initial value should remain the same as that used in the interim regulations. NMQAAC recommended that these requirements be moved to the quality assurance section and FDA agreed. The requirements have been codified under § 900.12(e)(5)(i).

In the proposal, FDA had specified that the system meet the requirements for AEC reproducibility at each available detector position.

(Comment 377). Three comments suggested that the test under § 900.12(b)(15)(vii) is necessary for only one detector position because the detector and associated electronics do not change.

FDA disagrees with these comments because some AEC detectors utilize individual detectors that are permanently fixed in position. The switching of position is actually a change in contact points or system logic to read the selected position. In such cases, the testing of one position provides no indication of the function at other locations.

(Comment 378). One comment suggested that the testing of photo-timer tracking with dosimeter positioning is usually not necessary unless multiple detectors are used.

The agency believes that when the process is accomplished by the relocation of the same detector to different positions, the functioning of the detector at each detector location is not guaranteed by testing at only one position. This could be influenced by broken wires, poor connections, or dirty contacts in the system.

(Comment 379). One comment stated that testing of the AEC at all detector positions will be dependent on the dimensions of the phantom. The respondent stated that the commonly used 10 cm x 10 cm phantom may not be large enough for all positions and that this will drastically increase the time required to perform this test.

FDA does not agree with this comment. The phantom could be placed near the focal spot and thereby cover all available detector positions without being repositioned.

(Comment 380). One comment suggested that with multiple detectors it is not necessary to test the tracking over the entire range of phantom thicknesses.

FDA interprets this comment to mean that, once the detector reproducibility at each position has been established, the testing of reproducibility for additional thickness need be performed at only one position. FDA does not agree with this comment; it does agree, however, that when one detector is used and moved from position to position, once it is established that the detector is reproducible over the entire range of thicknesses at one position, it is only necessary to establish the correct functioning for one thickness at each other position. In response to these comments and in recognition of the costs associated with testing reproducibility at multiple positions, FDA has deleted the specification for

testing at each detector position. Because the agency remains convinced that the best way to ensure that the detector(s) functions properly at each position is to test it/them at each position. FDA encourages facilities and the medical physicists to include such testing as a routine part of the annual survey. The remaining provisions of proposed § 900.12(b)(15) are codified as § 900.12(b)(10).

q. *Disabled examinees (proposed § 900.12(b)(16))*

In this paragraph, FDA proposed that each facility choosing to schedule disabled patients have equipment and protocols in place to ensure that the facility could adequately accommodate such disabled patients. This proposal did not require each facility to accept disabled patients, but did require those doing so to be capable of performing the service.

(Comment 381–382). Many comments expressed the mistaken belief that FDA was seeking enforcement powers under the American with Disabilities Act (ADA) or to duplicate the ADA.

Other comments on this section ranged from calling the requirement too lenient to calling it unnecessarily intrusive. The majority of the comments, although not opposed to accommodating disabled patients, were concerned that the screening of patients prior to their examination would be difficult or impossible because many appointments are not made by the patient. Comments also expressed concern that accepting disabled patients under this requirement would obligate facilities to be able to accommodate all disabled patients. Some comments also questioned whether there was equipment available that could offer this range of use.

Another area of concern was related to mobile units and facilities which, because of their size and stand-alone nature, would be difficult to adapt to accommodate the range of disabilities the facilities might encounter. NMQAAC consumer representatives supported this section and urged FDA to require facilities to either serve disabled patients or refer them to a facility that can. Other comments questioned the value of referrals, citing lack of knowledge regarding other facilities' equipment, staff, and ability to deliver the services necessary.

Because of the lack of consensus on the need for this requirement and the concerns raised in the comments, FDA has decided to delete the proposed requirement and revisit it at a future date if a problem is perceived. FDA strongly urges facilities to voluntarily institute procedures that will direct patients with disabilities to facilities that are capable of serving this population. The agency believes that local consumer groups and all accreditation bodies can pool information and educate the public and the mammography community about the availability and locations of such services.

r. *X-ray film (§ 900.12(b)(11) (proposed § 900.12(b)(17)))*

In this paragraph, FDA proposed a requirement that X-ray film used for mammography must be designated for such use by the film manufacturer.

(Comment 383). One comment supported the proposed requirement. Three comments suggested that it was too vague, one comment questioned how one would know if a manufacturer's designated mammography film is adequate for doing quality mammography under the requirements, and another suggested the adoption of the storage recommendations from ACR's *Recommended Specifications for New Mammography Equipment*. NMQAAC supported this requirement as proposed.

FDA has not proposed regulations governing film storage because it believes that each facility should follow the manufacturer's instructions for the particular film being used. The goal of this requirement is to ensure that the film used by the facility is considered, at least by the manufacturer, as being suitable for mammographic use. The regulation is not intended to establish standards for film; the only requirement placed on the facility is to check that the film it uses has been designated by the manufacturer for mammography. The requirement is not vague once its limited scope is understood. FDA codified this requirement, without change, in § 900.12(b)(11).

s. *Intensifying screens (§ 900.12(b)(12) (proposed § 900.12(b)(18)))*

FDA proposed in this paragraph that only intensifying screens that have been specified by the manufacturer as appropriate for mammography may be used for mammography.

(Comment 384). One comment supported the proposed requirement. Again, one comment questioned how a facility would know if a manufacturer's designated mammography screens are adequate for doing quality mammography under the proposal. Another comment stated that xeromammography systems do not use intensifying screens and that § 900.12(b)(18) would serve to ban their use.

FDA does not intend a specification about screen requirements to apply to any modality that does not use screens in the production of its images. Therefore, the agency sees no impact of this requirement on xeromammography. Although NMQAAC supported the requirement, one member expressed concern that the wording of the proposal implied that the facility was responsible for matching the spectral sensitivity of the film and the screen. As explained in connection with the mammography film specification above, the intent of the requirement is not to address the quality of the product, but rather to ensure that it is one intended by the manufacturer to apply to mammography. In general, the facility is responsible for matching the spectral sensitivities of the screen with the film. However, the facility is expected to use the information provided by the manufacturers and not to derive the information independently. FDA has reworded the requirement to clarify this point and codified it as § 900.12(b)(12).

t. *Film processing solutions (§ 900.12(b)(13) (proposed § 900.12(b)(19)))*

In this paragraph, FDA proposed that facilities use film processing solutions capable of developing films in a manner equivalent to the film manufacturer's minimum specifications.

(Comment 385). Three comments supported this proposed requirement and requested that guidance documents be established for this area. Six comments suggested that the word ''minimum'' be deleted because, in the respondents' opinions, most facilities generally comply with the regulatory requirement and the regulation should encourage them to meet more than the minimum. FDA appreciates these comments and notes that facilities are free to exceed this minimum; the requirement, however, is intended only to establish that facilities comply with the manufacturers' minimum standards.

(Comment 386). Three comments questioned how a facility could demonstrate equivalence under § 900.12(b)(19) because some manufacturers of film processing chemicals refuse to acknowledge that other vendors' chemicals produce ''equivalent'' results. The comments requested that the wording be changed to clarify compliance.

FDA believes these comments are similar to the ones regarding quality of the film and screens used in mammography. It is not the intent of the requirement that the facility experimentally determine the compatibility of various solutions with the film, but only that the facility obtain documentation from the suppliers showing that their products are intended to be used for processing the

particular film used by the facility and that they provide results consistent with the film manufacturer's specifications. The facility would only be required to establish the equivalence independently if no documentation, in the form of labeling or specifications, were available from the chemical or film supplier.

(Comment 387). One comment questioned how the requirement can be met when the film manufacturer does not manufacture chemicals for film processing.

FDA notes that, in such cases, it would likely be easier to establish equivalence because the film manufacturer would specify the requirements for the processing as opposed to a manufacturer that supplies both film and chemicals and is likely to specify solutions only by name rather than characteristics.

(Comment 388). One comment recommended that FDA allow accreditation bodies to review and monitor the use of chemicals for film processing and eliminate the requirement from the regulations.

Although the agency is continually working with the accreditation bodies to divide responsibilities when such division is useful and possible, FDA did not adopt the recommendation. The MQSA requirements, even when administered by the accreditation bodies, are implemented through Federal standards. FDA may consider requiring accreditation bodies to collect and monitor information about chemicals used for film processing in the future. NMQAAC agreed with the requirement as proposed. FDA has codified the requirement in the final regulations under § 900.12(b)(13).

u. *Lighting (§ 900.12(b)(14) (proposed § 900.12(b)(20)))*

In this paragraph, FDA proposed a requirement that facilities provide special lights for use during interpretation with variable luminance capable of producing light levels greater than that provided by the viewbox.

(Comment 389). Four comments supported the proposal. One stated that ''it might reduce the number of retakes, and provide better detail to the interpreting physician.'' Two comments noted that the light should be required wherever the interpreting physician is reading films, but that it may not be necessary at all locations where images are taken. One comment noted that the proposed requirement in § 900.12(b)(20) was for a ''bright light'' or ''hot lamp'' for viewing dense areas of films. The comment suggested that the purpose of the lamp should be included and that it should only be required for facilities that use the screen-film modality.

FDA agrees that the light is only required where mammograms are interpreted but recommends that it may be useful to the technologist in evaluating the quality of the films. FDA also agrees that facilities not interpreting screen-film mammograms, or not reviewing previous screen-film mammograms for reference, do not need these special lights.

(Comment 390). Two comments stated that a fixed output lamp may give the same information as the variable output ''hot lamp'' proposed. NMQAAC supported the requirement, but recommended that the word ''variable'' be removed because it is the increased intensity and masking provided by the light rather than any variability in output that actually enhance the reading of the image.

FDA has accepted these suggestion and has reworded the final requirement accordingly.

(Comment 391). One comment expressed difficulty imagining the benefits of this requirement to the patient.

FDA believes the usefulness of this device is well established, especially in view of the trend toward denser films in mammography; by optimizing interpreting conditions for physicians, the regulation increases the likelihood that the patient's mammogram will be accurately interpreted.

(Comment 392). One comment recommended that FDA allow accreditation bodies to review and govern the proposed requirement in § 900.12(b)(20), and eliminate it from the regulations. As indicated above in response to a similar comment by the same individual.

FDA has not adopted the recommendation, although it may consider requiring such action by the accreditation bodies in the future.

(Comment 393). Four comments suggested that the proposed requirement was too vague. One comment suggested that the requirement be reworded to specify that a ''spot lighting'' device be provided.

FDA agrees with these comments and amended the final requirement to clarify this point.

(Comment 394). A number of comments chose this section to offer suggestions regarding requirements for the viewbox or the viewing conditions. FDA has discussed those comments in the general equipment section above.

Because of the deletion or movement of other paragraphs in the equipment portion of the proposed regulations, the reworded § 900.12(b)(20) was codified as § 900.12(b)(14).

v. *Film masking devices (§ 900.12(b)(15) (proposed § 900.12(b)(21)))*

In this paragraph, FDA proposed that all facilities ensure the presence of film masking devices that are capable of limiting the illuminated area of the viewbox to the exposed or smaller area of the film, that facilities using nonrectangular collimation ensure suitable masking, and that such devices be available to the interpreting physicians.

(Comment 395). Six comments supported the requirement. Two of these comments further suggested that the requirement be modified to clarify that any effective means of masking, including ''black film or manual or automatic masking devices,'' would be acceptable. One comment questioned how effective the film masking devices must be because the respondent believed that many presently in use do a poor job of blocking the unnecessary light. FDA has not attempted to specify particular mechanisms for masking, only that provisions for masking be available. Any device that blocks viewbox light not required for viewing and interpreting the image would meet the intent of this requirement. The level of ''blocking'' was not addressed, but with the light levels under consideration, the agency believes that the elimination of any noticeable transmission through the masking is easily achievable. The device need not be an expensive or elaborate system, but it must be capable of eliminating extraneous viewbox light.

(Comment 396). Two comments supported the proposed requirement to provide appropriate masking for nonrectangular images as a means to further promote the correct masking of all shape images, but another comment stated that the nonrectangular collimation referenced should be eliminated because ''there is no need for it and it causes significant problems in the masking of the films for proper viewing conditions.'' NMQAAC suggested that the requirement regarding nonrectangular masking was redundant and recommended that it be removed from the final regulation.

FDA does not intend to express a preference for rectangular or nonrectangular collimation. This section was included in the proposal to reinforce the point that, in all cases, the masking should be appropriate to the image. FDA is accepting the NMQAAC recommendation and deleting the provision relating to nonrectangular collimation from the final regulations; FDA agrees with NMQAAC that the

general masking specification covers all sizes and shapes of images.

(Comment 397). One comment questioned how much limitation of the exposed image the proposal intended the masking to provide and one comment proposed that the masking requirement be expanded to require limitation of ''the illuminated area to a region or regions substantially smaller than the exposed portion of the film.''

FDA has not accepted this recommendation because it may not be desirable, in all cases, to limit the view to an area ''substantially smaller than the exposed portion of the film.'' The intent of the section is that masking be as close to the full darkened film area as possible. The masking can certainly be variable, so that the darkened area can be reduced to a specific area of interest. This is not required, however. Discussions with interpreting physicians have led FDA to conclude that it is often desirable to visualize the entire image to establish a ''gestalt'' impression before further interpretation of the film. A masking system that prevented such a practice, therefore, may be undesirable and is not being required.

(Comment 398). One comment questioned to what extent the film masking devices were required to be available. The comment asked if all mammograms were required to be read on viewboxes equipped with masking devices or if the facility need only require adequate masking for one viewbox, even if multiple reviewers were reading film at the same time on different viewboxes.

In response to this comment, FDA has modified the final regulation to indicate that such devices should be available in sufficient numbers to allow each physician requiring one to have access to one. NMQAAC recommended that the requirement that the devices be available to physicians should be deleted, stating that any physician who desired to use masking could provide their own at little or no expense and that the facility need not provide such devices for them. FDA partially agrees with this assessment but has not accepted this recommendation because it has concerns about facilities that require significant numbers of films to be read daily and where the interpreting physician simply does not have time to individually mask images. Placing responsibility with the facility will ensure that masking devices are provided in such cases.

(Comment 399). Two comments recommended that the regulation mandate the use of film masking devices by the physician, and one of these suggested that masking should be used by the technologists in their film critique area. While FDA certainly agrees that both interpreting physicians and technologists should utilize masking, the agency believes that, if the devices are available, most individuals will use them and that requiring their use would be difficult to enforce.

(Comment 400). One comment stated that film masking devices may be expensive to obtain and cumbersome to use. This comment maintained that, although film interpretation may be improved by using these devices, requiring that facilities provide such devices appears to be excessive regulation and this requirement should be deleted.

FDA notes that the goal of the MQSA is to provide a consistent baseline of quality mammography services to all patients. If an item that is consistent with that goal is identified as having a positive impact on the diagnostic process, FDA believes it is important to assure women that facilities at least have these devices available for use on their behalf. FDA also notes that masking devices do not ordinarily entail significant expense. FDA has codified the requirement for availability of masking in the final regulations under § 900.12(b)(15).

w. *Film processors (§ 900.12(b)(22) (proposed § 900.12(b)(22)))*

In this paragraph, FDA proposed a number of requirements for the film processors used to develop mammograms. As proposed, § 900.12(b)(22)(i), covering processor setup and maintenance, would go into effect 1 year after final publication; § 900.12(b)(22)(ii) and (iii), requiring display of the time cycle and maintenance of the developer temperature, would be phased-in after 5 years; and § 900.12(b)(22)(iv) and (v), requiring the display of the developer temperature and for variable cycle processors to be interlocked to prevent new film being accepted by the processor until cycle parameters are stabilized, would be phased-in after 10 years.

Section 900.12(b)(22)(i) proposed that all such processors be set up and maintained at the technical development specifications for the film used for mammography at the facility.

(Comment 401). One comment requested a definition of technical development specifications, as used in the proposed regulations. Another comment stated that, if it is going to be mandatory to meet film manufacturers technical requirements, then manufacturers should be required to make written guidelines available as to what factors are needed to achieve the maximum result from the film.

FDA coined the phrase ''technical development specifications'' to represent a listing of the technical aspects of correct processing as provided by the film manufacturer. This would be expected to include such items as correct solutions, proper temperatures, applicable immersion times, replenishment rates, and any other instructions the manufacturer deemed appropriate and critical to the processing of its film. FDA believes that many manufacturers do provide such information and that the market advantage these manufacturers will enjoy will encourage all manufacturers to do so. The NMQAAC recommended that this section be moved to the quality assurance provisions and FDA has followed that advice.

The agency has reconsidered the proposed requirements in § 900.12(b)(22)(ii), (iii), (iv), and (v). FDA received a number of comments both supporting and opposing these proposals. However, based on the anticipated costs associated with these proposals compared with the marginal benefits they would provide, FDA has decided to delete them from the final regulations. If the agency proposes future regulations for these areas, all related comments will be reconsidered.

3. Medical Records and Mammography Reports (§ 900.12(c))

This section establishes quality standards for medical records and mammography reports as required by the MQSA under 42 U.S.C. 263b(f)(1)(G). The regulation provides, in general, that facilities prepare written reports of mammography examinations, that results be communicated to the patient or provider, and that films be maintained for a reasonable period of time or transferred to the patient.

(Comment 402). Public comments were received on § 900.12(c). The most controversial areas were specific provisions in the proposal for use of standardized assessment categories in the mammography report, written notification of all mammography results, and for original mammograms to be transferred to other facilities or entities upon patient request. Each of these areas will be discussed below in connection with those specific provisions.

a. *General comments*

As an initial matter, FDA disagrees with four comments that asked FDA to delete the entire regulation on medical records and reports because it was an intrusion of FDA into the practice of medicine and abridged the rights of

radiologists. The agency's authority and responsibility to regulate these medical records, mammography reports, and communication of results was established by Congress through specific provisions of the MQSA. The agency could not eliminate the entire regulation, even if it believed such action was appropriate. Discussions with NMQAAC clearly indicated the committee's support for regulations in this area as well.

b. *Contents and terminology (§ 900.12(c)(1))*

The proposal established standardized assessment categories for interpreting physicians to use to evaluate mammograms, ranging from ''negative'' to ''highly suggestive of malignancy.'' In addition, the regulation requires the interpreting physician to address clinical questions, if possible, and include recommendations, if any, in the report.

(Comment 403). Comments in support of the proposed standardized assessment categories stated that such categories: would ensure that a definitive result for each mammogram is reached; would establish consistency across facilities; are a valuable tool to assist consumers and clinicians in understanding results; should also be used in the written notification to patients; and permit efficient and uniform analysis of outcomes in medical audits. One comment in support of this section suggested that the title be changed to ''Contents, terminology and timeframes.''

Fourteen comments stated that it is inappropriate for the Federal government to establish medical terms for classification of mammography results through regulation. Other comments opposing the establishment of standard assessment categories stated that: Such categories would prevent any particular facility from continuing to use its customary terminology and, thereby, cause confusion to its referring physicians; the message, rather than the exact words, are important and resources would be wasted in monitoring the correct use of particular phrases; and that establishing standard classifications would reduce flexibility for the reporting physicians.

Some comments objected to the details of a particular classification category, rather than to the idea of standard classifications. One comment stated that a ''negative'' report may mislead a referring physician about the existence of breast cancer because mammography cannot detect all breast cancers, while another comment concluded that the term ''suspicious'' inherently suggests that the lesion is malignant, and proposed ''indeterminate'' as a substitute category.

After considering all these comments, FDA has decided to keep the proposed categories in order to promote consistency and clarity in mammography interpretations. In discussions with NMQAAC, the use of final assessment categories was supported because they promote consistency in communication of results among medical care providers and standard categories are necessary in the medical audit of mammography interpretation. These particular categories are based on similar categories developed by ACR. The ACR Breast Imaging Reporting and Data System categories are: Assessment Is Incomplete-Need Additional Imaging Evaluation; 1-Negative; 2-Benign Finding; 3-Probably Benign Finding—Short Interval FollowUp Suggested; 4-Suspicious Abnormality—Biopsy Should Be Considered; and 5-Highly Suggestive of Malignancy—Appropriate Action Should be Taken.

FDA believes that the medical community is familiar with these categories and the assessment classifications established under the final regulations (''negative,'' ''benign,'' ''probably benign,'' ''suspicious,'' ''highly suggestive of malignancy'') are equivalent to the ACR system. The medical community has already affirmed their usefulness and value through widespread use of the ACR system. Accordingly, the agency concludes that requiring these classification terms in mammography reports will not be burdensome, given their current level of use and acceptance.

FDA has made minor changes in particular assessment categories in response to comments. Two comments requested FDA to delete the word ''imaging'' from the proposed assessment category of ''needs additional imaging evaluation'' and substitute the ACR category of ''needs additional evaluation'' because physical examination may be part of further evaluation. In fact, the ACR category is ''Need Additional Imaging Evaluation,'' with ''incomplete'' as its descriptor. Accordingly, FDA is adding the word ''incomplete'' to the description of this category, which will now read: ''Incomplete: needs additional imaging evaluation.'' The mammographic result should be categorized into this or one of the other assessment categories. The agency notes that, if the result is ''negative'' or ''probably benign'' based on the mammogram, but physical examination is recommended, the recommendation for clinical followup, surgical consultation, biopsy, or other action should be stated in the recommendations section of the report. The agency also is aware that there are screening mammography practices that do not issue a final assessment until followup diagnostic mammography has been scheduled and performed. These facilities, and others, can continue their policy of not issuing an assessment, and can use this category of ''Incomplete: needs additional imaging evaluation.''

FDA's proposed language for the ''negative'' category stated that if the interpreting physician is aware of clinical findings or symptoms, these should be explained. One comment asked if this explanation must be written into the report or could be attached as a symptom in-take form. The agency believes that the recommendations section of the report is the most effective way to direct referring health care providers to further work-up based on physical findings or symptoms, despite negative mammographic results.

(Comment 404). One comment stated that it would be hard to determine compliance with the proposed requirement that clinical questions raised by the referring health care provider be addressed in the recommendation section of the report.

FDA responds that it can determine compliance with a regulation in a variety of ways, including review during an inspection of a facility's standard operating procedures. FDA inspectors can be trained to verify that each facility has in place a system that requires its interpreting physicians to address the concerns of referring health care providers in the recommendations section of the mammography report. FDA agrees with comments that suggested that the recommendation section of the report remain separate and unstructured; the agency has not proposed specific categories or language for this portion of the report in order to provide maximum flexibility for clinical management recommendations.

(Comment 405). One comment stated that there should be a unique patient identifier to distinguish between two patients with the same first and last name. NMQAAC also agreed, stating that the medical report and the mammography films should have a patient identifier in addition to the name. FDA agrees that an additional patient identifier in addition to the name will improve the accuracy and clarity of the results and subsequent followup and the proposal has been amended to require reports to have this additional identifier. However, the

choice of the additional identifier, such as the date of birth or hospital number, is left up to the facility because each individual practice has a better understanding of its particular needs in this matter.

(Comment 406). Two comments asked if a radiologist who did not read the film or dictate the report can sign a report if the radiologist who did perform the interpretation is unavailable and concurs with this practice. Another comment stated that FDA should allow signatures that are authenticated through computers, which are normally accepted in a court of law. A third comment stated that signatures should be evident on the report filed in the patient's permanent file.

FDA interprets the MQSA's requirement that each mammography report be ''signed'' by the interpreting physician to mean that each report must identify who interpreted the mammogram and rendered the reading on the written report. The final regulations state that the name of the interpreting physician must be on the mammography medical report. This name may be handwritten, typed, stamped, written electronically, or recorded in any other manner. However, with respect to ''signatures'' that are used to proof-read reports or to ''sign'' them out for purposes of authenticating such reports or releasing them to other parties or institutions, FDA believes that each facility is in the best position to devise its own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations in this area.

(Comment 407). One comment recommended that there be a requirement for facilities to maintain records that include the signature of the qualified radiologic technologist who performed or supervised the examination and the signature of any individual who conducted all or part of the examination under supervision of a qualified radiologic technologist.

FDA disagrees with this comment. The MQSA does not have a signature requirement for the technologist. The final regulations require ''technologist identification'' on each film image (§ 900.4(c)(viii)(E)) and the agency believes each facility can adopt its own system to identify technologists without having the agency mandate such procedures.

(Comment 408). One comment suggested that the term ''health care provider'' should be replaced with ''referring physician.'' FDA disagrees because patients are referred for mammograms by nonphysicians, such as physician's assistants, nurse practitioners, and other health care workers.

c. *Communication of mammography results to patients (§ 900.12(c)(2))*

This provision requires that: (1) Each facility establish a system to ensure that results are communicated to patients; (2) patients without health care providers receive medical reports and lay summaries of their mammography results; (3) each facility establish a referral system for patients without health care providers, if necessary; and (4) results that are ''suspicious'' or ''highly suggestive of malignancy'' be communicated as soon as possible.

(Comment 409). FDA received hundreds of comments on the proposal that all patients receive written results of their mammography examination. Comments that objected to this proposal generally focused on disruption of doctor-patient relationships, confusion for patients, and additional expense to facilities without commensurate patient benefit. Ninety comments stated that the referring health care provider is responsible for communicating results to patients and is best able to convey such results and answer patient questions. Other comments that raised concerns about disrupting the referring doctor-patient relationship stated that written notification from the facility would allow patients to bypass a referring physician and never get a physical breast examination. Many comments stated that written notification to every patient would cause confusion for the patients. Twenty-three comments said confusion would arise if patients were notified about results before such results were reviewed by their referring physicians; twenty-one comments stated that many patients would misinterpret their reports; ten comments stated that the difference between the information provided in a lay notification and the information contained in a copy of the actual written report would confuse patients who received both.

Seventy-two comments stated that the additional cost associated with written communication to every patient would cause financial hardship for mammography facilities. In general, these comments and others argued that the cost of providing or ensuring written notification in every case outweighs any patient benefit that might result. Ten comments stated that radiologists would have to police referring physicians who agreed to provide patient notifications and followup. Other comments stated that: (1) Small or rural facilities would be burdened by patient notification requirements, especially those without a computerized system; (2) producing patient notification reports is time-consuming and hinders the accomplishment of daily operations, and would not directly improve patient care; (3) developing a notification document that could explain every possible scenario involving diagnostic findings is virtually impossible; and (4) radiologists and providers of mammography would become more frequent targets of litigation because of this reporting requirement. Thirty-seven comments stated that it is unrealistic to expect radiologists, who may never see patients, to determine the literacy level, ethnic, cultural, and social sensibilities of those patients in order to tailor an appropriate written notification. Fifteen comments stated that the requirement would create excessive waste paper for the environment. Some comments found the proposal for written notification unnecessary in light of other reporting and followup requirements, the individual patient's responsibility to communicate with her physician, and the belief that patients are always informed of results by their physicians. Two comments asserted that written notification for all patients was not authorized by the MQSA.

FDA also received 66 comments that supported the proposal for all patients to receive written notification of mammography results including comments offering strong support from national breast cancer patient groups. These comments generally focused on the fact that women otherwise were not assured of timely and accurate information about their mammography examinations and that such written notification could save lives by encouraging initiation of necessary followup.

It was also noted that the experience of facilities that instituted such notification was positive. Comments in support of written patient notification stated that such notification was appropriate because patients are entitled to know the results of their exams, it is the facility's responsibility to inform patients of results, and there is a public health need for written notification because not all referring physicians discuss results with their patients.

(Comment 410). Comments described written notification as an important addition to quality mammography practice, a crucial component to ensuring reliable mammography and consistency across the country, and a major step toward fostering better communication between doctors and their patients. One comment supported the proposed system to ensure that patients and referring physicians receive reports, and that all patients receive a

report in lay terms, but also stated that the referring physician should continue to be responsible for patient followup. Another comment stated that FDA should not allow any party, other than the facility, to distribute these written notifications.

Many comments asserted that written notification for each patient may ultimately reduce health care costs and extend lives because of earlier treatment. Five comments stated that written notification empowers the medical consumer and minimizes the possibility of tragic error when abnormal results slip through the cracks of the referring physician systems. Comments asserted that referring physicians do not always communicate results to patients, even when the results are abnormal. Several breast cancer survivors commented positively on this proposed requirement and one author stated that such written notification saved her life. Seven comments stated written notification has reduced medical liability of facilities, but that costs should be offset with increased reimbursement.

Comments from State health officials and some facilities having experience with written patient notification reported that the experience had been positive. Facilities that have instituted written notification stated that the practice is appreciated by patients and does not cause the facility any particular hardship. Massachusetts has required such written notification since 1994. The comment from a State official stated that, although initially resisted, the procedure is now accepted by physicians throughout the State; facilities in Massachusetts receive positive feedback from patients and no facility has closed in that State because of this additional requirement.

Some comments recommended that the notification include additional information. Twelve comments asked that the written notification also include information about the location of the films, directions about how a woman could obtain them, and the facility contact person for questions concerning the result. Another comment said the notification should include information about the importance of clinical breast examinations by a qualified physician, monthly self-breast examinations, and mammograms at appropriate times, especially for patients without physicians. Some comments wanted facilities to be required to provide written notification to referring physicians and patients.

Many comments suggested alternatives that were variations to the proposed requirement for written patient notification. Ten comments supported the current interim regulations, which require written notification from the facility only to those patients who do not have a health care provider or referring physician. Thirteen comments stated that, for referred patients, the required notification should simply state that the mammogram report has been mailed to the physician and the examinee should contact that physician. Twelve comments stated that only those patients who request a written report should be sent one.

Other comments agreed that patient notification of results by the facility was appropriate, but preferred to leave the method of communication up to the facility, which could tailor notification procedures to its practices and the circumstances of particular patients. Comments observed that in some screening cases, where the radiologist never speaks to the patient, written notification of results makes sense; however, where there is extensive interaction and verbal communication with the examinee onsite, written notification can be redundant, expensive, and wasteful of paper. Five comments stated that patients should be verbally told at the time of the examination to contact her physician's office and not to assume that ''no news is good news.'' Other alternatives suggested by comments included several that were in direct contradiction to each other: (1) Require written notification only to those patients who have not received the final report verbally at the facility or, if findings are negative, by telephone; (2) encourage notification of patients with abnormal studies; (3) require patient notification in lay terms only if the results are negative and notify referring physicians, including followup notes, when there are abnormal results; (4) send referring physicians lists of patients who had mammography at a facility with positive studies highlighted; (5) require notification of patients who request results after a specified time period has passed in order to allow communication between the patient and the referring physician and to prevent duplication and failure to inform; and (6) require that every patient receive a copy of her mammography report, if desired, or by default if her preference is not stated.

After reviewing and considering the hundreds of comments FDA received concerning patient notification, the agency concluded that these many comments all share the common goal of providing an effective mechanism for communicating mammography results to patients, but that the comments clearly advocate different approaches to achieving this goal. FDA agrees with consumer groups that written notification of mammographic results represents ''best practices'' in ensuring that each and every woman is clearly and effectively notified of the results of her mammogram. These ''best practices'' are outlined clearly in a series of recommendations published by AHCPR in Chapter 4 of the 1994 guidelines entitled, ''Quality Determinants of Mammography'' (Ref. 2). In these guidelines AHCPR strongly recommends that mammography facility personnel provide each patient with written notification of the results of her mammography examination either onsite or by mail. Studies cited by AHCPR have shown that direct communication with patients, which is in addition to written communication to health care providers, dramatically increases compliance with followup recommendations. However, FDA also recognizes that many in the health care community have strong reservations, for the many reasons cited above, about making written notification to all patients a Federal requirement. Finally, FDA notes that although the MQSA requires mammography facilities to notify patients' referring physicians, in writing, of the examination results, the statute requires those facilities to notify patients directly in writing, only in those instances where the patient has no referring physician. FDA believes that the best way to reconcile the many different points of view on this subject—and achieve the goal of effective patient notification consistent with the statute—is to issue a general rule requiring patient notification, together with a recommendation that facilities follow the AHCPR guidelines regarding written notifications to patients. The relevant portions of the AHCPR guidelines have been printed as an appendix to the preamble of this document for ease of reference.

Accordingly, the agency has revised the final rule to eliminate the requirement for written notification to every patient and has substituted a performance-based regulation that requires each facility to ensure that the results of each mammographic examination are communicated to the patient. Under the final rule, each facility will be responsible for establishing a system of notification, through its own efforts or in cooperation with third parties, that guarantees that patients are informed of the results of their examinations in a timely manner. The system must also ensure that women who do not have health care

providers receive written notification, along with the mammography medical report, no later than 30 days following an examination and that each facility communicate abnormal results as soon as possible.

As noted above, FDA continues to believe that written notification of mammographic results is the most reliable way to guarantee that each patient is notified of results and that any necessary followup will occur. Comments from consumer groups and breast cancer survivors about the importance of early and accurate communication to patients supports the public health need for systems that ensure patient notification. Written notification to a patient of results can permit that patient to make informed medical decisions at critical times. One cancer survivor informed the agency that having the actual results of an abnormal study in hand allowed her to pursue treatment options that saved her life. Furthermore, the agency disagrees with comments that assume all patients are notified of their mammographic results; many referring health care providers do not communicate results of mammograms to patients and the adage ''no news is good news'' still rings true for many patients. During the MQSA inspections, FDA has uncovered a handful of facilities that do not even issue written mammography reports to referring physicians. Accordingly, the agency is continuing to require each facility to establish systems that will ensure that patients are notified of the results of their mammograms.

FDA believes that high quality mammography extends from the production of high quality mammographic images to the communication of results to the patient. Ensuring that patients get their results is the responsibility of all participants in the mammography imaging chain: The patient, the facility, and the referring health care provider. The final regulations fully charge facilities to meet their responsibility.

At its January 1997 meeting, NMQAAC recommended that all facilities should not be required to provide written notification. While some concern was voiced about difficulties in directly notifying all patients who underwent diagnostic mammography, many members advised FDA to require some type of direct notification of all patients and that this notification be documented. Although the agency continues to support written notification to all patients as the optimum practice under most circumstances, the final regulation does not prescribe any particular form of notification. Comments from facilities and physicians indicate that facilities have devised a variety of systems of communication to notify patients of mammography results. These include verbal conversations at the time of the examination, telephone communication after the examination, cooperative arrangements with referring physicians who convey the results verbally to their own patients, and written communications that are either directly issued from the facility and convey results or instruct the referring physicians to issue these reports. The AHCPR guidelines recommending direct written communication to all patients also provided examples and suggestions about the other types of communication.

Under the final regulation, in the case where a facility decides to rely on a third party to communicate results (either written or verbally), there should be a documented agreement between the facility and the third party that establishes this cooperative responsibility. This documentation may be in the form of attestation by the third party or letters of agreement signed by the third party. In addition, the agency reserves the right during inspections to confirm not only the presence of such documentation, but also to ask for further documentation from the facility to verify that patients were indeed notified. Further documentation can include copies of referring physician medical records documenting that results were discussed or sent to the patient. These descriptions of systems and documentation are intended to be examples; others may also be acceptable. However, if third parties do not provide the mammography facility with further documentation when requested during inspections, the mammography facility is subject to regulatory enforcement action under the MQSA for failing to document that results were provided to patients. Thus, for facilities that choose to rely on third parties for communicating results, whether they be referring physicians or communication consultants or other parties, the facility still has ultimate responsibility to meet the patient notification requirements of the final regulations.

The agency also believes that the approach taken in the final regulation will address the concerns about communication and cost that were raised by so many of the comments. The flexibility that has been built into the final regulation will permit facilities to tailor notification systems to the particular needs of the general patient population and individual patients they serve. At the same time, requiring each facility to establish and document the existence and operation of such systems achieves the primary goal of ensuring that patients receive the results of their mammograms.

In addition, the agency notes that the requirement for reasonable attempts at immediate communication when results of an examination are ''suspicious'' or ''highly suggestive of malignancy'' has been retained in the final regulation. Potential delays in diagnosing and treating breast cancer are reduced with this requirement that facilities directly notify patients who have no health care provider of abnormal results as soon as possible. (The same requirement for immediate communication in the case of ''suspicious'' or ''highly suggestive of malignancy'' findings applies to the facility's communication with the referring physicians of those women who have identified health care providers). The agency concludes, therefore, that the most significant public health risk that may result from failure to communicate results is addressed in the final regulation.

The final regulation continues to require written notification by facilities to patients who do not have referring physicians, as specified in the MQSA. The statute also sets forth, and the regulation incorporates, the requirement that such self-referred patients receive a copy of the actual mammography report that would be prepared and sent to the referring physician, if there were one. In response to comments that questioned the agency's authority to require patient notification, FDA notes that the language of the MQSA is very explicit with respect to patient notification of test results and the form that notification must take in these particular circumstances (see 42 U.S.C. 263b(f)(1)(G)).

(Comment 411). Many comments urged FDA to require referring physicians to be responsible for the communication and followup of results of mammography examinations. FDA agrees that a physician with knowledge of a particular patient's entire medical history is often the best source of communication and followup of results. However, FDA's primary jurisdiction under the MQSA is related to mammography facilities and not individual practices of referring health care providers.

One comment suggested an arrangement whereby facilities and each provider of care enter into a written agreement that the referring physician assumes responsibility and liability for informing his or her patients of mammography results, and the mammography facility would be

allowed to breach this contract at any time when a patient requests the results in writing. FDA agrees that this arrangement would meet the requirements of the final regulations. However, if referring physicians fail to communicate results to patients despite their agreement to do so, the mammography facility is responsible under the MQSA for failing to ensure communication of results and is subject to regulatory action by FDA.

FDA intends to look for documentation during inspections to establish that patient notification systems are in place and operational. For example, if a verbal communication system is used to tell patients of results, this communication should be documented in the patient's medical record and should be capable of verification by the MQSA inspectors. If a facility sends letters to patients, records of that correspondence, or standard operating procedures describing this correspondence, must be available for inspection. In circumstances where a facility relies on referring physicians or other third parties to communicate results to patients, the facility must provide documentation of these arrangement and their implementation, as described above. In those cases where the mammography facility is the primary breast care provider for the patient, there must be documentation of results being conveyed to the patients. By allowing a variety of notification systems, the agency has attempted to ensure that communication of results will be accomplished effectively, but without undue burden on mammography practices or unnecessary increases in the cost of mammography services. Finally, the agency notes that the regulations being issued to require facilities to establish and maintain systems that ensure patient notification of results does not preclude any patient from requesting additional reports or records from the facility. Nothing in the record and report section of the MQSA should be construed to limit a patient's access to the patient's medical records (42 U.S.C. 263b(f)(1)).

(Comment 412). One comment stated that FDA's intention to inspect and monitor systems established by facilities to verify that patients receive notification of results in lay language is unrealistic and that facilities should not be required to establish such systems.

FDA disagrees. FDA has issued interim regulations, as required by the MQSA, that required notices in lay language to be issued, along with the actual report when patients do not have a referring health care provider (42 U.S.C. 263b(f)(1)(G)(ii)(IV)). This is a current requirement for all facilities and is already subject to inspection and verification.

(Comment 413). One comment stated that complex situations, such as when a mammogram is assessed as negative, but the patient has clinical findings, need careful explanation to patients so that the importance of the situation and recommendation for followup will be understood. This comment recommended that the mammography facility be responsible for patient care if it is accepting women who have no physicians.

FDA believes this practice standard is largely being adopted by the mammography community and supports this. Under the final regulations, each facility is required to maintain a system for referring patients to health care providers when clinical followup is recommended and the patient has no physician.

(Comment 414). One comment stated that followup reminder letters are critical and should be mandated.

FDA disagrees that these should be mandated. Rather, each practice should be allowed to determine if such letters or other forms of reminders are needed.

(Comment 415). One comment reflected confusion about the immediate followup call to patients required under § 900.12(c)(2), which is in addition to the notification requirements. Although notification is required for all patients under the system established by the facility to ensure such communication, FDA believes that special efforts at communication are required when there are abnormal results and the patient does not have a referring physician. In these cases, the facility is expected to contact the patient who has no health care provider as soon as possible and the 30-day timeframe for sending reports and long summaries is superseded. Under the final regulations, this immediate communication is required only in situations where the probability of cancer is high (mammograms assessed as ''suspicious'' or ''highly suggestive of malignancy''). In cases where such immediate notification is required, the facility remains obligated to also provide the necessary written notifications within 30 days as followup.

(Comment 416). One comment supported the requirement that, when an examination shows suspicious findings, a facility should directly communicate with a nonreferred patient. This provides patents the assurance that they will receive the care they need.

FDA agrees and the final regulations contain this requirement.

(Comment 417). One comment stated that, in cases where assessments are ''suspicious'' or ''highly suggestive of malignancy'' and results must be ''immediately'' communicated to the examinee or physician, FDA should define what ''immediately'' means. Another comment suggested ''immediately'' be defined as 24 hours.

FDA believes that the variety of circumstances that may arise when followup is required make a rigid definition of ''immediate'' unreasonable. Because there are circumstances when immediate communication is not possible, FDA has revised the requirement to communicate abnormal results from ''immediately'' to ''as soon as possible.'' Health care professionals understand the importance of accomplishing such notification when there are suspicious or highly suggestive findings. Although it is impossible to establish a precise timeframe, FDA expects such communication ordinarily can be accomplished within 48 to 72 hours and not later than a week following the examination.

(Comment 418). One comment stated that 30 days is an unreasonably long window in which to notify patients of results. Three other comments agreed with FDA that 30 days was reasonable. Another comment stated that reports and notification should not be sent out for at least 5 days in order to wait for outside comparison films; otherwise, addenda lay notification and reports would confuse patients and physicians. Another comment recommended that notification to patients should wait until all mammography imaging work up has been completed.

FDA believes that issuing medical reports to health care providers (or to patients with no health care providers along with lay summaries) within 30 days is a reasonable standard. This does not mean facilities must wait 30 days, as the first comment suggests, but rather that 30 days is the outside limit. FDA disagrees that notification of results should be delayed until the total imaging work-up is completed because situations arise when imaging work-ups can extend over more than 1 month. Therefore, FDA is requiring a report of the medical finding for each mammogram to be generated within 30 days. Under the final regulations, facilities must also ensure that patients have their results communicated to them within that time. Many facilities may notify patients or have other parties notify patients after written medical reports are provided to physicians; other facilities may choose to communicate

results to patients prior to the issuance of the medical report to the referring provider by means such as providing verbal results at the time of the mammography examination. As discussed above, a variety of systems will be acceptable as long as they ensure that results are communicated to patients and that communication is timely.

(Comment 419). Eight comments stated that patients without health care providers should not get the actual medical report along with the lay notification. These comments claimed that the terminology in the medical reports would confuse patients and either generate more inquiries or keep them from understanding that further studies are needed. They recommended instead, that patients can request the report be sent to a physician if further medical advice is desired. One comment also stated that, while it is critical to include the patient in the information loop for the results of her mammogram, it is poor medicine to send the patient who is self-referred the copy of the mammogram report that is intended for the physician.

FDA disagrees. The MQSA expressly requires facilities to provide patients without referring physicians both the medical report and the lay summary (42 U.S.C. 263b(f)(1)(G)(ii)). This requirement allows the patient to provide her mammography report immediately to a subsequent health care provider, if needed.

(Comment 420). Two comments asked what is meant by ''reasonable attempts'' to communicate results of suspicious studies to patients without referring physicians as soon as possible. The comments asked whether a certain number of phone calls or a registered letter would be acceptable.

FDA does not intend to mandate procedures for communication with patients in these circumstances because different methods are likely to be more or less effective with different facilities and patient populations. Telephone calls and registered mail are examples of attempts at communication that may work. Verification that contact has been made is the goal. Each facility can consult with its risk management director to establish procedures to convey results and document attempts at communication that are ''reasonable.'' FDA recommends that mammography facilities utilize the AHCPR's guidelines in ''Quality Determinants of Mammography'' that address the effective communication of mammography results to patients and follow those guidelines with respect to written notification to patients. That document includes excellent sample lay notices that facilities could adopt. As noted previously, information from Chapter 4 of these guidelines has been reprinted as an appendix to the preamble of this document for ease of reference.

d. *Communication of mammography results to health care providers (§ 900.12(c)(3))*

The final regulation requires each facility to provide the mammography report to a referring or named health provider within 30 days of the date of the examination. The regulation also requires a facility to make reasonable attempts to communicate with the health care provider or the provider's designee as soon as possible when an examination reveals suspicious results. These requirements paralleled those for communication of suspicious results to patients without identified health care providers.

(Comment 421). Five comments requested guidance in defining who is a responsible designee of the health care provider.

In response, the agency notes that when referring health care providers are not available, they ordinarily have responsible designees, such as medical coverage services or partners, to assume medical responsibilities for the unavailable provider's patients. These requirements parallel and complement those related to patient notification.

(Comment 422). Twenty-nine comments stated that 30 days is a reasonable time period for getting reports out (unless there are delays in obtaining comparison studies). Three comments asked FDA to define the timeframe required for ''immediately'' communicating the results of suspicious or highly suggestive mammograms to health care providers. One comment expressed concern that the requirement to attempt to communicate ''suspicious'' or ''highly suspicious of malignancy'' findings to health care providers immediately will impose an unmanageable burden on understaffed facilities.

FDA disagrees with this last comment but, as with the provision relating to communication with patients, the agency has changed the language from ''immediate'' to ''as soon as possible'' because immediate communication may not be possible given the variety of circumstances that may be associated with communication of suspicious results to a particular provider. FDA believes health professionals understand the urgency of the situation when a patient has a suspicious or highly suggestive mammogram and they are mandated to communicate this result to the referring health care provider in an attempt to expedite diagnosis or treatment. Again, although it is not realistic to mandate a rigid schedule, the agency expects that such communication ordinarily can occur within 48–72 hours, and not later than a week following the evaluation of the examination. NMQAAC discussed this section and supported the regulations as revised.

(Comment 423). One comment questioned the ability of physicians who read only twice a week to comply with the requirement to communicate with health care providers within the mandated timeframes. FDA believes timeframes and procedures are sufficiently flexible to balance the need to protect patient health with the realities of good mammography practices. Reading twice a week does not preclude a physician or the facility that employs that physician from complying with the requirements.

(Comment 424). Another comment recommended that radiological reports transmitted to the referring physician be acknowledged by electronic signature, which should be kept in the electronic file indefinitely. As stated previously, with respect to proof-reading reports and ''signing'' them out (for authentification or release), FDA assumes that facilities are able to devise their own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations at this time.

e. *Recordkeeping (§ 900.12(c)(4))*

FDA's final regulation implementing recordkeeping standards for facilities requires each facility to maintain films and reports at least 5 years or until the patient requests them or requests their transfer. If the film and report represent the only mammogram for that patient, the facility must retain them for 10 years or for any longer period of time that is required by State law or until the patient requests them or requests their transfer.

FDA received numerous comments supporting its proposal to require transfer of the original mammogram upon the request of the patient.

(Comment 425). Fourteen comments stated that original films should be transferred because copies are frequently poor quality and jeopardize successful followup. Four comments stated that the request for transfer should be in writing and that the regulation should state ''temporary or permanent transfer.''

FDA believes each facility should be free to establish its own procedures for transfer of films and may wish to consult its risk management director for

guidance. FDA agrees in part with the last comment and has modified the final regulation to clarify that a patient may request that the transfer of the original films be temporary or permanent. FDA will leave it to the facility to decide whether the request for transfer should be in writing or may take some other form. NMQAAC also supported the addition of this language to the final regulation.

The agency has also amended the language of the provision to clarify that a request for a transfer supersedes a facility's responsibility to maintain the films for a particular length of time and that the request may be made by an individual on behalf of the patient as, for example, might be necessary in cases where the patient is incapacitated or has a legal guardian.

(Comment 426). Two comments agreed that original mammograms should be sent for comparison to other facilities. However, these comments stated that FDA's suggestion in the preamble to the proposal that facilities make a copy is very difficult and expensive. Another comment stated that copying originals to retain in the record when transfer is requested should not be required because this would increase costs, would not be adequate for comparisons, and would delay sending films out in the timely manner.

In response to these comments, the agency notes that there are no requirements for facilities to make copies of films they are requested to transfer. If this suggestion to make and keep a copy of the mammograms is not practical or useful to a facility, it need not be followed.

(Comment 427). Three comments supported the transfer of original films, but would require their return within 30 days in cases of temporary transfer.

FDA does not intend to establish a time limit on transfer of films at the request of patients. Even in cases where the transfer is temporary, the originals may be used during clinical procedures that may not be completed in 30 days. However, FDA does support the return of films in a timely manner and expects facilities that transfer and receive films under such circumstances to cooperate in the interest of the patient's treatment.

(Comment 428). FDA also received many comments expressing concerns about original film transfers. Twenty-six comments stated that transferring original films is problematic because the films may be lost, their transfer may breach confidentiality, the originating institution will not be able to make comparisons, and patient may be denied access to films at a later date. One comment stated that FDA should clarify if the transfer of original films conflicts with State or locals laws and how facilities should proceed if that is the case. Four comments urged FDA to delete the proposal because the films themselves are historically the property of the physician or institution which generated them and their absence would disadvantage those physicians or institutions in defending against claims asserted against them. Fourteen comments asked if FDA will indemnify the radiologist for not having original films in the event of a malpractice action. One comment stated that there is no enforcement provision against those facilities who refuse to release original mammography studies on the grounds of ownership or the potential for legal action.

FDA understands that the transfer of original films has not been a universal practice among facilities and that physicians may have concerns about the consequences of loss or misplacement. Nevertheless, the agency has concluded that the overwhelming benefit to patients from access to original films by other facilities or physicians providing followup for patients justifies the need for this provision in the final rule.

All expert comments FDA received on this matter, including advice from NMQAAC, emphasized the value of having original films for comparison to subsequent studies or followup clinical procedures. There was general agreement that copies of mammograms could not adequately substitute for originals when difficult diagnoses or additional procedures were required, and that clinical decisions, such as whether to do surgery, require review of original films. The agency notes that even those practitioners who criticized the proposal agreed that the transfer of films was likely to enhance patient care. Those who objected did so on grounds that were unrelated to patient care, namely potential for liability and difficulty in defending malpractice actions.

FDA has not been persuaded that these concerns are insurmountable or that they are sufficient to override the public health benefits associated with the provision.

Many facilities do routinely transfer films upon the request of patients and have established procedures and systems to implement that process. Those procedures may include written requests from patients, release forms that establish transfer of responsibility for the films, and agreements with receiving institutions for subsequent return. In some cases, facilities that transfer films do make and retain copies for their own files; other facilities have determined that the expense of copying is not warranted. Loss of films will not be indemnified by FDA.

With respect to facility concerns about defense of malpractice claims, FDA notes that rules of evidence, including civil discovery, establish judicial procedures that are designed to protect each party's ability to develop its case. Judges have authority and discretion to craft remedies in situations where a patient has lost, withheld, or is resisting production or examination of a necessary original record.

FDA is not aware of any State laws that conflict with the requirement that original films be transferred upon the patient's request. State laws governing the management and retention of medical records appear to be silent about the transfer of original films. Rather, they are likely to state that patients are entitled to copies of their records or that doctors are required to maintain records. This was the case with the Florida and New York laws that were brought to the attention of the agency.

Were a State to enact a law that conflicts with this regulation or if, contrary to FDA's understanding, such laws currently do exist, those State laws would be preempted. The agency disagrees with comments that have inferred such laws would be permissible under the provision of the MQSA that allows States to establish more stringent requirements relating to mammography (42 U.S.C. 263b(m)). The public policy considerations underlying any State laws that would restrict a patient's access to original films and the quality data that may only be available from these original studies would not be related to the public health objectives of the MQSA. Accordingly, such State laws could not be characterized as more stringent than the MQSA or this regulation. The agency also notes that the records provision of the MQSA that is being implemented by this regulation explicitly states that nothing in that provision shall be construed to limit a patient's access to that patient's medical records (42 U.S.C. 263b(f)(1)(G)).

(Comment 429). One comment recommended that FDA add that, upon receipt of authorization to release mammography film, the mammography facility must forward the films to the requestor in a reasonable timeframe to minimize reporting delays. Another comment suggested that each facility be required to provide original films and copies of reports within 10 working days of receipt of a written request.

FDA does not believe it is necessary or useful to mandate the details of such transfers. The agency believes that each

facility will develop standard operating procedures to implement this standard and that those procedures will reflect the controls required by risk management and acceptable practice standards.

(Comment 430). Six comments suggested that the facility that took the most recent mammogram should maintain ownership of all the originals because this practice would make it easier to keep the films available for future comparisons. FDA's final regulations do not preclude this arrangement if the patient requests transfer of previous films to the current facility.

(Comment 431). Twenty-four comments asked who should bear the cost of copying films when the original is released. One comment stated that facilities should only be able to charge a nominal fee for transfer of films and reports. Another comment believed that the fees must be closely monitored; the comment noted that reports have been received in the past from facilities charging unreasonably high fees for sending reports and copies of mammography films. A third comment stated that FDA should develop fee guidelines for charges for copying film and postage to prevent some institutions from charging high fees.

FDA generally agrees with these comments and its final regulations limit charges to the documented cost of the transfer, so as to not deter patients from requesting transfers when necessary. The agency notes that nothing in the regulations requires facilities to charge fees for transfer of records. If copies are made as part of the facility's standard transfer process, then the cost of copies may be documented and included in the transfer fee charged by the facility.

(Comment 432). One comment asked if the fee can include a storage charge or is it for medical records transfer only.

The regulations clearly state that any fee is for services provided under § 900.12(c)(4)(ii), which is the transfer of films and reports.

(Comment 433). Twelve comments stated that the proposal that fees charged for transfer of films and records not exceed costs appears to be price controls, if not price fixing.

The agency does not agree that it has taken any action to establish prices. FDA is responding to complaints that fees charged for transfers of records have been unreasonable. This practice prevents consumers from making such transfers and obtaining medical care with the best quality medical data. The regulation does intend to control such charges in order to ensure access by patients to their films but the final rule does not require facilities to absorb additional expenses. Instead, each facility that decides to charge consumers for this service must limit its charges to documented costs.

(Comment 434). Nine comments stated that original mammograms should be provided by other facilities for comparison purposes free of charge as a courtesy among institutions.

FDA supports this process; the final regulations do not mandate a charge. However, if any fee is established, FDA's regulation requires that it not exceed costs of transfers of such records.

(Comment 435). Two comments suggested that FDA's regulations should consider future technology, which may include the electronic transfer of films.

FDA regulations are for screen-film and xeromammography. As other technology is approved for medical use, alternative standards under the MQSA will be issued.

(Comment 436). One comment asked if a facility must retain a series of mammography records for 10 years and discard them as each record is 10 years old, or discard them when the oldest record is 10 years old. FDA interprets the provision in the MQSA to mean that, if there is a series of mammograms for a patient, the oldest mammogram of the series can be 5 years old. If there is only one mammogram for a patient, it must be kept 10 years unless a transfer is requested. One comment stated that mammograms should be maintained for longer than 10 years if mandated by State or local law. In fact, the MQSA mandates this and FDA has written its regulations to conform to this provision.

(Comment 437). Two comments recommended that mammograms be kept indefinitely in order to spare a patient an unnecessary biopsy and another comment recommended that FDA establish a standard retention period of 5 to 7 years.

The final regulations do not preclude facilities from keeping mammograms longer than what is required by the statute as a minimum. However, the agency rejects the 5 to 7 year standard because the timeframes set forth in the regulation are prescribed by the statute.

(Comment 438). One comment recommended that FDA reinstate a HCFA requirement that previous mammograms be obtained for comparison with present films.

FDA believes that this is good medical practice, but it is not an appropriate focus for FDA regulations under the MQSA.

f. *Mammographic image identification (§ 900.12(c)(5))*

This provision describes the elements that must be included on any mammography film to identify the image. They are: patient identifier, date of examination, view, laterality, facility identification, technologist identification, cassette/screen identification, and unit identification, if the facility has more than one unit.

The NMQAAC advised FDA that these elements need to be present on all mammogram films to ensure proper patient care. FDA agrees. These are the same elements as those established by § 900.4(c)(2)(viii) to identify films submitted to accreditation bodies for clinical image review. Comments received from the public relating to these elements for film identification are addressed in that section of the preamble that discusses § 900.4(c)(2)(viii).

4. Quality Assurance—General (§ 900.12(d))

This paragraph was intended to identify the individuals responsible for the actions required by § 900.12(e) and (f), including those intended to ensure that safe radiation dose levels were used. With one or two exceptions, the requirements of this paragraph were included in the ACR quality assurance manuals that were made part of the interim regulations by reference. The ACR manuals are not referenced in the final regulations. However, certain significant aspects of those manuals, such as the requirements in this section, were incorporated into the proposal because there is broad agreement that these principles are basic to a good quality assurance program.

a. *General comments on quality assurance*

(Comment 439). Two comments stated that all facilities should follow the same set of universal guidelines to maintain the same quality of results.

FDA notes that the MQSA and the implementing regulations are designed to require that facilities meet universal minimum standards. Nothing in the statute or regulations is intended to prevent a facility from applying additional, more stringent standards or procedures that strengthen QC at that facility.

(Comment 440). One comment stated that FDA should eliminate this entire paragraph except for a single provision that would require each facility to have a quality assurance manual and to verify, through the signature of a responsible official, that the manual is followed.

FDA does not believe that the general requirement suggested by the comment would effectively establish minimum levels of quality assurance at all facilities.

b. *Responsible individuals (§ 900.12(d)(1))*

This paragraph identified the responsibilities of the individuals associated with the quality assurance program.

(Comment 441). Two comments recommended that FDA be more specific about what responsibilities should be listed and to whom they should be assigned.

FDA does not believe that additional detail will be useful in these provisions. Greater specificity would limit the facility's flexibility to design a quality assurance program that best meets its individual needs and to quickly change its program in response to changes in circumstances or technology.

(Comment 442). One comment expressed the author's disappointment that this section and the rest of the regulations failed to allot any responsibility to administrators and Chief Executive Officers (CEO's), who have the authority to make the decisions that control quality but seem to be more motivated by financial concerns.

FDA agrees that administrators, CEO's, owners, and operators of facilities share responsibility for the quality of mammography at their facilities. However, individuals working more directly in and with the mammography facility on a daily basis often are better able to determine when quality problems exist and how to correct them. The agency recognizes that it is sometimes difficult for the staff to obtain the administrator's support for necessary actions. Nevertheless, if necessary actions are not taken to correct quality assurance defects, the result could be sanctions against the facility by FDA. Because such sanctions can affect the reputation and profitability of any facility, FDA believes that administrators and CEO's will cooperate to support actions to improve or maintain mammography quality.

c. *Lead interpreting physician (§ 900.12(d)(1)(i))*

This provision requires facilities to identify a lead interpreting physician to have the general responsibility for ensuring that the quality assurance requirements of § 900.12(d) through (f) are met. This is a change from the interim regulations, which assigned this responsibility to a mammography medical physicist. This change drew a number of almost evenly divided comments.

(Comment 443). Eleven comments plus NMQAAC supported the change. Various comments pointed out that the medical physicist often does not have the authority to implement needed actions, especially if he or she is a contract physicist who is rarely at the facility, and the medical physicist usually does not have the expertise to deal with nonequipment issues. One comment noted that Massachusetts' regulations have a similar provision to the proposal and it had been found to improve the quality assurance programs.

Eleven other comments opposed the change. Some of these comments stated the belief that interpreting physicians did not have sufficient knowledge of or interest in quality assurance to properly handle this responsibility. Others said that, in modern medicine, the physicians also lack authority to implement necessary changes and pointed out that interpreting physicians may also be contract employees and not actually at the facility. A related comment warned that, if the interpreting physician is to be given responsibility for oversight, he or she must also have authority to institute necessary changes. One comment stated that while it is important to have an interpreting physician in this role, it is more important to assign this responsibility to someone at the facility, even if it means involving a nonphysician. Another comment questioned the basis for designating a lead interpreting physician if he or she can assign their responsibilities to other people. Two comments suggested that wording be changed to allow each individual facility to decide who would be most appropriate for this responsibility. Finally, one comment stated that the MQSA specifically said that the medical physicist was to have responsibility for the quality assurance program.

After considering all these comments, FDA has decided to leave this responsibility in the hands of an interpreting physician, as proposed. Because the interpreting physician is the final arbiter of the quality of a mammogram, it is logical that the responsibility for the quality assurance program rest with an interpreting physician. The agency recognizes that interpreting physicians in some facilities face the same limitations on their authority as medical physicists. However, FDA believes that an interpreting physician is more likely to have adequate authority, or the ability to influence those that do, than a medical physicist. The agency also recognizes that the interpreting physicians may not be located at the facility itself. Even in those circumstances, interpreting physicians have more regular interaction with the facility through their mammography interpretations than do contract medical physicists conducting annual surveys. Again, the agency realizes that interpreting physicians may not have the knowledge to carry out all aspects of the program themselves, but notes that this is likely to be true of any other individual in this position. For this reason, the final regulations do not require the lead interpreting physician to perform all of the duties personally, but rather to see that they are carried out in such a way as to meet the requirements. The basic responsibility remains with the interpreting physician, even if some or all individual duties are delegated to people with specific training to carry them out. Contrary to the opinion expressed in one comment, identifying a lead interpreting physician is valuable because it assigns this basic responsibility and establishes accountability even when tasks are delegated.

Many important duties will be delegated to the medical physicist. FDA is aware, as one comment noted, of the MQSA provision that requires the medical physicist to ''survey mammography equipment and oversee quality assurance practices at each facility'' (42 U.S.C. 263b(f)(1)(F)). As noted above, the interim regulations did assign to the medical physicist the overall responsibility for quality assurance. FDA's experience under the interim regulations, however, established that the interpreting physician, who ordinarily has more interaction with the facility and is more likely to be onsite, also has an important role in the oversight of quality assurance. As discussed, members of NMQAAC and public comments pointed out problems with the medical physicist having the primary responsibility for all quality assurance at the facility. After evaluating its experience and the comments, the agency proposed, and now intends, to shift overall responsibility for the quality assurance program to the lead interpreting physician. The medical physicist will continue to do the annual survey and oversee quality assurance practices, especially those related to the equipment, as required by the MQSA and the agency expects that the physicist's expertise will inform all final decisions that are made on quality assurance issues. The final regulation, however, requires additional oversight through the lead interpreting physician. FDA believes this change from the interim regulations is in accordance with its general authority to require the facility to establish an effective quality assurance program (42 U.S.C. 263b(f)(1)(A)).

Section 900.12(d)(1)(i) requires the lead interpreting physician to determine whether individuals assigned to quality assurance responsibilities are qualified to carry them out. FDA agrees with the comment that urged that the lead interpreting physician also be given authority to make needed changes because effective quality assurance will require facilities to respond appropriately to situations that need improvement or correction. Internal administrative and budgetary decisions, however, are beyond FDA's authority and the agency cannot control the business and management relationships that will affect any lead interpreting physician's ability to institute change.

d. *Interpreting physicians (§ 900.12(d)(1)(ii))*

This paragraph was intended to emphasize the role that all interpreting physicians should play in establishing and maintaining quality mammography at a facility. As previously mentioned, the interpreting physicians are the final arbiters of the quality of mammography images. It is important that they communicate their satisfaction or dissatisfaction with the quality of the images they are provided to interpret to the technologists who produced them. Such communication is the crucial first step in the identification of problems and the initiation of corrective actions. FDA is aware that this communication has not always occurred in the past, especially if the interpreting physicians are not located at the facility. Media investigations and many anecdotal accounts have illustrated this failure in communication.

None of the 17 comments on this provision disagreed with the basic premise that interpreting physicians should provide feedback to facility staff producing the mammograms. However, there were some misunderstandings as to just what was required.

(Comment 444). In particular, 13 comments mistakingly assumed that each interpreting physician was required to contact every technologist about the quality of each film taken. These comments requested that the requirement be limited to reporting technically inadequate mammograms to the QC technologist. Another comment pronounced the requirement as excellent, but asked whether a report was required on the technologist's performance for every film or if a summary of each technologist's performance was sufficient. Another comment suggested that feedback be given to the lead interpreting physician or, in his or her absence, to the QC technologist. One comment requested that this provision be more specific, and another recommended that all interpreting physicians be required to have training in the technical aspects of mammography, quality assurance, and QC.

FDA drafted the proposed regulation to be general in order to give each facility the flexibility to design a feedback system that best fits its own situation. The agency believes this flexibility should be retained in the final regulations. In response to the comments, however, FDA has clarified that followup activities by interpreting physicians are required only when the image is of poor quality. FDA recommends, however, that positive feedback also be given when warranted because such feedback is an effective incentive for maintaining quality performance.

e. *Medical physicists (§ 900.12(d)(1)(iii))*

This paragraph summarizes the role of the medical physicist in establishing and maintaining quality mammography.

(Comment 445). Eleven of the comments received on this provision suggested various wording changes. Seven of these supported changes that would state that the physicist is to evaluate the equipment and to survey it. An eighth comment wanted to amend the language to give the medical physicist authority to take necessary steps to ensure quality in his or her area of responsibility. Two comments suggested changes that would limit the physicist's responsibilities to overseeing the equipment-related quality assurance practices. These comments further suggested limiting the physicist's review of the QC technologist's work to verifying that it is performed and not to include providing advice on tests or suggestions for corrective measures. Another comment, however, clearly disagreed with this point of view and stated that the medical physicists should be required to oversee the facility's entire quality assurance program.

FDA agrees that the physicist should be involved in equipment evaluation and the annual survey and notes that changes made elsewhere, in the survey definition and in § 900.12(e), will achieve this goal. FDA cannot require that the medical physicist be given authority to initiate changes at the facility to improve quality for the same reasons that it did not issue regulations giving the lead interpreting physician similar administrative and budgeting authority. The agency does agrees that the physicist's oversight responsibility should be focused primarily on the equipment-related areas. The definition of the position of lead interpreting physician in § 900.12(d)(1)(i), as discussed previously, should clarify that general overall responsibility rests with that physician while responsibility for equipment-related matters resides with the physicist. FDA does not agree with the suggestion that would limit the medical physicist's role in the oversight of the QC program to merely verifying that the technologist's work was done. The agency believes that, as the equipment and imaging physics expert, the physicist's role must be more active and that ensuring an adequate QC program clearly should be part of the medical physicist's duties. The medical physicist should not stop with verifying that the QC tests were performed but should also ensure that they were performed properly, that the results were analyzed, and that any problems detected by the analysis were corrected.

(Comment 446). A final comment on this paragraph suggested that a new intermediate position be created at a level between the QC technologist and the physicist. The comment recommended that the person in this position could do tests that do not require a physicist but are beyond a technologist's training, and noted that such a position has been quite useful in the respondent's facility.

Provisions of § 900.12(e) require that surveys and mammography equipment evaluations be performed by medical physicists. Under the interim or final regulations, a facility is free to create an intermediate position for personnel to perform other testing during the time periods between the surveys and evaluations, including performance of the tests normally done during surveys. However, the agency does not have sufficient evidence to demonstrate that it would be beneficial to make this a general requirement and believes each facility is in the best position to decide whether such a position would be of value in its situation.

f. *QC technologist (§ 900.12(d)(1)(iv))*

This provision describes the QC technologist's responsibility to perform all quality assurance duties not assigned to the lead interpreting physician or the mammography medical physicist. The main issue raised by the comments on this provision was about the qualifications of the individual holding this position.

(Comment 447). Eighteen comments expressed the opinion that the person doing these tests should be a radiologic technologist who meets all of the requirements necessary to perform mammography examinations. Seven additional comments stated that the QC technologist should be a technologist but, to increase flexibility for the

facility, should not necessarily have to be qualified to do mammography examinations. One of these seven recommended that the QC technologist should have some training in mammography. Ten comments argued that the individual performing at least some of the tests did not even have to be a technologist, as long as that person had training in the test performance. Some of these pointed out that requiring a technologist to do the tests would increase facility costs without an equivalent increase in the quality of mammography.

After considering the comments, FDA has revised the proposal to permit nontechnologists to perform tasks for which they were trained, as long as their work is supervised by a QC technologist who meets the requirements to do mammography examinations. FDA believes this change strikes the proper balance between the need for expert oversight and the need to reduce unnecessary costs for facilities.

NMQAAC discussed this issue at several meetings and, at different times, expressed varying points of view. However, after its own review of the public comments, NMQAAC supported the approach FDA has taken in the final rule.

(Comment 448). Twelve comments suggested changes, primarily to allow or prohibit the facility from having more than one QC technologist.

FDA agrees that there are advantages to the consistency that can be achieved if there is only one QC technologist. The agency also recognizes that the facility may find it useful and necessary to have more than one QC technologist, e.g., to ensure coverage when one QC technologist is ill or on leave. The agency notes that facilities also have the option of having the lead interpreting physician or medical physicist fill in for the QC technologist, assuming they have the necessary qualifications, by temporarily ''reassigning'' the technologist's duties.

(Comment 449). Another comment suggested that the QC technologist should report directly to the lead interpreting physician rather than to the medical physicist.

FDA notes that the regulations permit the facility to decide for itself what lines of communication to the lead interpreting physician should be established. The agency believes that this flexibility should be retained.

(Comment 450). Another comment suggested that all mammographers should be trained in all QC tests and procedures.

From the context of the comment, it was clear that the author was using the term ''mammographer'' to refer to technologists doing mammography, and not, as is becoming increasingly common, to interpreting physicians interpreting mammography. Section 900.12(a)(2)(ii)(A) does require such training as part of initial training for technologists who will begin performing mammography after the final regulations become effective. Training in these areas could also be used to fulfill initial requirements under the interim regulations, so many technologists presently doing mammography will have had this training. Although FDA encourages all radiologic technologists currently practicing to include such training as part of their continuing education, the agency does not believe that the benefits of retroactively requiring all present technologists to receive this training would outweigh the costs.

(Comment 451). A final comment suggested that adequate time should be allotted for the quality assurance/QC duties.

FDA fully agrees with this comment but does not believe that this kind of commitment can be codified through a regulation. The agency also notes that the amount of time needed will vary significantly, in view of the different situations in different facilities and the differing abilities of the individual QC technologists. As discussed in connection with earlier sections, FDA believes that owners, operators, and managers will have new incentives to ensure that quality assurance programs are properly implemented and that these programs meet the Federal standards with which all facilities must comply.

g. *Quality assurance records (§ 900.12(d)(2))*

The provisions of this paragraph have been significantly changed from the proposal. The proposal required that the facility have a quality assurance manual covering the procedures to be used in meeting the requirements of § 900.12(e) and (f). The manual was to be readily available to all staff members and documentation that it was read and approved by the lead interpreting physician and the medical physicist was required. A list of individuals assigned quality assurance responsibilities and details of their assignments was also to be available to all staff members. Records were to be kept showing that these individuals were qualified for their assigned duties. Records were also to be kept showing the data obtained during monitoring of the facility 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. The records were to be kept for each test for a minimum of 1 year or until the test had been performed two additional times at the required frequency, whichever was longer.

In response to comments received, as summarized below, and in keeping with the FDA's goal of less prescriptive and more flexible regulations, this paragraph has been greatly simplified. The final regulations do not require any description of the procedures to be followed in performing the QC tests or a list of the individuals with quality assurance responsibilities and their responsibilities. The proposal requiring records documenting the qualifications of these individuals to perform their duties is changed to simply require that records be kept concerning employee qualifications. No review, revision, or sign-off of the manual is required at any frequency but there is a general requirement that the lead interpreting physician, a QC technologist, and a medical physicist are to ensure that records are maintained and updated. The time that the records of testing and followup actions must be kept has been clarified but remains essentially the same.

The proposal divided the provisions of § 900.12(d)(2) into four paragraphs, (i) through (iv). As a result of these changes, paragraphs are no longer needed but the comments received on the proposed four paragraphs will be discussed, following the general comments.

h. *General comments on quality assurance records*

(Comment 452). One comment asserted that keeping quality assurance records was an unnecessary burden but did not suggest an alternative means by which a facility could demonstrate that it had carried out the quality assurance tests and all necessary followup activities. A second comment recommended that mammography facilities be required to retain written specifications in a standardized format from the processor manufacturer.

FDA cannot accept the first of these comments without an adequate alternative to keeping records. FDA agrees there would be value in processor manufacturers providing specifications in a standardized format but believes it would be premature to make this a requirement. The agency's previous attempts to encourage the provision of processor operating characteristics for different types of film showed that there are significant problems to be solved, among them the very large number of

possible combinations of film, chemistry, and processors.

i. *Records to be kept (proposed § 900.12(d)(2)(i), (ii), and (iii))*

(Comment 453). A few comments were received on the records to be kept. Three comments opposed the change from requiring the use of the ACR manual to allowing the use of whatever manual best fits the facility's needs.

FDA believes that the increased flexibility provided by allowing the use of manuals other than the ACR manuals is desirable because it permits facilities to more rapidly adjust their programs to incorporate improvements in quality assurance procedures or new techniques for new technology. When a manual is specified in regulations, the regulations may have to be amended to facilitate use of even a new edition of that manual, let alone an improved manual from another source. To increase flexibility even further, in the final rule FDA has dropped the use of the word ''manual'' altogether because it seemed to imply a certain format. Facilities will now be able to keep the required records in any suitable format.

(Comment 454). A number of comments recommended addition of items to the list of those required to be kept. Six comments suggested adding technique charts to the required records, while a seventh suggested adding documents related to the medical outcomes audit program. Another comment stated that documentation for darkroom cleaning, screens, and view boxes should not be eliminated.

NMQAAC members pointed out that there was already a requirement in the ACR manuals, which were incorporated into the interim regulations by reference, that a technique chart be available. Although there was some difference of opinion, NMQAAC seemed to support retaining a requirement for keeping a technique chart with the equipment but not necessarily in the manual. With respect to the quality assurance manual in general, the view of NMQAAC seemed to be that elements required in the final regulations were ''key'' or ''basic'' to the success of a quality assurance program. At least one NMQAAC member expressed reservations about the detail required and would have preferred to limit the regulation to a general requirement that there be a quality assurance manual. However, both this member and a second member recognized that enforcement by inspectors would be difficult without more detailed requirements.

FDA notes that documentation of facility cleanliness activities is required in § 900.12(e)(11). The list of other records that must be kept, although not necessarily in a ''manual,'' has been revised as discussed previously.

(Comment 455). Other issues that drew a number of comments were who should sign off on the manual and how often should review, revision, and sign-off take place. Nine comments supported having the QC technologist sign-off in addition to the lead interpreting physician and mammography medical physicist. A tenth comment would limit the physicist sign-off to only those items related to his or her responsibility. Three comments stated that the review, revision, and sign-off should occur at least annually. NMQAAC supported both adding the QC technologist to the sign-off list and the annual review, revision, and sign-off.

FDA has replaced the requirement for a formal sign-off with a general statement that the lead interpreting physician, QC technologist, and medical physician should ensure that the specified records are kept.

(Comment 456). Another comment stated that qualifications of the individuals assigned responsibilities in the QC program should be kept on record only if those individuals are not listed in the facility's application (presumably for accreditation).

FDA disagrees with this comment. The accreditation bodies do not check the qualifications of personnel to perform quality assurance tasks during the accreditation process.

Proposed § 900.12(d)(2)(ii), which required that a list be kept of the individuals with quality assurance assignments and their assignments, drew only one comment. The comment supported the list but urged that the requirement be clarified so it was not construed to mean that only the listed individuals could carry out the duties. As discussed above, FDA has eliminated this proposed requirement.

The only comment on the proposal for keeping records of qualifications of quality assurance personnel, § 900.12(d)(2)(iii), suggested that those records should be kept indefinitely. As discussed above, FDA has reworded the requirement slightly. Requirements for record retention are discussed below.

j. *Monitoring performance (proposed § 900.12(d)(2)(iv))*

As proposed, this provision would have required facilities to maintain records related to monitoring of their facility's performance for 1 year or until the tests has been performed two additional times at the required frequency, whichever was longer.

(Comment 457). One comment stated that the words ''for a minimum of 1 year'' should be replaced with ''from inspection-to-inspection'' because inspections may not occur precisely at annual intervals. FDA has changed the wording to ''until the next annual inspection has been completed and FDA has determined the facility is in compliance with the quality assurance requirements.'' This change addresses concerns raised by this comment and clarifies that an inspection includes the followup and the actual visit to the facility.

5. *Quality Assurance—Equipment (§ 900.12(e))*

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. In order to achieve this objective, the performance parameters of the equipment must be tested at appropriate frequencies, the test results must be analyzed promptly to determine if the performance of the equipment is satisfactory, and any identified problem must be corrected as soon as possible. Followup tests must also be conducted to determine whether the corrective actions were effective and adequate. Requirements for the types of equipment tests to be performed and for the necessary followup actions were proposed in § 900.12(e). These requirements have generally been retained in the final rule. However, on the basis of a number of valuable comments the agency received in response to its proposals, some revisions to the proposal have been made. Many of the revisions have been made after discussions with NMQAAC. In addition, tests for radiation output and decompression have been added to the annual QC tests as § 900.12(e)(5)(x) and (xi). The action limits for these tests were proposed as equipment specifications in § 900.12(b).

a. *General comments on equipment quality assurance*

In the preamble to the proposal (61 FR 14912), FDA specifically requested comments on the value of a simple daily total system test based upon the evaluation of the optical density and artifacts on an image of a uniform phantom. The agency believed that the total system test, when performed in conjunction with the processor performance test set forth in § 900.12(e)(1), would ensure the overall quality of X-ray machine and processor performance and of the films produced. This test would only takes a few minutes to perform and records of the test would enable a medical physicist to

quickly detect the source of a problem when it occurs.

(Comment 458). A large number of comments opposed the idea of such a test. Several of these comments, however, confused this test with the alternative phantom testing identified earlier as a possible basis for performance-based standards (See 61 FR 14860). Some members of NMQAAC also opposed this test. The agency also received a number of comments supporting this test. Several comments agreed that more frequent phantom testing in conjunction with daily processor testing is important.

In view of the mixed comments, FDA concluded that it should not require the test until it gathers additional data on its usefulness. However, FDA strongly encourages facilities to test their machines as frequently as possible, either by a phantom evaluation or by the total system test.

A number of comments requested that FDA provide a detailed description of all QC test procedures. Several comments wanted FDA to reference ACR QC manual, while some comments considered the proposed Quality Assurance-Equipment requirements to be appropriate.

FDA notes that § 900.12(e)(1) through (e)(5) lists the minimum performance tests to be conducted on screen-film systems and their required frequency. Action limits for the tests are also specified. The agency has refrained from providing extensive detailed requirements or prescriptive descriptions of test procedures, as some comments recommended, in order to provide facilities with the flexibility to use their own judgment as to what testing methods best enable them to meet the required criteria. FDA has also decided not to base its QC requirements on a single manual and, therefore, no such manual has been referenced. In addition, NMQAAC has advised FDA that the ACR manuals were intended to be used as guidelines, not in a prescriptive manner. A facility may consult any appropriate manual on agency guidance to meet the requirements in § 900.12(e)(1) through (e)(5).

(Comment 459). One comment stated that some of the tests should be more rigorous. The comment further questioned why a monthly visual checklist was not included.

While conducting regular visual checks of the equipment is a desirable practice, it is not an action that can be confirmed from test data. Therefore, the agency has decided to encourage this and similar desirable practices through educational means instead of making them regulatory requirements.

(Comment 460). Another comment stated that FDA should only issue more stringent requirements if their benefits clearly exceed their costs.

FDA agrees with this comment and believes that the tests it has required meet this criterion.

(Comment 461). One comment stated that numerous paragraphs refer to films, optical densities, and processors, without limiting the requirements to any specific modality.

FDA notes that the initial words in each paragraph from § 900.12(e)(1) to (e)(5) are ''Facilities with screen-films shall * * *,'' making it clear what modality is referred to.

(Comment 462). Another comment maintained that FDA should require proper QC tests for stereotactic units. One comment stated that the quality assurance standards should include a requirement to use a digital mammography evaluation phantom developed by the author's company that has been designed specifically for QC of digital machines for stereotactic biopsy.

Interventional mammography is presently exempt from the MQSA requirements for reasons discussed in response to the comments on the definition of mammography in § 900.2(y). The agency is in the process of developing quality standards for interventional mammography and these will include QC tests. QC tests for other mammographic modalities have been addressed in § 900.12(e)(6).

(Comment 463). Another comment stated that FDA should provide its inspectors with more latitude to accept variations from regular inspection procedures, if the physicist can adequately explain the rationale for the deviations and demonstrate how the standard is met. From the context, the agency assumes that the author of the comment is actually referring to survey procedures rather than inspection procedures.

FDA has instructed inspectors to discuss variations with QC personnel or medical physicists available in the facility during inspection. In some cases, the inspectors, after receiving satisfactory explanations for variances in test procedures, have refrained from giving citations or withdrawn citations initially given to the facility during inspection. However, because it is essential that the evaluations of facility conformance with the quality standards be consistent nationwide, the latitude provided to inspectors necessarily has to be limited. Moreover, those wishing to use alternatives to the requirements of the regulations who can demonstrate that their alternative provides assurance of quality mammography equal to the regulatory requirement, may do so in accordance with § 900.18.

(Comment 464). A few comments urged FDA to require testing with all cassettes wherever that is appropriate.

In the proposed regulations, the agency proposed that screen speed uniformity of all cassettes in the facility be tested. In the final regulations, FDA added that artifact evaluations should be performed with all cassettes in the facility. The agency also considered requiring performance of the phantom image quality test with all sizes of image receptors. However, when FDA staff members carried out phantom image evaluations using two different image receptor and cassette sizes with five different mammography machines, no difference was seen in the phantom image scores when results with larger image receptors were compared to those with smaller. NMQAAC strongly advided FDA not to require weekly phantom testing for all image receptor sizes because the members do not believe that phantom image quality is affected by receptor size. NMQAAC pointed out that the ACR manual did not recommend phantom image evaluation with large image receptor sizes. Based on all this information, the agency concluded that facilities should not be required to conduct phantom image quality tests with all available sizes of image receptors.

b. *Daily QC tests—screen-film system (§ 900.12(e)(1))*

The only daily tests required under the final regulations are those that ensure adequate processor performance by assessing base plus fog density, mid density, and density difference, using mammography films used clinically at the facility.

(Comment 465). Five comments stated that there should be a maximum limit between time of exposure and time of processing. NMQAAC discussed this issue in connection with requirements for mobile units, for which image degradation due to delayed processing is a particular concern. The committee concluded that, in general, this was not a significant enough problem to require a regulatory requirement and FDA accepted this position.

(Comment 466). Ten comments suggested the word ''examinations'' should be replaced with ''films'' and the word ''performed'' with ''processed.'' The agency agrees with these comments and has made such changes in the final regulations.

One comment suggested adding the words ''and evaluate'' after ''shall perform.''

FDA notes that § 900.12(e)(8) generally defines tests for which the evaluation of test results (and corrective actions) must be performed before further examinations are conducted. The processor tests are among them.

(Comment 467). Several comments suggested that the last few words in § 900.12(e)(8)(ii), ''of no less * * * 1.2 OD, [optical density]'' should be deleted. These comments stated that in some cases, the step averages may turn out to be lower, for example 1.05, and that should be acceptable if the next higher step shows a substantially higher OD, such as 1.4. Another comment offered a similar argument, noting that the proposed rules would not allow the use of modern high gradient mammography films where the change in optical density between adjacent steps in this density range can be as high as 0.7.

FDA agrees with these comments and has deleted ''of no less * * * 1.2 OD'' in § 900.12(e)(8)(ii).

(Comment 468). One comment stated that QC measures should be in place for densitometry and sensitometry equipment.

FDA requires all sensitometers and densitometers its inspectors use to be properly calibrated. If FDA inspectors detect problems in the processor performance, the facility will have to identify the cause. If the cause turns out to be related to inadequate performance of the facility's sensitometry or densitometry equipment, the effort required to determine the nature of the problem will give the facility sufficient incentive to take actions to avoid a recurrence without the need for a regulatory requirement.

(Comment 469). Three comments asserted that the ± 0.15 OD action limits for mid-density and density difference were too restrictive as proposed and requested changing this limit to allow a wider range.

Under the interim regulations, facilities have been required to comply with this limit and the inspection data reveal that most facilities are able to do so. The agency does not find that there is adequate reason for changing this limit in the final regulation.

(Comment 470). One comment stated that a guidance document should be published to provide a clear explanation of the scientific basis for establishing an H&D curve and the importance of parameters taken from this curve to monitor trends in processor QC.

FDA believes that this is a widely accepted practice and the most effective procedure that is currently available. Sufficient materials providing the type of guidance requested already exist.

c. *Weekly QC tests—screen-film system (§ 900.12(e)(2))*

In the proposal, the image quality test using a phantom approved by FDA, which was required monthly by the interim regulations, was made a weekly test.

(Comment 471). Twenty comments opposed changing the phantom testing from monthly to weekly, arguing that the additional cost of performing phantom image evaluation weekly would be burdensome to many facilities. However, a larger number of comments supported this change, many indicating that their facility already performs phantom tests weekly.

FDA is convinced by the experience of the facilities that have been performing phantom image evaluation at a higher frequency that the test should be performed weekly. The agency believes that the benefit outweighs a slight increase in costs. As noted in the preamble to the proposal, if the daily total system test had been required, returning the required frequency of the image quality test to monthly could have been justified. However, because FDA is not mandating the total system test at this time, it is essential that all facilities perform weekly phantom image evaluation as an overall assessment of all aspects of the imaging chain.

(Comment 472). Some comments suggested changing ''image contrast'' to ''density difference'' and ''assess density difference'' to ''assess image contrast'' in § 900.12(e)(2)(iv).

The agency agrees with these comments and has revised the wording.

(Comment 473). One comment stated that the density difference between the background and the test object needs to be defined. The comment further stated that there is presently confusion over the ACR recommendation for a density difference of 0.40 at 28 kVp.

FDA notes that, with the changes made as suggested by the previous comments, it is clear that the density difference is measured between the background and a test object added to the phantom to assess the image contrast. The agency has determined that the regulations should not specify a number for the operating level for this density difference, specify the test objects, or prescribe any technique factors to achieve the desired operating level, because all these variables may change with future changes in technology. However, FDA considers it important that facilities make sure that the measured density does not vary by more than ± 0.05 from the established operating level.

(Comment 474). Several comments considered the requirement of a minimum 1.20 optical density (OD) at the center of a phantom image to be high and believed that many facilities will not be able to meet that standard. One comment stated that higher OD is achieved at the expense of patient dose. Some comments considered 1.20 OD too low. One comment recommended that there be an upper limit of OD. Another comment stated that OD within ± 0.20 is reasonable if the film manufacturer's tolerance is better than 0.3 OD from batch to batch.

FDA believes that proper OD is vital to the early detection of micro calcifications and, with the advent of new mammography screen-film systems, an OD of 1.2 with a variation of no more than 15 percent can be achieved if the processors and the units perform properly. NMQAAC also advised FDA to require that the film OD at the center of the phantom image be no less than 1.2 for the purposes of this test. The agency, however, believes that a requirement for an upper limit on OD may hinder any future development of mammography screen-film systems. Therefore, the agency will retain § 900.12(e)(2)(i) and (ii) as proposed.

(Comment 475). One comment stated that the point of the image quality test is to determine constancy; therefore, it was unnecessary to mandate the measuring position of optical density as the center of the image, as long as the same location is measured each time.

The intention of this requirement is that the OD be measured at the same location of the phantom image each time, as the comment suggested. The agency believes that the center of the phantom image is a reasonable and easy place to locate such measurements. Further, it is not advisable to measure OD too far away from the center towards the anode side of the phantom image in order to avoid a decrease in density due to the heel effect. This could lead to a failure to meet the ≥ 1.2 OD requirement when it might have been met if measured at the center of the same phantom image.

(Comment 476). One comment recommended that § 900.12(e)(2)(iv), the phantom image contrast requirement, be deleted because daily film sensitometry already measures this parameter.

FDA disagrees. The daily sensitometry test only uses light that simulates the screen phosphor luminescence. However, emitted light due to X-ray induced fluorescence from the screen phosphors is different both in spectral dependance and in intensity from the light output from the currently available sensitometry equipment. It is

very important that contrast is evaluated when the film is exposed by the emitted light from the actual screen phosphors, induced by the X-ray beam. For this reason, the daily film sensitometry test cannot replace this test of image contrast.

(Comment 477). Several comments noted that the current phantoms are not tissue equivalent and recommended that FDA specify only one type of phantom and minimum acceptable performance criteria. A related comment urged FDA to provide guidance to establish the adequacy of image quality. Another comment requested specification of the test object and measurement conditions for phantom evaluation.

FDA has refrained from specifying phantom or test object type, performance criteria, or scoring methodology in order not to inhibit future advances in phantom technology. 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 specification and performance requirements, which will have to be substantially the same among the different accreditation bodies.

d. *Quarterly QC tests (§ 900.12(e)(3))*

Two QC tests were required to be performed quarterly in the proposal. These were a test of the fixer retention in film and the repeat analysis.

e. *Fixer retention in film (§ 900.12(e)(3)(i))*

This test determines the quantity of residual fixer in processed film, which is an indicator of insufficient washing. Insufficient washing may have a considerable adverse effect on image quality.

(Comment 478). One comment believed that the fixer retention test should be a semiannual test.

FDA notes that quarterly performance was recommended by the ACR manuals and required under the interim regulations. The agency believes that it is generally accepted that facilities should perform this test quarterly and has retained the frequency requirement of this test as proposed.

f. *Repeat analysis (§ 900.12(e)(3)(ii))*

Facilities must perform this test quarterly with repeated and rejected films. If the repeat or reject rate, calculated as a percentage of the total films included in the analysis, changes by more than 2 percentage points from the rate determined the previous quarter, the cause of the change must be identified. (For example, if the repeat rate the previous quarter was 4 percent and this quarter it is 7 percent, the cause of the change must be identified. If the repeat rate this quarter is 6 percent, no further action is needed.)

(Comment 479). A few comments suggested changing ''repeat'' to ''reject.'' One comment stated that it might be more appropriate to simply refer to repeat rate change, rather than repeat or reject rate change.

FDA believes that while the repeat rate is perhaps the better indicator of unnecessary radiation exposure in the facility, the reject rate gives a better picture of the image quality situation. Both rates give useful information and should be calculated.

(Comment 480). Some comments recommended that FDA define repeat and reject to ensure that all but nonclinical films are analyzed. Several comments requested FDA to clarify that films repeated to correct positioning should be included in the repeat analysis. FDA believes that it is current practice that all repeated films are included in the repeat analysis, regardless of the cause of such repeats, and so a regulation mandating this practice is not needed.

Other comments expressed opinions on the most desirable frequency of the repeat analysis. One comment suggested that all repeats be evaluated and corrective action be taken when possible. Several comments recommended monthly repeat analysis and stated that this test would be less useful if it were done quarterly. Another comment urged monthly repeat analysis with 400 films. Another stated that the current method of repeat analysis every 3 months was sufficient.

FDA believes that low volume facilities would not have sufficient numbers to conduct a meaningful analysis if the required frequency is increased. Similarly, if the minimum number of films is set too high, the time period required to collect them in a low volume facility will be so great that problems could go undetected for a significant period of time. FDA, therefore, has left the required frequency as quarterly and has not specified a minimum number of films to be included in the analysis. The agency notes that nothing in the regulations would preclude a high volume facility from performing the analysis at an increased frequency and with as many films as it wished.

(Comment 481). Several comments urged FDA to include an acceptable limit of repeat rate in the regulations, some suggesting that it be 2 to 5 percent. Two comments wanted FDA to require corrective action to lower the observed repeat rate.

FDA again notes that, while most of these comments referred to ''repeat'' analysis, an analysis of both the repeated and the rejected films is required. In response to these comments, FDA observes that it has long been recognized that the parameter with the greatest impact on the repeat or reject rate is the subjective opinion of the physicians doing the interpreting as to what is acceptable. As noted in the preamble to the proposal (see 61 FR 14860), the repeat or reject rate could be reduced by a facility through acceptance of lower quality films. Any range or maximum value for repeat or reject rate that was established as acceptable through a regulation thus could quickly be rendered meaningless as an indicator of acceptable facility performance by such action. Consequently, the agency believes that, while it is important to keep the repeat or reject rate low, it is more important and useful to assess the cause of any change (increase or decrease) in the repeat or reject rate from the previously determined value. Therefore, the agency has retained the proposed requirement that the cause of a variance of more than 2 percent from the value previously determined must be properly assessed and recorded.

In looking for the cause of the change, the agency strongly advises facilities to assess all the factors that can affect repeat or reject rate. These can include personnel ability and preferences, changes in personnel, or variance in machines, processors, films, or chemistry performance.

(Comment 482). Some comments asked why a decrease of 2 percent requires action.

FDA notes, that while it may appear that a decrease in repeat or reject rate is a desired goal and should not require further assessments of the results, this is not necessarily so. For example, if a facility added a mobile unit to its operations, the interpreting physician might feel a subtle pressure to interpret films taken with that unit that he or she might normally reject because of the greater difficulty in scheduling repeat examinations at mobile units. This practice could lead to a reduction in the repeat or reject rate that does not necessarily indicate an improvement in quality. Therefore, the agency believes that the cause of either an increase or a decrease of more than 2 percent from the value previously calculated must be determined and any corrective actions should be recorded and assessed.

(Comment 483). A few comments stated that repeat analysis for each technologist should be evaluated and followup studies should be standardized. One comment wanted

such analysis performed for each machine used in the facility.

The agency supports the idea that analysis of the repeat rate for each technologist, radiologist, and/or machine can be valuable. However, many facilities with a sufficient volume for a meaningful analysis of their total operation would not have a sufficient volume for meaningful analysis of each technologist, interpreting physician, or machine. For this reason, FDA does not believe that a separate analysis for each technologist, interpreting physician, and machine should be a regulatory requirement. However, the agency recommends that each facility consider whether such analysis would be useful in its particular situation.

(Comment 484). One comment urged FDA to provide more guidance, either in a guidance document or by reference to the ACR QC Manuals, as to criteria for repeat and reject rate evaluation and corrective action. Another comment stated that this section needs to be elaborated to specify the frequency at which this test needs to be performed both for large and small volume facilities, guidelines about whether the analysis should be site- or technologist-specific, and acceptable repeat or reject rates. FDA notes that it has provided guidance for establishing an effective repeat and reject analysis program in the past and may provide additional information in the future. However, the agency believes that, as repeat or retake analysis has been an established procedure in radiology for 20 years or more, abundant guidance is also available from other sources. As stated previously, the agency in the final regulation will not reference any manual in order to provide the QC technologists and the medical physicists with flexibility to design their own analysis, recording, and corrective action procedures.

g. *Semi-annual QC tests (§ 900.12(e)(4))*

The proposal included requirements for semiannual tests of darkroom fog, screen-film contact, and compression.

The test of darkroom fog in § 900.12(e)(4)(i) is intended to be performed to identify light sources in the darkroom that can cause significant mammographic film fogging.

(Comment 485). One comment supported § 900.12(e)(4)(i) as written. The comment further stated that retaining the paragraph as proposed would eliminate variables for inspectors when performing this test. Several comments urged that certain test conditions be required, such as: ''Carry out the test under clinical conditions, with or without the safelight;'' ''use previously sensitized film;'' or ''place the test film on the counter top or on the processor feed tray (if not covered), whichever is closer to a safe light that remains on when the film enters the processor.'' Several other comments recommended adding words such as ''emulsion side up'' or ''where the mammography film is usually handled'' at specified points in the requirement.

After discussions with NMQAAC, FDA concluded that the comments did not provide a basis for amending the provision. The agency has retained § 900.12(e)(4)(i) as proposed, except that the words ''emulsion side up'' have been added for clarification. The agency will provide information on test procedures, as some comments requested, separately. Each facility can design its own procedures to meet the generally accepted features of an adequate darkroom fog test.

(Comment 486). A number of comments suggested requiring the darkroom fog test after any change in the darkroom that could result in an increase in the amount of fog.

FDA agrees that many changes in the darkroom could produce darkroom fog but it also believes that it is difficult to specify which changes will lead to increased film fogging. The agency has left it to the judgment of the facility as to which changes may lead to increased film fogging and thus warrant an additional darkroom fog test.

(Comment 487). One comment recommended that the acceptable value of darkroom fog be raised to 0.10 OD and believed that 60 percent of facilities will not be able to pass the test as written.

FDA does not agree that the majority of facilities will not be able to meet the required acceptable level of dark room fogging within 0.05 OD. This requirement is currently in effect under the interim regulations and the agency's inspection data indicate that most facilities are in compliance with this requirement.

(Comment 488). One comment urged FDA to require a clearly written procedure that ensures that the darkroom tests are performed using mammography films.

The agency considers this a good practice and recommends that facilities adopt such procedures. However, FDA does not believe that this requires a regulation.

The screen-film contact test in § 900.12(e)(4)(ii) is intended to ensure that proper contact is maintained between the screen and film in each cassette used in the facility for mammography.

(Comment 489). Several comments noted that the material of the 40 mesh screen used for the test was not specified and suggested that it be copper or a material with an atomic number similar to copper.

FDA agrees with these comments and has specified the requirement of 40 mesh copper screen in the final regulation. It has also clarified that all cassettes used in the facility for mammography must be tested.

(Comment 490). Two comments asserted that a minimum background density needs to be specified for the screen-film contact test, with one of these stating that it should be 0.60 to 0.85 so that the films are not underexposed leading to false readings. One comment wanted acceptance levels to be prescribed in some detail, while another comment stated that additional information was needed as to what constitutes an adequate screen-film contact test result. Two comments suggested the following criterion: ''Areas greater than 1 cm are not acceptable, five or more areas less than 1 cm are acceptable.''

FDA considers this test very important. A 40 mesh copper screen provides adequate resolution and contrast with a mammography film when exposed to a proper density. However, evaluations of these test results can be subjective and cannot be verified against a quantified acceptance level. Therefore, the agency cannot prescribe a numerical value of acceptance level in the regulation, as some comments suggested, because it would not be readily enforceable. FDA notes, however, that it does not agree with the comment that stated that five or more areas of poor contact with a size smaller than 1 cm are acceptable. The agency intends to provide further information on this test. The agency also notes that advice is also available in most QC manuals.

Compression testing is required to ensure that a mammographic system provides adequate compression and, at the same time that the equipment does not allow dangerous levels of compression to be applied. In the proposal, FDA required the compression device to meet specifications described in § 900.12(b)(12)(i) and, in accordance with § 900.12(e)(4)(iii), to be tested semi-annually to see if the specifications continue to be met. After further consideration, the agency determined that in the final rule it would be more appropriate to treat the compression forces as performance outcomes rather than equipment specifications. As a result, the standards for the amount of the compression force

have been transferred from § 900.12(b) to § 900.12(e)(4)(iii). The comments received on this aspect of proposed § 900.12(b)(12)(i) are discussed at this point with the related comments received on § 900.12(e)(4)(iii).

(Comment 491). A number of comments stated that some of the characteristics of the compression system described in § 900.12(b)(12)(i) did not need semiannual QC testing.

FDA agrees with these comments and, in the final regulation under § 900.12(e)(4)(iii), has required that only the compression force be tested.

Under § 900.12(b)(12)(i)(c) FDA proposed that, 5 years after publication, the compression device shall provide a maximum compression from the power drive between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(Comment 492). Several comments urged FDA to make the compression force requirement in the power drive mode effective immediately, not 5 years from publication as proposed. On the other hand, one comment disagreed with the April 1996, recommendation of NMQAAC that the proposed requirements be implemented 1 year after the publication of the final rules. One manufacturer stated that this requirement would affect approximately 2,000 of their units in the field and noted that it would be impossible to upgrade many of these units to the full 25 pounds. Additionally, the retrofit kit is likely to be very expensive and not welcomed by users who find a precompression force of 17 pounds adequate when accompanied with appropriate manual compression.

Although NMQAAC did recommend making the requirement effective 1 year after publication at its April 1996 meeting, they reversed that position in January 1997 after considering the possible cost of the action. The agency has thus retained in the final rule at § 900.12(e)(4)(iii), the requirement of compression force in power drive mode 5 years from the date of publication, as proposed in § 900.12(b)(12)(i)(c).

FDA, however, also considers it important that all mammography machines used currently provide adequate compression force. Under the interim regulations, facilities are required to use equipment that provides a minimum compression of 111 newtons. The agency is continuing to require this minimum compression force. In case of machines where such force is not available in power drive mode, the facilities may use the manual compression to attain this minimum compression requirement. However, 5 years after the publication of the final rule, all machines must provide a maximum compression force in power drive mode of between 111 newtons (25 pounds) and 200 newtons (45 pounds).

h. *Annual QC tests (§ 900.12(e)(5))*

Section 900.12(e)(5)(i) through (xi) lists a number of tests a facility must perform annually. Action limits for the test results are specified, except for the system artifacts (§ 900.12(e)(5)(ix)) and decompression (§ 900.12(e)(5)(xi)) tests; the nature of these do not allow the agency to provide any quantified acceptance level. The tests described in § 900.12(e)(5)(i) through (ix) were proposed as QC tests. The tests in § 900.12(e)(5)(i)(x) and (xi) have been moved from § 900.12(b) of the proposal after FDA concluded that they are more performance than specification oriented and, therefore, are more appropriately located in § 900.12(e) in the equipment quality assurance section of the final regulation.

(Comment 493). One comment stated that the regulation should require these tests to be done by a qualified medical physicist. FDA notes that this requirement already appears at § 900.12(e)(9), which requires that these tests be done as part of the facility survey and further requires that the survey be performed by a qualified medical physicist.

Two comments questioned why the proposed requirements under § 900.12(e)(5) established testing limits different from those used by the accreditation body. The comments claimed that these ''discrepancies'' will hinder compliance. FDA believes that the authors of these comments are mistaken. The agency assumes that by ''testing limits,'' the comments are referring to action limits. FDA notes that the action limits of § 900.12(e)(5) are the same as those in the ACR manuals, and thus, the same as those the facilities and the accreditation bodies are using under the interim regulations.

The automatic exposure control (AEC) test in § 900.12(e)(5)(i) measures several parameters of the AEC system.

The first action limit specified for the AEC is that it shall be capable of maintaining the film optical density within ± 0.30 of the mean optical density as the phantom thickness and kVp are varied in § 900.12(e)(5)(i)(A).

(Comment 494). Some comments wanted a definition of ''Mean Optical Density.''

FDA notes that such a definition was provided in § 900.2(w) of the proposal, now § 900.2(ee) in the final regulation.

(Comment 495). Other comments asked FDA to specify the type of phantom needed for this test or asked if the same phantom used for the image quality test is required. A related comment stated that the test blocks used by the physicists should be specified to be 15 x 15 mm homogeneous material, in order to ensure an even scatter pattern or distribution that would not be affected by the position of the AEC and inhomogeneous scatter. The comment suggested that phantoms made up of either acrylic or BR12 can be used. Another comment wanted the test details and acceptance levels to be prescribed.

The agency requires the thickness of the phantom to be varied from 2 to 6 cm. These thicknesses are currently required under the interim regulation and the facilities may use any homogeneous material of appropriate thicknesses that will provide a film OD of no less than 1.2 at the center of the image. The agency has previously discussed its rationale for not providing detailed test procedures.

(Comment 496). One comment requested FDA to clarify whether testing is required with all available thicknesses and kVp's. FDA has changed the wording in the final regulation to clarify that AEC tracking is required only for phantom thickness varied over a range of 2 to 6 cm and for kVp's varied appropriately for such thicknesses over the kVp range used clinically.

Proposed § 900.12(e)(5)(i)(C) established an alternative to proposed § 900.12(e)(5)(i)(A) by allowing the development of a technique chart of kVp and density control settings to ensure that the film optical density requirements of § 900.12(e)(5)(i)(A) would be met in cases where it could not be done directly by AEC.

(Comment 497). Two comments stated that a technique chart should be required for all machines under all situations. Two others stated that the proposal created a loophole for the AEC equipment specification requirements proposed in § 900.12(b)(15)(vii)(A). One comment asked if a technique chart would be acceptable in the year 2000 when all machines are expected to meet the ± 0.3 OD variance requirement. One comment suggested eliminating the option of using a technique chart.

The agency has combined the provision permitting the use of a technique chart with § 900.12(e)(5)(i)(A) in the final rule. After consideration of the comments, FDA has decided to permit the use of a technique chart to meet the ± 0.3 OD variance requirement only for 5 years after the publication of the final regulation. After 5 years, the AEC equipment must meet the ± 0.30 OD variance requirement directly.

FDA has moved a provision proposed as an equipment requirement in

§ 900.12(b)(15)(vii)(B) to the quality assurance paragraph as § 900.12(e)(5)(i)(B). As explained earlier, the move was made because this provision was more appropriately located with the QC performance tests than with the equipment specifications. This provision requires, effective 5 years from the publication of this regulation, that the film optical density be maintained within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. Use of the technique chart to compensate for inadequacies in the AEC will no longer be permitted after that date.

(Comment 498). In response to the original proposal in § 900.12(b)(15)(vii)(B), one comment requested that FDA clarify whether compensation steps using a technique chart will be allowed. The comment also stated that ± 0.15 OD criteria can not be met if the film manufacturers allow 0.3 OD variation from one film batch no another.

As noted in the previous paragraph, FDA will permit the use of a technique chart to compensate for inadequacies in the AEC for 5 years after the publication of the final rule; after that time the technique chart can no longer be used as an aid in maintaining the film optical density within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. The agency also advises facilities to use films from the same batch so that film variability, if any, is not introduced while testing AEC performance. Because film variability can be eliminated as a source of bias in the AEC performance test, there is no justification for increasing the AEC actions limit to ± 0.30 OD because that would simply mean that the facility would have to contend with variability of ± 0.30 from the film and another ± 0.30 from the AEC.

(Comment 499). Two comments stated that the proposed requirement was too lenient, while two others believed that it was too restrictive. Three comments supported the proposed requirement.

FDA believes, after discussion with NMQAAC, that it is reasonable to require that the ± 0.15 OD limit be met by all units 5 years after publication of the final rule. The agency believes that the cost to meet this requirement will be minimized by the fact that, by the end of this period, many of the units unable to meet the ± 0.15 OD requirement will have been replaced by facilities on their normal replacement schedules. The agency does not believe it has any basis to require a tighter limit than ± 0.15 OD.

Section 900.12(e)(5)(i)(C) (proposed § 900.12(e)(5)(i)(B)) proposed that the operating OD be no less than 1.20.

(Comment 500). Several comments suggested deleting the word ''operating.'' One comment requested the definition of ''Operating OD.''

FDA agrees that the word operating should be deleted. This requirement is now moved to § 900.12(e)(5)(i)(C) in the final rule.

One comment urged FDA to require a mean optical density of at least 1.3 OD. FDA notes that the regulation allows facilities to use a higher film OD if they believe that will make the test a better indicator of the ability to detect micro-calcifications and will aid in improving image quality. However, the agency does not consider it necessary at this time to require any higher OD. The agency also notes that NMQAAC advised FDA to retain the 1.2 OD requirement as proposed.

The annual test in § 900.12(e)(5)(ii) tracks the kilovoltage accuracy and reproducibility.

(Comment 501). A large number of comments stated that kVp accuracy should be within 5 percent instead of the proposed ± 10 percent.

The agency is persuaded by these comments and has made the change in the final regulation.

(Comment 502). One comment questioned the justification of a very tight coefficient of variation for the kVp reproducibility.

FDA believes that the coefficient of variation of a given set of kilovoltage measurements should be less than 0.02, as was proposed. This is the standard presently required under the interim regulations and most facilities are currently in compliance with it; there is no justification for relaxing the standard, either from the point of view of public health or a cost consideration.

(Comment 503). Several public comments and a member of NMQAAC expressed concern that one widely used kVp testing instrument does not read below 23 kV, while kilovoltage settings as low as 21 or 22 kVp are sometime used. A few comments suggested requiring kVp testing at two clinical setting values. One comment stated that § 900.12(e)(5)(ii)(B), as written, could be interpreted to mean kVp reproducibility should be measured from 25 to 30 kVp in 0.5 kVp increments. Another comment stated that it should be acceptable to test kVp reproducibility in just one setting within the clinical range.

In response to these comments, FDA has revised the final regulation to require that the lowest kVp at which accuracy be tested is the lowest clinical used kVp that can be measured by a kVp test device. The agency, however, disagrees with the comments that recommend testing kVp at one or two clinical settings only. FDA considers it important to test kVp accuracy at least at the highest and lowest measurable clinically used values, and at the facility's most commonly used clinical kVp. The agency, however, has modified the regulation to require that the coefficient of variation of reproducibility be determined at the most commonly used kVp only.

One comment claimed that the kVp accuracy requirement should be checked with all focal spots. The agency has no reason to believe this is necessary.

The focal spot condition (proposed as system resolution) test in § 900.12(e)(5)(iii) was proposed to evaluate the performance of the mammography unit by assessing the resolution capability of the system.

(Comment 504–505). A few comments stated that some mammography machines could not meet the proposed resolution requirement even though the focal spot size was adequate. One comment maintained that the line pair resolution requirement was too restrictive. A member of NMQAAC stated that, in magnification mammography, the resolution requirement would be difficult to meet. These comments suggested that the focal spot size measurement be added as an alternative requirement, as is the current practice under the interim regulation. Two other comments also urged FDA to continue to permit focal spot dimension measurements as part of acceptance tests for mammography equipment evaluation. One comment supported replacing focal spot measurement with performance related specifications of system resolution.

FDA considered the immediate economic impact on facilities of meeting the resolution requirement as proposed and decided to permit continued use of the focal spot size measurement as an alternative to the measurement of system resolution for a period of 5 years from the publication of the final regulation. During this period, facilities may evaluate the condition of the mammography unit by determining either the system resolution, proposed as § 900.12(e)(5)(iii) (new § 900.12(e)(iii)(5)(A)), or the focal spot dimensions as described in § 900.12(e)(5)(iii)(B). The agency believes that by the end of this period, when the regulation will require the evaluation of system resolution only, many of the units unable to pass the system resolution test will have been replaced by the facility on its normal replacement schedule.

The agency believes the benefits of assessing overall performance of the system through use of the system resolution test justify their transition. NMQAAC also advised FDA to require the system resolution test.

(Comment 506). One comment suggested that FDA should only require that the resolution shall be sufficient so that the system can detect micro-calcifications of 300 µm and greater sizes.

FDA notes that available scientific data indicate that 50 µm resolution is necessary in mammography imaging for early and proper detection of micro-calcifications. This is equivalent to about 10 cycles (lp)/mm resolution when the bar pattern is used. The agency believes that all new equipment meets this requirement as proposed. Under the interim regulation, this criterion is already being met by the facilities which chose to evaluate focal spots by assessing system resolution. Further, NMQAAC advised FDA to adopt such a requirement in the final regulation. For these reasons, the agency did not accept the comment.

(Comment 507). A member of NMQAAC advised FDA that the units should be specified in SI units and suggested using ''ycles/mm'' in place of ''ine pairs/mm.'' One comment stated that the height of the line-pair test pattern above the image receptor must be specified in association with the resolution limits and suggested that the height should be 4.5 cm. Other comments requested clarification of ''parallel'' and ''perpendicular'' to the axis in terms of the bars of a test pattern whose orientation was being described. Three comments urged that test specifications be included in the regulations.

In response to these comments, FDA has added a new § 900.12(e)(5)(iii)(A) to specify that the high contrast resolution bar patterns must be placed 4.5 cm above the breast support surface and be oriented parallel and perpendicular to the anode-cathode axis. FDA has also introduced cycles/mm as the primary unit.

(Comment 508). One comment asked at what magnification the system is required to resolve 11 and 13 lp/mm. Another comment suggested that the tests should be performed at all magnifications used. Two comments urged FDA to require focal spot assessment for all focal spot sizes. One comment suggested that the system resolution should be tested with the grid in use. One comment suggested that the grid should not be in the imaging chain during magnification.

FDA reiterates that 5 years from the date of publication of the final rule, all facilities must perform the system resolution test annually and must meet the requirements specified in § 900.12(e)(5)(iii)(A)(1), both in contact mode and in all magnification mammography modes used in the facility. The agency believes that if a machine can meet the requirements using the large focal spot size used in contact mode, it will meet the requirements using the small focal spot size also. The agency also believes that the resolution test must be conducted under the normal operating condition, that is, for contact mammography the resolution assessment must be performed with the grid in place whereas for magnification mammography, the grids should be removed. The agency intends to provide more discussion about these procedures in educational documents.

(Comment 509). Two comments stated that the line-pair minimum should be increased.

FDA believes that the present values are generally accepted as representing the best cost/benefit compromise.

(Comment 510). One comment recommended requiring a monthly phantom test with indicators of what should be expected in resolution capabilities at a given magnification to ensure adequate performance between physicist surveys. The comment also recommended that the system resolution in magnification mode be monitored to determine whether it diminishes with time.

Although it encourages facilities to carry out this type of performance-based study, FDA does not believe there is adequate evidence to show that these additional tests would produce benefits that outweigh the costs facilities would incur in performing them. Therefore, at this time, the agency is not including them in the regulation.

The beam quality and half-value layer (HVL) paragraph as proposed in § 900.12(e)(5)(iv), required the HVL to meet the specifications provided in § 900.12(b)(11). Two comments stated that the exact specifications should be included under § 900.12(e)(5)(iv), rather than merely by reference. Two comments suggested that the upper HVL limits described in the 1994 ACR QC Manual should also be included and that HVL limits should be specified for other target filter combinations.

In the final rule, FDA has specified HVL requirements only in § 900.12(e)(5)(iv). The specifications for kVp's in the mammographic range are provided in a tabulated form. Values not shown in the table may be determined by linear interpolation or extrapolation. NMQAAC members were unable to reach a consensus on the value of having an upper limit of HVL or on what the upper limit should be. FDA views this as an indication that there is a general lack of consensus on this topic in the mammography community and, therefore, the agency has decided not to include any upper limit in the regulation.

The breast entrance exposure and AEC reproducibility paragraph, as proposed in § 900.12(e)(5)(v), established the action limit for the coefficient of variation of these two variables at 0.05.

(Comment 511). Three comments suggested deleting the breast entrance exposure requirement, while another considered it to be an equipment standard. This last comment further stated that lack of AEC reproducibility will be identified by other QC tests and the phantom image. Another comment inquired whether it was the intent of the provision to require facilities to calculate exposure reproducibility for data points consisting of mR divided by mAs, or to separately measure the reproducibility of exposure and mAs.

FDA believes that this test must be performed at least annually and that the coefficient of variation must be calculated for both exposure and mAs. If a unit does not indicate a post-exposure mAs value, then mAs should be obtained by a secondary method. In accordance with the movement towards the use of SI units discussed in connection with the new definition of air kerma (§ 900.2(d)), the agency has also introduced air kerma as the primary quantity to be measured in this test. Breast entrance exposure remains as an alternative quantity.

The dosimetry test in § 900.12(e)(5)(vi) determines the mean glandular dose delivered during a single cranio-caudal view using an FDA approved phantom simulating a standard breast. When the mean glandular dose exceeds 3.0 mGy, corrective action is required.

(Comment 512). A number of comments were received on the specifications for the phantom to be used in performing this test. Some comments stated that most facilities are using phantoms simulating a 4.5 cm breast and it would not be cost effective to change to phantoms simulating a 4.2 cm breast. One comment suggested that FDA should recognize that most technique charts are set using whole number thicknesses, arguing that 4.0 cm is probably the most reasonable. One comment stated that ACR phantoms are not tissue equivalent phantoms.

Another comment stated that, to date, most dose data had been set using the RMI accreditation phantom. The comment questioned its actual tissue equivalence and further stated that dose standards should be set using a phantom that correlates as closely as possible to actual thickness.

In the preamble to the proposal (61 FR 14912), FDA solicited comments about actual thickness that the existing phantoms simulate. FDA did not receive enough evidence in response to this question to convince the agency that the existing phantoms simulate a 4.0 cm compressed breast more closely than they simulate a 4.2 cm compressed breast, which is the figure currently used. The agency, therefore, continues to require that the dose should be determined under the assumption that the phantom simulates a 4.2 cm compressed breast and that the technique factors should be chosen accordingly. FDA did not propose, nor has it required in the final rules, any change in the phantoms currently being used. As stated earlier, the agency believes that accreditation bodies should establish phantom specifications and related performance criteria. In the future, if better tissue equivalent phantoms are available to simulate a different compressed breast thickness that can change dose calculations significantly, the agency will revise the thickness requirement for average dose calculation. FDA also notes that a change from 4.2 cm to 4.0 in thickness does not result in a significant change in the calculated dose.

(Comment 513). One comment stated that calculation of the entrance dose to the phantom is not necessary if kVp, HVL, and mAs for the exposure are within limits. Another comment stated that, because the existing image quality phantom simulates a 4.2 cm compressed breast, not 4.5 cm, the dose limit could be lowered. One comment stated that the regulations should not allow any dose less than 0.8 mGy, while another comment stated that there is no reason for accepting 300 mrad as a maximum mean glandular dose because, even at 25 kVp, the typical mean glandular dose is 120–150 mrad (1.2–1.5 mGy). This comment recommended setting the dose limit at 250 mrad (2.5 mGy). Another comment recommended that FDA consider lowering the patient dose requirements to that of the State of California requirement.

FDA strongly believes that a proper dose calculation at least once a year for each unit is critical for public health and safety. FDA further believes that the present dose limit of 3.0 mGy provides adequate protection from unnecessary radiation and does not want to change the dose limit to 2.5 mGy or establish a lower limit of 0.8 mGy, in order to avoid the possibility of inhibiting future advances in imaging technology, as discussed in the preamble to the proposal (61 FR 14912).

(Comment 514). One comment suggested that the phantom kVp and mAs must be compared to the average of 20 or more 4.2 cm clinical breast mammograms to ensure that the measured glandular dose is consistent with patient radiation doses.

In response to this comment, the agency notes that the dose must be determined with technique factors and conditions used clinically for a standard breast. The agency understands that, for some facilities, commonly used technique factors may be slightly different from what would be technique factors for a standard size breast and therefore different from what would be used for the available phantom, which simulates a standard breast. However, the agency does not believe that dose will vary so significantly that it will exceed the required limit of 0.3 mGy in cases of patients with non standard breast size, as long as the mammography unit is capable of meeting the dose requirement using a phantom simulating a standard breast.

(Comment 515). Two comments urged FDA to require that the time of exposure be less than or equal to 2.5 seconds. FDA did not accept this comment because the agency believes that it does not have enough evidence to confirm that 2.5 seconds is the absolute maximum exposure time needed to cover all patient sizes. The agency recommends that facilities determine the proper exposure time for their needs through consultation with the medical physicists and the equipment manufacturers.

The requirements for X-ray field/light field/image receptor/compression paddle alignment in § 900.12(e)(5)(vii) are intended to ensure that: (1) All systems have beam limitation devices that prevent the patients from receiving unnecessary radiation dose, permit imaging of the critical breast tissue near the chest wall, and avoid white borders on the film; (2) if a light field is provided, the congruence of the light field with the X-ray field should be such that the sum of misalignments on opposite sides between X-ray field and light field is within 2 percent of the SID; and (3) the alignment of the edge of the compression paddle with the chest wall edge of the image receptor is sufficient to permit pulling the breast tissue away from the chest wall for imaging and to keep the shadow of the vertical edge of the paddle from being visible on the image. The test also ensures that the extension of the edge of the paddle is within 1 percent of the SID so that the patient's chest is not pushed away from the breast support surface.

(Comment 516). One comment stated that § 900.12(e)(5)(vii) should include exact specifications rather than just a reference to those specifications in § 900.12(b)(5). One comment argued that confinement of the X-ray field within the image receptor cuts off useful film area and misses some of the breast tissue. The comment further suggested that this requirement should be changed so that the X-ray field can extend slightly beyond the edges of the image receptor in order to make full use of the film area and not potentially miss any breast tissue that is overlying the image receptor, and to blacken what would be an otherwise clear border.

In the final regulation, FDA has moved the X-ray field/light field/image receptor/compression paddle alignment specifications to § 900.12(e)(5)(vii). FDA notes that § 1020.31(f)(3), which the agency referenced in the proposal, allows extension beyond the chest wall edge of the image receptor by as much as 2 percent of the SID so as to properly image breast tissue on the chest wall side. In the final rule, the agency allows extension of the X-ray field beyond all edges of the image receptor but limits this extension to within 2 percent of the SID.

(Comment 517). Two comments suggested that the term ''image receptor'' should be defined. In the agency's earlier discussion of the definitions, the agency has referenced § 1020.31 as providing a definition of image receptor.

(Comment 518). One comment stated that the requirement for a light field in this section imposes an unwarranted expense.

FDA notes that a light field is not required but if one is present, it must meet the light field-X-ray field alignment requirement.

(Comment 519). One comment urged FDA to consider relaxing the requirement for the alignment of the compression paddle and the breast support surface. One comment questioned whether limiting the extension of the compression paddle beyond the image receptor to within 1 percent of SID is achievable in all units. Another comment suggested that this requirement be written to more accurately reflect the need to extend past the edge of the image receptor, although by no more than 1 percent of the SID. Three comments stated that it appeared from the proposed regulation

that it was permissible for the compression paddle to be visualized on the mammography film.

FDA believes that the one percent extension limitation can be achieved and notes that the current requirement under the interim regulations is one percent. The agency has also clarified the final rule to emphasize that the shadow of the compression paddle shall not be visible on the image.

(Comment 520). One comment requested clarification on whether the reference was intended to be with respect to a vertical line or with respect to a line connecting the focal spot and edge of the image receptor when the requirement that the chest wall edge of the compression paddle not extend beyond the chest wall edge of the image receptor by more than one percent of SID is being met.

(Comment 521). One comment suggested that FDA specify whether this requirement is with respect to the interior surface of the paddle or the exterior surface. The comment, however, acknowledged that this is not an important issue with a 1 or 2 mm paddle thickness.

FDA disagrees with comments that suggest including all these details in the regulation. However, the agency wishes to clarify that the reference is the vertical line and the requirement refers to the interior surface of the paddle.

One comment stated that this requirement should be met with all image receptors. FDA notes that the regulation as written requires this test to be performed for all full-field aperture sizes used for beam limitation in the facility; this will ensure that all image receptors meet the requirement.

The screen speed uniformity test, as proposed in § 900.12(e)(5)(viii), requires that at least once a year, each facility must ensure the consistency of the screen speed among all cassettes used in the facility for mammography. The same test is required currently at the same frequency under the interim regulation.

(Comment 522). One comment stated that § 900.12(e)(5)(viii) did not allow for slow and fast screen variations due to large and small screens having different relative speeds. Another comment suggested that the maximum optical density difference should be reduced to 0.15.

FDA believes that the difference between the screen speeds of all cassettes, small or large, should be such that the OD variation is within 0.3 OD. The agency, however, does not believe that tightening the restriction on density difference to 0.15 is justified. Members of NMQAAC supported this view.

One comment requested FDA to describe the test procedure to be used. As discussed earlier, FDA made a general decision to refrain from describing specific test procedures for QC tests in the regulations. The agency will include a more detailed description of some tests in its guidance document.

System artifacts in § 900.12(e)(5)(ix) mean artifacts produced by any part of the mammographic system, including the X-ray machine, screen-film system, and/or processors. This subparagraph requires the facility to determine the level and possible adverse effects of artifacts produced by its systems. These artifacts should be distinguished from the patient related artifacts.

(Comment 523). One comment stated that the evaluation should be done for all full-field image receptor sizes.

FDA agrees and has added this requirement to the final regulation.

(Comment 524). One comment recommended elimination of this test because the physicists always watch for artifacts whenever a film is taken.

FDA strongly believes that a separate test solely meant for artifact evaluation is necessary. Further, this test should also evaluate the whole imaging chain for the source of any artifacts detected.

(Comment 525). One comment stated that the test can also be done with a smaller phantom positioned closer to the collimator. As advised by NMQAAC, FDA proposed that artifacts should be evaluated through the use of a test object of high grade defect-free material that is large enough to cover the mammography cassette.

FDA notes the intent in requiring an object of this size is to capture and identify artifacts that are caused anywhere in the cassette and its screen-film combination. In this way, the quality of the entire film can be better assured. FDA understands that there may be other ways of accomplishing this goal, such as the method suggested in the comment, but the agency lacks data to confirm that the suggested procedure will produce equivalent results. The agency notes that the alternative requirement mechanism of § 900.18 provides a way by which alternatives to the requirements can be evaluated, and possibly accepted, by FDA.

(Comment 526). One comment stated that more guidance should be provided on evaluating artifacts. One comment wanted the test details and acceptance levels prescribed.

Again, FDA has decided that test details are subjects more appropriately addressed separately from the regulations. The agency also notes that the acceptance level for artifacts is at present a subjective assessment and not amenable to the establishment of specific numerical standards.

(Comment 527). One respondent believed that testing X-ray systems for artifacts does not require the use of a test object. Another comment stated that use of a thick (4 cm) acrylic test object will harden the beam to the point that it will mask grid and/or carbon fiber cover artifacts and may even mask grid lines.

FDA disagrees. The agency believes that an exposure time sufficient to image appreciable artifacts may not be achieved if a test object is not used, while these artifacts would be visible during a normal patient exposure.

FDA has moved the radiation output requirement from § 900.12(b)(15) to § 900.12(e)(5)(x) because it concluded that it was more appropriate to treat this test as an annual QC test rather than an equipment specification. This test is intended to determine if the mammographic system is capable of producing a minimum required output. Five years from the publication of the final rule, the requirement will change to require a higher output from each system.

(Comment 528). Two members of NMQAAC opposed this requirement as an annual test. One member stated that a 3-second field test of the unit may cause damage to the tube. The same NMQAAC member further stated that averaging the results over a 3-second exposure time would not reveal whether the output rate dropped unacceptably low at any time during the exposure.

FDA does not have evidence indicating that any significant fluctuation in exposure takes place within an exposure time of the order of 3 seconds. However, the agency has revised this requirement in § 900.12(e)(5)(x)(B) from that originally proposed in § 900.12(b)(14) to clarify that no instantaneous radiation output requirement is intended; instead, the requirement is the output averaged over a 3-second period. Also, because the exposure times can be lengthy for some patients, the agency does not consider 3-second exposure time unreasonable. The agency also considers a yearly check of radiation output important and reasonable.

i. *QC tests—other modalities (§ 900.12(e)(6))*

This provision requires facilities using image receptor modalities other than screen-film to establish a quality assurance program that is substantially the same as that recommended by the image receptor manufacturer, except that the maximum allowable dose is not allowed to exceed that established in

§ 900.12(e)(5)(vi) for screen-film systems.

No public comments were received on this paragraph and it has been codified as proposed.

j. *Mobile units (§ 900.12(e)(7))*

This provision requires mammography units used at more than one location to meet all of the quality assurance requirements established in § 900.12(e)(1) through (e)(5). In addition, at each visit at each examination location, before any additional examinations are conducted, the facility is required to verify the performance of such units using an adequate test method.

(Comment 529). Three comments supported the additional testing of mobile units. One of these noted that the many environments in which the units operate made the testing necessary. Six comments opposed the additional testing. The most common reasons given for the opposition was concern about being able to process the test images before mammography is performed and that the additional testing was unnecessary because moving the unit did not create any problems.

When the need for additional testing of mobile units was discussed at the NMQAAC meeting of September 1994, it was noted that a recent ACR survey of facilities operating mobile units had found that about one in seven facilities reported quality problems with their mobile units at least weekly. Largely based on this information, NMQAAC recommended that postmove, preexamination testing of mobile units be included in the final regulations. NMQAAC continued to support this proposed requirement at its January 1997 meeting.

FDA agrees that no change should be made to the proposal. The agency further notes that several of the opposing comments based their concern upon the difficulty of processing phantom images at the mobile site. However, the final regulation does not require the use of any specific test, only that the test method be able to verify that adequate image quality is being produced by the unit. This gives the facility the option of using other tests that do not require processing of images before examinations are conducted, as long as the test can demonstrate that adequate image quality is likely to be achieved. One such test, based on the consistency of mAs readings, was described by a speaker at the September 1994 NMQAAC meeting.

(Comment 530). Five comments expressed concern about the fact that acceptable testing methods were not specified in the regulations. Three of these comments asked who a facility should consult to determine if its test method would be considered adequate by FDA. Related comments on this issue asked how inspectors would determine adequacy without guidance and noted that the State of Massachusetts left it to the medical physicist to determine what test method should be used. One comment urged that a test based on the mAs reading be considered acceptable, while another stated the performance test required by the State of Illinois should be recognized by FDA.

FDA plans to issue information describing test methods that it is likely to consider acceptable for verification of performance of mobile units after a move and before examinations are conducted. It is expected that at least one of these methods will not require the processing of images before the examinations begin. Because these methods will not be regulatory requirements, FDA may accept other test methods proposed by facilities, medical physicists, or other interested parties. Facilities are always free to discuss any particular method with FDA prior to establishing its use.

(Comment 531). One comment opposed allowing central film processing for mobile services out of concern for degradation of the latent image during the time between exposure and development.

This issue was discussed at some length at two NMQAAC meetings and the conclusion was that this degradation would not be significant during the typical times between exposure and development of mobile facility images. FDA, therefore, has not prohibited central processing.

(Comment 532). One comment stated that if diagnostic imaging is done at a mobile facility, a radiologist should be present. Practice of medicine issues have made it difficult to define the distinction between screening and diagnostic mammography. Because of this difficulty, FDA has issued the final regulations to apply to all mammography, rather than addressing specific requirements to one area or the other.

k. *Use of test results (§ 900.12(e)(8))*

The provisions of this proposed paragraph were intended to ensure that the facility did not stop with the performance of the quality assurance tests but analyzed the results of the tests to determine if problems existed and took necessary actions to correct those problems. Ongoing anecdotal evidence and the MQSA inspection data indicate that, even 20 years after the introduction of the concepts of quality assurance, some facilities are still neglecting to take the important final steps in the process.

Section 900.12(e)(8)(i), as proposed, requires facilities to compare the results of their quality assurance tests with action limits specified in § 900.12(e)(1) through (e)(6) and, if their results fall outside the action limits, to repeat the tests immediately to verify that the testing process was not responsible for the result.

(Comment 533). Thirteen comments opposed, at least in part, the requirement to repeat the tests immediately. Some of these comments urged that it be applied only to the processor QC, screen-film contact, and average glandular dose tests. Two comments supported exempting annual tests. Four of the comments stated that the decision about what tests should be repeated should be left to the medical physicist. NMQAAC recommended complete deletion of the proposed requirement that the tests be repeated immediately. One comment took the opposite view, stating that this requirement helps facilities identify trends.

FDA notes that this requirement was originally added to ensure that the facility confirmed whether the problem was due to the equipment rather than an improperly performed test before it went to the trouble and expense of taking corrective actions. However, the agency has been persuaded that a facility that goes to unnecessary expense to correct an equipment problem that was actually a testing problem is likely to take steps on its own to avoid repetition of such a situation. In view of that conclusion, and the public comments, the requirement to repeat the test has been deleted from the final regulations.

Section 900.12(e)(8)(ii), as proposed, stated that if the repeated tests continue to produce unacceptable results, the problem shall be identified and corrected before any further examinations are performed.

(Comment 534). Seven comments stated that this provision, as proposed, was too broad and that at least in some cases it would not be necessary to shut down the entire facility until the problem was solved. Other comments gave the views of their authors as to which tests, if failed, indicated problems serious enough to require the facility to stop doing mammography until the problem was solved. The most frequently mentioned tests in this category were the processor QC tests of § 900.12(e)(1) and the average glandular dose test of § 900.12(e)(5)(vi), each of which was listed by 13 comments.

(Comment 535). Seven comments included the image quality test of § 900.12(e)(2) and six each, the screen-film contact test of § 900.12(e)(4)(ii), the compression test of § 900.12(e)(4)(iii), the tests for modalities that did not use screen-film of § 900.12(e)(6), and the additional test for mobile units of § 900.12(7) on their lists of tests important enough that their failure required problem detection and correction before mammography continued. The system resolution test of § 900.12(e)(5)(iii) was listed in five comments. One comment each also would include the artifact test of § 900.12(e)(5)(ix) (if there were ''serious'' artifacts), the kVp test of § 900.12(e)(5)(ii), and tests of output and the phototimer (if the errors were ''large'') on the list.

NMQAAC as a group supported the requirement that the problem must be corrected before mammography continues only in the cases of the processor QC tests, the average glandular dose test, and the screen-film contact test. However, the medical physicists serving as committee members and consultants for NMQAAC, when discussing specific tests in their individual comments, presented somewhat different and conflicting views. They agreed that the processor QC and the average glandular dose tests were of sufficient importance that, if they were failed, the facility should cease doing mammography until the problem was corrected. They also supported adding the image quality test to that list. Opinions of these physicists were split on whether the screen-film contact test, the automatic exposure control tests of § 900.12(e)(5)(i), the breast entrance exposure and AEC reproducibility test of § 900.12(e)(5)(v), the tests for modalities other than screen-film, and the additional test for mobile units should be considered important enough that their failure would require problem correction before mammography continued.

After consideration of the comments, FDA agrees that not all test failures are serious enough to require the facility to cease doing mammography until the source of the problem is corrected. The agency also agrees with two additional comments that stated that, even if the test failure does indicate a problem that requires immediate correction, it may not be necessary to shut down the entire facility. For example, if the processor QC tests are failed, it may be possible to continue to perform mammography, but to delay processing the films until the processor problem is corrected, as long as the anticipated processing delay is not of such duration that image degradation becomes a concern. Similarly, if the facility has more than one mammography unit, the failure of one unit would not be a reason for stopping the use of another unit that did pass the tests.

In response to these considerations, FDA has revised § 900.12(e)(8)(ii) by dividing the tests into two groups. Those tests listed in § 900.12(e)(8)(ii)(A) are those whose failure requires immediate problem evaluation and correction. However, the wording has been changed to state that the corrective actions must be taken ''before any further examinations are performed or any films are processed using the component of the mammography system that failed the test'' (emphasis added). If the failure is related to a component for which there is no alternative, for example, a failure of the facility's only mammography unit, then the facility will still have to cease doing mammography until the problem is corrected. However, if there is another unit or processor that has passed the tests, the facility will be able to continue producing and processing mammograms with that equipment while the problem with the first unit is corrected.

Included in § 900.12(e)(8)(ii)(A) are the processor QC tests (§ 900.12(e)(1)) and the average glandular dose test (§ 900.12(e)(5)(vi), both of which everyone who commented on this paragraph agreed were important enough that their failure required evaluation and correction of the problem before the piece of equipment was used for further mammography. FDA has also included the image quality test (§ 900.12(e)(2)) in this group, even though it was mentioned in fewer comments. The importance of this test is underscored by the fact that the primary goal of the MQSA is to ensure adequate quality mammography for all women. The agency has also included the additional test for mobile units (§ 900.12(e)(7)) because it is a test that directly evaluates image quality.

FDA has also included the tests for nonscreen-film modalities (§ 900.12(e)(6)) on this list. This particular provision was intended to facilitate the introduction of new modalities because it ensures that facilities using the new modality will have an adequate quality assurance program, while at the same time not requiring amendment of the requirements of § 900.12(e) before the new modality can be used. Because it is not possible to predict in advance what new modalities may appear and what QC tests may be required for them, FDA believes they must be placed in § 900.12(e)(8)(ii)(A) to adequately protect the public. Should it prove to be the case that some or all of the tests that are applicable to the new modality might more appropriately be placed in § 900.12(e)(8)(ii)(B), regulatory relief can be provided through the alternative requirements mechanism of § 900.18 until § 900.12(e)(8)(ii) can be amended.

FDA has also agreed with comments urging that the screen-film contact test (§ 900.12(e)(4)(ii)) and the compression test (§ 900.12(e)(4)(iii)) be placed on the list of those tests whose failure should require taking a piece of equipment out of service until the problem is detected and corrected. The agency notes that the new wording referred to above means that failure of the first of these tests only requires taking the cassette in question out of service and, as one comment pointed out, the corrective action most likely will simply be replacement of the cassette. The compression test is included out of concerns raised by both anecdotal accounts and reports to FDA's Medical Device Reporting System of injuries resulting from excessive compression and the knowledge that inadequate compression can lead to poor quality images.

Finally, FDA retained the darkroom fog test (§ 900.12(e)(4)(i)) on this list, even though it was not mentioned by any of the comments. FDA has concluded from studies, such as the Nationwide Evaluation of X-ray Trends program of the Conference of Radiation Control Program Directors, that excessive darkroom fog is more pervasive and has a greater impact on image quality than is commonly realized. The agency also notes that the detection and correction of the problems contributing to darkroom fog is a relatively uncomplicated process and can be carried out relatively rapidly. Often the problem is associated with the safelight and simply discontinuing use of the safelight until it can be replaced or repaired may provide a temporary correction that would permit returning the darkroom to service.

FDA has placed all other tests under § 900.12(e)(8)(ii)(B). These are tests whose failure indicates that there are problems that must be corrected, but, for various reasons are not considered to present a health hazard serious enough to require taking a piece of equipment out of use until the problem is corrected. Retake analysis is included in this group (§ 900.12(e)(3)(ii)). In this case, mammography must be allowed to continue to determine if the corrective action has indeed had the desired effect on retake rate. Also in this group are tests such as kVp accuracy (§ 900.12(e)(5)(ii)) and alignment (§ 900.12(e)(5)(vii)), for which, as one of

the NMQAAC physicists argued, there are compensation methods that can be used as temporary corrective actions until the problem can be given a more permanent correction. Other tests included in this group, such as the system resolution test (§ 900.12(e)(5)(iii)—called the focal spot condition test in the final regulations) are early warning tests that give an indication of possible approaching problems. In the case of the system resolution test, FDA has accepted the argument of the NMQAAC physicist who believed that, unless the system resolution was so poor as to lead to failure also of the image quality test, some time could be permitted for the correction of the resolution problem. Of course, if the image quality test is failed, the piece of equipment will be taken out of service until the problem is corrected. Finally, this group includes the artifact test (§ 900.12(e)(xi)), for which there are no objective action limits against which to compare the test results.

Although problems revealed by the tests in the second group are not considered serious enough to take a piece of equipment out of service until corrected, FDA believes that they must not be allowed to exist indefinitely. Therefore, § 900.12(e)(8)(ii)(B) requires that when tests in this group are failed, the problems must be evaluated and corrected within 30 days.

l. *Surveys (§ 900.12(e)(9))*

This paragraph required that a facility survey be performed by a medical physicist no less often than once a year. The tests and reviews that, at a minimum, were to be included in the survey were specified along with requirements that the medical physicist provide a survey report to the facility within 30 days of the survey. Identification of those who performed the survey was to be provided in the report.

(Comment 536). Two comments were received on § 900.12(e)(9)(i), which specified that the surveys should be conducted annually. One comment indicated confusion about the requirement by stating that an annual FDA inspection was not needed if a certified physicist conducted biannual surveys. The other comment asked that the requirement be modified to allow the annual surveys to take place in a year plus or minus a reasonable period.

FDA notes that an inspection is not a survey but rather is a check by an independent authority on how well the facility is meeting the requirements. An inspection and a survey serve different functions and are both required under the MQSA. Furthermore, the inspection does not duplicate the physicist's work. The inspection involves conducting only the tests that provide the most general picture of the equipment performance but also includes review of other aspects of the facilities performance such as personnel qualifications and reporting and recordkeeping practices, which are not considered by the physicist during the survey. Recognizing the unique characteristics of both the survey and the inspection, and the benefits of multiple oversight mechanisms, Congress required that each be conducted annually. Performance of more frequent surveys, semi-annually, e.g., does not eliminate the need for inspections. FDA has retained the requirement for an annual survey in accordance with 42 U.S.C. 263b(e)(1)(B)(iv). This requirement does not prohibit the facility from having a survey more frequently if it wishes. In response to the second comment, FDA notes that it has exercised its enforcement discretion under the interim regulations, and intends to continue to do so under the final regulations, to permit short periods of additional time beyond 12 months for the facility to obtain a survey under certain circumstances. The agency has done so in recognition of the difficulty that facilities that rely on contract physicists have in scheduling surveys. However, this exercise of enforcement discretion in a particular year is not intended to set a pattern that will permit facilities to impemissibly lengthen the timeframes between surveys to longer than annually.

(Comment 537). Several comments were received on the survey report required under § 900.12(e)(9)(iii). One comment recommended that a standard physicist report format should be required to facilitate review. Another stated that there should be provision for identification of units if the facility has more than one unit or has installed a new unit in an old room. A third comment stated that the report should include the calibration dates of the exposure measuring instruments.

FDA recognizes the advantages of a standardized report and in the past has encouraged the use of the report format recommended in the ACR quality assurance manuals. This format includes provision for identification of the unit being evaluated; such information has been and will continue to be implicitly required, because without it, the facility is unable to prove that a particular unit was included in the survey. FDA also believes that there has been a move towards standardization under the interim regulations because reports that inadequately provide the information needed during inspections have created extra work for facilities and physicists who must provide the information. This has led to improvements in later reports. However, while there are advantages to a standardized report, FDA also recognizes the need to allow flexibility in this respect to cover special situations and to permit the use of individual initiative in developing improved formats. The agency concludes, therefore, that it is both unnecessary and needlessly restrictive to require a specific report format by regulation.

Because the calibration requirement for exposure measuring instruments (§ 900.12(e)(12)) is a new requirement, this information has not been checked during inspections under the interim regulations. Because it is now a requirement under the final regulations, FDA expects that, in most cases, this information will be included in the survey report and that there is no need for a specific regulation requiring it to be there. However, if the facility wishes to provide the information in some other format, it will have the flexibility to do so.

(Comment 538). Four comments were related to the requirement of § 900.12(e)(9)(iv) that the report be provided to the facility within 30 days of the survey. One comment suggested shortening the interval to 2 weeks. Another stated that Massachusetts had found that a requirement that the facility's lead interpreting physician sign the report within 30 days had been effective in ensuring that the findings of the medical physicist were implemented. A third comment proposed that the deficiencies noted by the medical physicist be corrected within 1 month. The fourth comment urged that if the report is not received within 30 days, the facility be required to take the equipment out of service. This, it was believed, would stimulate the physicist to be timely.

FDA believes that a shorter time period would be unreasonable in situations where contract physicists might do several surveys in a several day trip before returning to his or her office to complete the reports. The agency also believes that it is common practice that before leaving the facility, the physicist gives a preliminary report to the facility staff, which would include identifying conditions that require prompt action. The new provisions of § 900.12(e)(8), which require correction of certain serious test failures before the failed equipment is used for further examinations, will further stimulate the provision of

preliminary reports. The agency continues to believe, therefore, that the 30-day timeframe is reasonable. With respect to the second and third comments, the agency believes that the new § 900.12(e)(8) adequately ensures that the more serious failures are corrected before the equipment is used again and that all identified problems are corrected within 30 days. A separate requirement is not needed here. With respect to the fourth comment, FDA believes that there is already sufficient incentive for the facility to make sure it receives its report within the 30 days without need for the drastic action suggested.

(Comment 539). The last comment on this paragraph endorsed the requirement in § 900.12(e)(v), that not only the physicist, but anyone who is performing part of the survey under the physicist's direct supervision be identified.

FDA retained this requirement when the regulations were codified.

m. *Mammography equipment evaluations (§ 900.12(e)(10))*

FDA proposed this provision to resolve several somewhat conflicting concerns. The basic goal was to ensure that newly installed equipment or equipment that had undergone major changes is tested for adequate performance by a qualified person before the equipment is used for examinations. However, this goal had to be achieved within the statutory limitations that provide for the issuance of provisional certificates prior to the completion of the survey and that require review of QC data as part of the survey. Such data cannot be generated unless the unit is in clinical use (42 U.S.C. 263b(c)(2)). The agency was also concerned about the costs that might be incurred by a facility that required two visits by the physicist, one visit for the original equipment check and the second for the full survey. There was also concern about the possibility of reduced access attributable to delays in putting the equipment into use due to inability to arrange for a visit by a physicist for some period of time.

Proposed § 900.12(e)(10) was an attempt to balance these conflicting concerns by requiring a mammography equipment evaluation of units or processors that were either new or had undergone major changes before those units were put to use in performing examinations. The evaluations were to be done by a qualified person, who could be a physicist or could be another individual, such as an installer or manufacturer's representative, and any problems found were to be corrected before the equipment was used clinically.

(Comment 540). One comment supported this paragraph as written, but 27 comments opposed allowing anyone but a medical physicist who met the requirements of § 900.12(a)(3) to perform the mammography equipment evaluation. NMQAAC also supported requiring that the physicist perform this evaluation.

In view of these comments, FDA has changed the wording to limit the performance of the mammography equipment evaluation to a medical physicist or someone under the direct supervision of a medical physicist. As noted above, this may mean a delay of some weeks in the use of the equipment at some facilities until a medical physicist can be scheduled for the evaluation. However, the agency has been persuaded by the unanimity of the public comments and the advice of NMQAAC that the benefits of having a medical physicist perform the evaluation outweighs the disadvantage of a possible delay. The agency also notes that by planning ahead, the facility may be able to minimize this delay.

(Comment 541). Several comments addressed the issue of the content of the mammography equipment evaluation. Two comments urged that this be a complete survey but a third noted that the equipment would have to be in use for a period of time before the complete evaluation could be done. Four other comments suggested some specific tests to be included in the evaluation, but two more comments recommended leaving the decision about necessary testing to the person doing the testing.

As noted above, the MQSA provisions relating to provisional certificates and the physical impossibility of checking QC data before the equipment is put into use preclude the possibility that the mammography equipment evaluation can be the full survey required by the statute. Although the agency agrees that it may be beneficial to do a variety of tests at the time of the equipment evaluation, it does not intend to designate particular tests in the regulations. The revised provision simply requires that the evaluations determine if the new or changed equipment meets the applicable requirements of § 900.12(b) and (e), thereby focusing on the primary public health concern, which is to establish that units are not put into clinical use without proper testing. This more general wording, the agency believes, also eliminates the need to consider processors and mammography units separately with respect to this evaluation, as suggested by six comments.

Related to the content of the mammography equipment evaluation is FDA's concern, mentioned earlier, about the expense to the facility if two physicist visits are required, one for a mammography equipment evaluation and another, later, for the survey. The agency's original efforts to reduce costs was its proposal to permit the mammography equipment evaluation to be performed by qualified individuals other than physicists. The revised final regulations eliminate this possibility. In a different approach to limiting costs to the facility, FDA plans to permit the initial survey of the new or changed equipment to be done in two stages. The first stage, the mammography equipment evaluation, will obviously require a facility visit by the physicist. If the facility and physicist can cooperate to produce adequate documents, FDA will permit the second stage, the review of the QC data after it is available, to be done by mail. Presumably, this will cost the facility less than two onsite visits to the facility by the physicist. The agency stresses that this two-stage process is intended to help contain costs associated with a facility's initial survey of new or changed equipment and is entirely optional and within the discretion of the facility and its physicist. The agency will require subsequent annual surveys of that equipment to be done at one time through an onsite visit.

The proposal required a mammography equipment evaluation for new equipment and also after major components of the equipment were changed. FDA specifically asked for comments on what should be considered to be ''major components'' but received relatively few responses.

(Comment 542). One comment suggested processor rollers in the case of the processor. For the X-ray unit, two comments suggested the X-ray tube and one of these went on to add the bucky, the screen-film system, and the photo-timing system. Two comments also suggested changes in the ventilation system because such changes can cause major artifact problems. Another comment simply suggested that repairs by service personnel should require testing.

FDA found these suggestions useful and will take them into account in determining what constitutes a major component. With respect to the regulations themselves, in view of the limited number of comments, the agency decided to continue to keep the wording general.

(Comment 543). One comment opposed the entire idea of a mammography equipment evaluation before the equipment was put into use, stating that it would only increase the cost of installation. Another comment, however, strongly supported the correction of all problems before any equipment was put into use. FDA agrees that there will be some cost associated with mammography equipment evaluations, but believes that the dangers inherit in permitting the use of untested equipment in patient examinations more than justifies this requirement. Therefore, the agency has retained the requirement in the final rules and clarified that the evaluation is also required for new and reassembled equipment, or whenever a major component is changed or repaired.

n. *Facility cleanliness (§ 900.12(e)(11))*

This proposed paragraph required the facility to establish and implement protocols for maintaining darkroom, screen, and view box cleanliness and to document that the protocols were followed.

(Comment 544). Six comments stressed the importance of darkroom, screen, and view box cleanliness, primarily because of the likelihood that dirty conditions will lead to artifacts. Three comments took the opposite position, stating that the section should be deleted due to lack of evidence of a hazard. Seven comments urged FDA to go further and establish protocols for cleaning in the regulations. On the other hand, 13 identical comments questioned whether it would be possible for FDA to establish regulations on cleanliness.

FDA believes that proper standards of cleanliness contribute to quality mammography; e.g., they do reduce undesirable effects associated with artifacts. However, as the agency stated in the preamble to the proposed regulations, there are a variety of cleaning protocols and a variety of circumstances affecting the cleaning needs of a facility. FDA continues to believe that facilities must be given the flexibility to establish cleaning protocols that best fit their needs. The presence and use of such protocols can easily be determined during inspections and their effectiveness, or lack thereof, will be demonstrated by the results of the QC tests, such as the artifact test.

(Comment 545). Six comments stated that FDA was paying attention to disinfecting the equipment but not to screen cleanliness, apparently a reference to § 900.12(e)(13), discussed below.

FDA disagrees with these comments and believes that adequate attention has been paid to both areas. The agency also notes that the infection control requirements will also address the concerns raised by the comment, which stated that cleanliness requirements for bucky and compression paddle and examination room cleanliness should be added.

o. *Calibration of air kerma (exposure) measuring instruments (§ 900.12(e)(12))*

This paragraph, as proposed, required calibration of the instruments used by medical physicists in their annual surveys to measure exposure, at least annually. Ten years after publication of the regulation, additional requirements would have to be met by those doing the calibration.

(Comment 546). Numerous comments urged FDA to change the required frequency of calibration to once every 2 years. A few comments opposed the requirement entirely, while others suggested calibration more frequently than annually. In response to these comments, FDA changed the required frequency to once every 2 years as a normal practice, but also retained the requirement for calibration after a repair of the instrument.

As discussed in connection with the definitions of kerma and air kerma, the agency has also introduced the quantity of air kerma into this rule in accordance with the move towards use of SI units. Also in accordance with the agency cost concerns discussed earlier, the requirements proposed in § 900.12(e)(12)(ii) to be phased-in over 10 years have been eliminated.

p. *Infection control (§ 900.12(e)(13))*

This paragraph was proposed in recognition of the fact that, while transfer of disease caused by blood borne pathogens during mammography has never been reported, it is theoretically possible. Therefore, the agency concluded that appropriate precautions should be taken. Because FDA believes that this concern is not unique to mammography, it did not propose specific requirements for mammography equipment but stated instead that the facility should follow the general requirements for infection control related to medical devices.

(Comment 547). Seven comments opposed this requirement. Reasons given included that it was redundant, unnecessary, and time-consuming; would create needless paperwork; and did not deal with a radiation control problem. Two comments, however, urged additional measures, such as requiring informed consent and the use of protective covers. Another comment warned that any material placed between the breast and the image receptor would cause increased dose and degradation of image quality.

FDA believes that the comments do not provide convincing arguments for a change in the agency's position in either direction. The agency continues to believe that at least a theoretical concern about disease transmission exists and that the best way to deal with this concern is to address it as part of infection control procedures to be followed during the use of medical devices in general.

6. Quality Assurance-Mammography Medical Outcomes Audit (§ 900.12(f))

This paragraph requires that every mammography facility establish and maintain a mammography medical outcomes audit program for followup on mammographic assessments and correlation of pathology results with the interpreting physician's recommendations. This program should be designed to ensure the reliability, validity, and accuracy of interpretation of mammograms.

a. *General comments on medical outcomes audit*

(Comment 548). A single comment was received on the general difficulty in conducting a medical outcomes audit faced by facilities that rely on contract interpreting physicians. Specifically, the comment noted that there would be a higher potential for bias in medical outcomes audits conducted for small facilities that employed a relatively greater number of interpreting physicians.

FDA disagrees that the use of a number of contract interpreting radiologists will necessarily result in biases in medical outcomes data. Data should be calculated both for the aggregate facility data base of patients and again for each interpreting physician. Because the data are to be calculated for individual physicians, any particular set of data that represents unusual or anomalous results will be readily identified and additional calculations can be performed by the facility to project average outcomes without that outlying data. The benefit of tracking these results, therefore, includes the ability to identify problems and find trends. The facility will be required to designate a reviewing interpreting physician to review these data and to notify all interpreting physicians, including contract interpreting radiologists, of both aggregate and individual results. Such analyses may require followup actions, which are to be documented by the reviewing interpreting physician.

b. *Confidentiality*

The issue of maintaining confidentiality of medical outcomes audit information collected by the

facility during its mammography medical outcomes audit was a highly controversial area and generated a diverse number of comments. Five comments stated that FDA should collect audit results and publish the information in aggregate form for the public's information. Two additional comments argued that interpreting physician performance data should be made available to any third party or examinee.

On the other hand, 25 comments urged that FDA ensure confidentiality of medical outcomes audit data either through Federal legislation or under the MQSA. Thirteen comments sought to protect the data by making it available only for internal purposes and restricting its submission to FDA and other agencies. One respondent expressed concerns relating to the use of data by third parties, such as facilities, radiologists, and patients. The comment went on to say that, in the instance of a law suit, all such information would be subpoenaed. Five comments stated that due to lack of common definitions and public understanding of the statistics most likely to be captured in the medical outcomes audit, such data should not be made available to any person not affiliated with the facility. Nine other comments agreed that medical audit data should not be shared with others outside the facility, even though they agreed that valuable use can be made of the medical audit within the facility in assessing the accuracy of interpretations. Two comments argued that, unless false negative cases are required to be included in the medical outcomes audit and also protected from discovery, there will be incentives to conduct poor quality audits. Finally, one comment stated that medical outcomes audit requirements inevitably will increase third-party requests for medical audit data in order to select providers.

FDA recognizes the very sensitive nature of the issue of confidentiality of mammography medical outcomes audit data. Under the final regulations, there are no requirements for dissemination or reporting of the data to public bodies or other agencies, including FDA. There is, however, a requirement that each facility establish and maintain a system to conduct followup and make that system available for review by the inspector. Followup is required for all positive mammograms and for those patients who are known to have developed breast cancer after having had a mammogram at the facility. There is also a requirement for internal facility review of these data. FDA believes these regulations ensure the establishment and use of medical outcomes audit data to help protect the public health without necessarily jeopardizing the confidentiality of such data or the incentives facilities and practitioners have to use these data to improve performance. Future regulations are possible in this area.

(Comment 549). Fifteen comments wondered if radiologists could refuse to allow an inspector to copy audit data in addition to visually reviewing it. As discussed previously, FDA does not intend to have inspectors obtain photocopies of medical outcomes audit information. The agency is requiring inspectors only to verify that systems are in place for the facility's use as part of a quality assurance program (see earlier discussion in the preamble to the proposal at 61 FR 14875).

c. *General requirements (§ 900.12(f)(1))*

This paragraph requires facilities to establish and maintain a system for collection and review of outcome data and correlation of pathology results with initial mammographic results. The active collection and followup of data are to focus on positive mammograms with correlation between pathology results and interpreting physician's initial mammographic interpretation.

(Comment 550). Overall the comments about this paragraph were generally positive. Eight comments stated that the requirement would be beneficial to mammography facilities and staff. A small number of comments advocated that followup data be collected for all abnormal mammograms, including those requiring additional imaging before a final mammographic interpretation can be made.

FDA notes that the current language of the final regulations states that a system is to be in place to collect and review outcome data for all mammograms with required followup for positive mammograms. Although followup is required only for positive mammograms, facilities that wish to follow all their cases are encouraged to do so. Future MQSA regulations may include such a requirement for broader followup, including for those mammograms requiring additional imaging before determination of a final mammographic result.

Followup for patients with abnormal mammographic results has been conducted successfully by several different groups, including the National Cancer Institute Breast Cancer Surveillance Consortium, CDC, individual groups of radiologists, and on a statewide basis in Colorado. Followup for all patients with abnormal mammographic results, or symptomatic for breast cancer, or requiring additional imaging studies was successfully accomplished in Colorado through the Colorado Mammography Advocacy Project (CMAP).

As mentioned previously under the discussion on the use of the mammography medical outcomes audit as an alternative approach to design and process-based regulations, the National Cancer Institute's Breast Cancer Surveillance Consortium has also established a major research project to understand the full effect of breast cancer screening on cancer outcomes. Data on breast cancer screening practices from nine sites across the country are being linked to population-based cancer registries. By 2000, the database will contain information on nearly 3.2 million mammographic examinations and over 24, 000 cases of breast cancer. Standardized procedures and tools were created and are being tested by the surveillance consortium that will assist mammography facilities in data collection and auditing. Results and outcomes of the consortium will help establish performance standards for mammography and FDA will evaluate these for appropriateness for future standards under MQSA.

CMAP is a centralized data management system that conducted followup for all women with abnormal mammograms and women with symptoms of breast changes. CMAP also prompts return for regular rescreening through a series of reminder letters to women and their physicians. This system involves voluntary participation of mammography centers, with most facilities in the greater Denver metropolitan area participating. CMAP services were also offered to some or all patients outside of the metropolitan region. The same tracking and followup and screening reminder methods were used at these facilities as for those in the Denver metropolitan area. Data collection for individual patients, facilities, radiologists, surgeons, and referring physicians is governed by stringent standards for confidentiality. During the 8 years of operation of CMAP, the Program ensured that there were no breaches in confidentiality protocols. Followup includes collection of all information about diagnostic procedures performed to evaluate mammographic abnormalities. Currently, CMAP is tracking more than 200,000 women and more than 300,000 mammograms with approximately 3 percent falling into the ''positive'' category based on radiologists' mammographic interpretation. The system has documented screening

compliance rates in excess of 85 percent and improved outcomes associated with the diagnosis of breast cancer. Specifically, women tracked by CMAP and diagnosed with breast cancer had smaller tumor sizes and earlier stages at detection when compared to a cohort of women with breast cancer who had not received the level of tracking and followup performed by CMAP.

(Comment 551). Twelve respondents supported the FDA requirement for collection of outcomes data, but requested that FDA establish guidelines for the content of the audit and the audit process in order to ensure comparability of medical outcomes data. In contrast, three comments supported the current FDA position to establish only very general requirements for the medical outcomes audit.

In the absence of any consensus standards for either mammography outcomes or data collection methods, FDA has chosen to defer proposing these parameters and methods until more research has been completed and clear guidelines can be formulated for mammography centers.

Despite the general support for the medical outcomes audit, 28 comments expressed concerns that there is no consensus on measures of mammographic efficacy. As discussed above, FDA acknowledges the lack of substantive research on appropriate and accurate measures to assess accuracy of mammographic interpretation and, therefore, has not required specific data to be collected for the medical outcomes audit. Instead, the agency has established a general requirement that mammography facilities have a system in place to collect and review outcome data for all mammograms. Followup is mandatory only for positive mammograms and for patients who were previously screened at a facility and were subsequently found by that facility to be diagnosed with breast cancer.

In addition, the same 28 comments maintained that there was no evidence that performance feedback about mammography outcomes affected the quality of care. In fact, however, the agency notes that there are several articles in peer-reviewed journals indicating that performance feedback is an effective strategy to issue positive behavior change (Ref. 3).

(Comment 552). Many comments expressed concern about the impact on audit results of serving diverse populations of patients. It was recommended that FDA keep such variations in mind when more clearly defined medical outcome standards are established in the future.

FDA acknowledges the importance of this point and will take population diversity into account in the future development of more specific audit parameters.

(Comment 553). Three comments stated that the medical outcomes audit requirement emphasized detection of false positives and expressed the opinion that this was a meaningless outcome. Three more stated that the most important measure was the rate of false negatives.

FDA notes that the final regulations do not require reporting of either false negatives or false positives. The emphasis is on collecting followup data for all patients with positive mammographic findings and for patients who received mammography at a facility and were later determined to have breast cancer. Such followup may yield a number of statistics, including false negatives and false positives.

NMQAAC has suggested that FDA provide reference articles to which facilities could refer if they wanted to compare their own statistics with those of other practices. FDA supports this type of educational outreach and intends to list such references in *Mammography Matters* as they become available. NMQAAC also noted that future revisions of the regulations may require specific performance standards to be issued for mammography once scientific evidence supports such performance standards. The agency agrees that such future developments are possible. However, the current regulation requires followup only for patients with positive mammograms as defined by the assessment categories of ''suspicious'' and ''highly suggestive of malignancy'' and for patients who received mammography at a facility and were later determined to have breast cancer.

(Comment 554). Twenty-seven comments expressed concerns about burdens imposed by the FDA requirement for medical outcomes audit. The burdens included both financial costs of conducting the audit and concerns about staff time to collect the outcomes data. A subset of these comments specifically cited costs associated with the need for sophisticated computerized systems and an increase in clerical staff in order to accomplish the amount of followup required by the regulation.

FDA notes that the number of patients requiring followup (i.e., those mammograms assessed as ''highly suggestive of malignancy'' or ''suspicious'') should be relatively small compared to the general population of women screened at a given mammography facility. In fact, data from CMAP and the other programs cited above suggests that an average of 3.0 percent to 5.0 percent of the total population of patients receiving mammograms at a facility will require active followup. While FDA recognizes that there may be some increase in costs associated with staff time to conduct such followup for all positive mammograms and patients subsequently diagnosed with breast cancer, the benefits of followup are considered to outweigh the costs. In addition, the small number of patients requiring intense followup will not place an undue burden on an individual mammography facility when it is measured against the education and experience acquired by facility personnel. The information gained by staff has been shown to have a positive impact on interpretation skill. Feedback about patients with positive mammograms is extremely important information for both radiologists and technologists. Finally, it was the general consensus of the members of NMQAAC that the benefits of medical outcomes outweighed the costs, especially when one considers the small number of cases the current regulations will affect and data from centralized mammography tracking systems, such as the CMAP, which indicated that costs of followup can be minimized. One Committee member also noted that such followup actions could reduce costs associated with medical liability actions.

(Comment 555). Sixteen comments assumed that the medical outcomes audit would require computerized systems and more clerical help, thereby resulting in increased costs.

FDA notes that a computerized tracking system is not required by the final regulations. In fact, many facilities rely on a manual notecard tickler file to ensure appropriate and timely followup for eligible patients. Some facilities have joined a consortium of mammography centers where followup can be accomplished by a centralized data collection effort. Centralization of followup was designed and implemented very successfully for CMAP, with significant economic benefits and opportunities for data comparisons between one facility and the aggregate of all participating facilities. Utilization of unique identification numbers for patient, facility, referring physician, radiologist, and surgeon preserved confidentiality. Information on the type of data to collect and methods of data collection and interpretation will be forthcoming from FDA.

(Comment 556). Three comments asserted that the responsibility for followup should remain with the surgeon and/or referring physician.

FDA agrees that followup by the referring physician or surgeon may well be the most effective way to communicate with patients and collect outcome data. However, the agency's authority under the MQSA is focused on mammography facilities. FDA cannot establish audit or followup requirements for physicians who do not work as interpreting physicians in mammography facilities.

(Comment 557). One comment suggested that certified facilities be required to share patient outcome data with other certified facilities, especially if that information is necessary in order to complete the medical outcomes audit.

FDA has no evidence at this time that facilities are unwilling to share followup information with other facilities that have treated their patients. Upon implementation of the final regulations, FDA will monitor this cooperation and determine if there is a need for such a requirement in subsequent regulations.

It was requested that FDA define 'correlation' of mammographic results with pathology results. FDA has addressed this in the comments on § 900.2(bb) of the final regulations.

d. *Data collection (§ 900.12(f)(2))*

(Comment 558). This provision requires that data be collected on an ongoing basis for at least all patients with positive mammograms. The majority of the comments related to this paragraph suggested that the regulations require surgeons, referring physicians, and/or pathology laboratories to submit outcomes data to the mammography facility rather than requiring proactive followup by the facility for all positive mammograms.

FDA agrees that such reporting would facilitate the efficient collection of accurate outcomes data. FDA has taken actions to encourage other medical entities to voluntarily provide this data (Journal of the American Medical Association, 1995), but as noted above, FDA's authority under the MQSA focuses on mammography facilities. FDA cannot require other entities or health care practitioners to collect data and forward it to mammography facilities.

(Comment 559). One comment stated that it ''was not right to force a physician to file statistics with FDA just for statistics sake.''

FDA believes that it is important to point out that the final regulations do not require reporting of any medical outcomes audit statistics to FDA. If such requirements are established in the future, it would only be because it was justified by public health benefits and not ''just for statistics sake.''

(Comment 560). A number of comments raised concerns about the medical-legal implications of collecting outcomes data and some of these urged FDA to mandate audit protection for every facility in every state. Concerns were raised that the data could be subject to subpoena, used against facilities in malpractice claims, or evaluated by third-party payers to award contracts. Discussion among members of NMQAAC, on the other hand, indicated that collection and review of data does result in improved breast cancer detection outcomes and can also serve to protect a facility in the instance of a legal claim.

Although State laws on protection of medical audit data do vary, FDA believes such information is protected from use against facilities or physicians in the majority of cases. The Committee supported the regulations as they are currently written. As stated previously, the regulations only require that a system be in place to conduct followup and that such followup would be required for all positive mammograms. The regulations do not require disclosure of any outcomes data to FDA or any other entity outside the facility. The agency has concluded that the final regulations strike the proper balance because the benefit of audits in improving accuracy of interpretation outweigh concerns about forced disclosure to third parties.

e. *Frequency of audit analysis (§ 900.12(f)(3))*

This paragraph establishes guidelines for the frequency of the medical outcomes audit.

(Comment 561). The majority of comments relevant to this point supported an annual audit of medical outcomes, but also recommended that the audit period end 6 to 12 months prior to the date of the audit in order to ensure collection of complete patient information. FDA recognizes the need for adequate time to elapse in order to collect all relevant data. In response to the comments, the provision was amended to clarify that the audit analysis may be completed up to 12 months following the close of the audit period. This additional time for completion of followup was supported by NMQAAC. However, because the requirement is to do an annual audit, a subsequent audit period will be in effect during the time the facility completes followup for the previous medical outcomes audit period.

Comments also recommended requiring quarterly review of audit data by interpreting physicians. FDA established the requirement for annual review of these data in order to maximize the number of cases eligible for followup and data analysis. Facilities are free to review their audit data at more frequent intervals if that is useful or desirable for that practice. FDA notes, however, that quarterly audit review may not yield sufficient numbers of cases for performance of valid statistical analyses.

Finally, one comment asked what was meant by individually and collectively' for review of medical outcomes audit data. FDA has revised the provision to clarify that the medical outcomes audit data is to be evaluated by the reviewing interpreting physician for the entire facility and for each individual radiologist reading mammograms for the facility.

f. *Reviewing interpreting physician (§ 900.12(f)(4))*

This paragraph requires that each mammography facility designate at least one interpreting physician to review medical outcomes audit data at least annually. This individual will also be responsible for analyzing results and identifying issues based on these results and recording any followup actions.

(Comment 562). Eight comments expressed concerns about the utility and feasibility of conducting medical outcomes audit reviews for individual physicians. These comments reasoned that the numbers would be so small that findings would not be of practical or statistical significance, and that such analyses would also be resource intensive.

FDA acknowledges these concerns, but expects that, over time, adequate data will be available for individual interpreting physicians that will become meaningful and will allow tests of statistical significance.

(Comment 563). Five comments supported the proposal to include 'taking corrective action and documenting such actions' in the requirement, while two others argued that this would not always be possible.

Review of these comments and discussions with NMQAAC prompted FDA to change the wording to recognize that the reviewing interpreting physician may not always have authority to institute corrective actions. As revised, the proposed regulation requires the reviewing interpreting physician to document what, if any, followup actions were taken following review of the individual and aggregate medical outcomes audit data.

(Comment 564). Nine comments noted that facility performance monitoring and corrective actions were not defined in the regulations and, therefore, this provision is unclear.

FDA agrees and has deleted these terms in revising the language of this provision.

(Comment 565). Finally, one comment recommended that the reviewing interpreting physician should also be the individual responsible for overall facility quality assurance.

FDA does not believe that this dual role is necessary or beneficial for every facility, e.g., a physician who is best suited for responsibility over audits may not be onsite sufficiently often to also be responsible for overall quality assurance. Although the final rule would permit a facility to designate the same person for both responsibilities, it is not required.

7. Mammographic Procedure and Techniques for Mammography of Patients With Breast Implants (§ 900.12(g))

This paragraph implements the MQSA provisions that require FDA to establish ''standards related to special techniques for mammography of patients with breast implants'' (42 U.S.C. 263b(f)(1)(H)).

a. *Breast implant inquiries (§ 900.12(g)(1))*

As proposed, this paragraph required each facility to have in place a procedure to inquire if an examinee has a breast implant at the time of mammography scheduling.

(Comment 566). More than 110 comments opposed making this inquiry at the time of scheduling. Reasons for the opposition included: privacy concerns of the patient, the fact that the patient may not be the person scheduling the examination, and the belief that the best way to obtain this information is by having the technologist question the patient at the time of the examination. Eleven comments supported this requirement, reasoning that this would aid in efficient scheduling and urged FDA to publicize the need for implant patients to inform the facility of their situation at the time of making an appointment.

After reviewing all comments and discussing this issue with NMQAAC, FDA has revised § 900.12(g)(1) to require all facilities to have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic examination, but not necessarily at the time of scheduling. Those facilities that believe it is important to identify breast implant patients at the time of scheduling, in order for the facility to allot the correct amount of time for the study, are free to do so. The comments indicate that many facilities will choose to use the patient questionnaire to obtain this information or have the technologist question the patient prior to the examination.

(Comment 567). Several comments stated that facilities should have the option of referring breast implant patients to facilities where such examinations are done regularly.

FDA agrees with these comments and notes that there are no regulations requiring facilities to perform studies on patients with implants. For those facilities electing not to perform mammography on patients with breast implants, FDA strongly recommends that they develop a mechanism to inform referring physicians and patients of this fact. This will decrease the chances of such patients arriving at a facility that does not ordinarily perform breast implant studies.

(Comment 568). Two comments suggested establishing a minimum volume for these types of examinations in order to concentrate them at facilities that are the best for this purpose.

FDA recognizes that increased experience with imaging patients with breast implants is likely to develop expertise. However, the agency believes that it is in the best interest of all concerned to have high quality mammography performed in as many facilities as possible. It is possible that one technologist at a particular facility may have had additional training in techniques for imaging such patients and be able to do excellent examinations despite relatively low numbers of such patients. It is not the intent of the MQSA to arbitrarily restrict access to mammography services.

b. *Maximizing the visualization of breast tissue for patients with implants (§ 900.12(g)(2))*

This paragraph requires that patients with breast implants undergoing mammography have mammographic views to maximize the visualization of breast tissue, except where contraindicated or modified by a physician's directions.

(Comment 569). Nine comments stated that it is important to take additional and specialized views of the implanted breast in order to achieve maximum visualization of tissue. The authors asserted that a minimum standard, such as requiring Eklund views, should be set. One contradictory comment stated that requiring mandatory views would cause unnecessary irradiation because not every implant can be displaced as in the Eklund procedure.

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. The agency and the committee also recognize that other methods may exist that would be preferable in particular cases. Because breast implant imaging is evolving, the agency believes that it would be premature to limit, by regulation, this imaging to only one technique. FDA does not believe that this regulation, as written, will result in unnecessary irradiation of patients because it allows facilities to customize the study to the individual patient.

NMQAAC recommended deleting the phrase ''and optimize breast cancer detection'' as being redundant. FDA agrees and has deleted the phrase from the final provision.

c. *Onsite supervision of mammograms of patients with breast implants (§ 900.12(g)(3))*

FDA received almost 300 comments opposing this proposal, which would have required that mammograms of patients with breast implants be supervised by an onsite interpreting physician. Reasons for the opposition included: Severe scheduling and access problems if an interpreting physician had to be present, no demonstrated medical need for an onsite physician, and the belief that technologists are capable of performing implant examinations without the supervision of an interpreting physician. Four comments supported the section as proposed, stating that it was important to have an interpreting physician onsite to check the quality of the images.

FDA has been persuaded by the comments and subsequent discussions with NMQAAC that requiring an onsite interpreting physician would result in a decrease in access to high quality mammography services for women with breast implants without a significant improvement in the quality of care. Therefore, FDA has deleted this provision.

8. Consumer Complaint Mechanism—Facility Standard (§ 900.12(h)) and Accreditation Body Standard (§ 900.4(g))

These paragraphs, as proposed, establish a process for facilities and accreditation bodies to collect and resolve serious consumer complaints. It provides patients with a mechanism to report what they believe to be seriously deficient mammography services and gives them the opportunity to have their complaints heard, investigated, and resolved.

Section 900.12(h), under facility standards, establishes requirements for facilities with respect to collecting and resolving serious consumer complaints, while § 900.4(g), under accreditation body standards, establishes requirements for actions that accreditation bodies must take to resolve consumer complaints referred to them.

Many of those who commented on the proposed regulations seemed unaware that different aspects of the complaint mechanism were addressed in these two separate paragraphs, and unaware that both sections should be read with reference to the definitions section of the regulations at § 900.2. Because the comments on these separate provisions tended to be similar, and in order to help illustrate the connection between them, FDA concluded that it would be most efficient to address public comments on the complaint mechanism sections of the proposed regulations as a group.

As the consumer representatives on NMQAAC noted, of all of the comments on the complaint mechanism, only two were from consumers. Almost all of the comments were from representatives of mammography facilities.

(Comment 570). Several comments agreed with FDA that facilities should have the flexibility to develop their own complaint mechanism and institute their own procedures for response and resolution. One comment supported the requirement that facilities develop a system for collecting and resolving serious complaints about mammography services and the proposed definition of serious complaints. Two comments, including one from a breast cancer advocacy organization, expressed support for the consumer complaint provision that FDA proposed.

One comment noted concern that there is no rule requiring feedback by facilities to FDA about an accreditation body. The comment suggested that FDA implement a communication mechanism for facilities to register complaints/comments with FDA about the accreditation body. The comment recommended that the mechanism guarantee followup, similar to the provision establishing a consumer complaint mechanism.

FDA believes mechanisms for facility feedback to FDA already exist. Facilities that wish to comment about accreditation bodies may contact FDA's DMQRP (address above) and will receive a response. In addition, the statutory requirement for FDA to audit the performance of accreditation bodies through inspections of selected facilities establishes additional opportunities for review and feedback.

(Comment 571). Two comments discussed the manner in which accreditation bodies might implement the complaint resolution process. One suggested that serious consumer complaints should be handled by an ACR Peer Review process. Another suggested that accreditation bodies could form boards to receive unresolved serious complaints.

FDA notes that the final regulations prescribe no particular method for accreditation bodies to use, believing that flexibility will permit each accreditation body to establish a system that works best for the facilities it accredits and the patients they serve. Establishing specific groups to review unresolved complaints is one acceptable method for fulfilling this requirement.

(Comment 572). One comment recommended that, because accreditation bodies have no enforcement authority other than to revoke or deny accreditation, FDA or the State certifying entity should retain authority to investigate consumer complaints.

In response, FDA notes that nothing in the MQSA or the regulations precludes FDA or a State from investigating complaints. However, the agency believes consumer complaints will be addressed most effectively and efficiently by a three-tiered approach. First, the complaint should be registered at the facility, where there is the greatest chance for resolution. Second, serious complaints that have not been resolved at the facility should be directed to the accreditation body. And, third, the accreditation body can forward serious complaints to FDA. Although consumers may choose to complain to the facility, the accreditation body, or FDA, the intent of these mechanisms is to resolve difficulties quickly at the level closest to the consumer.

(Comment 573). One comment suggested a name change for the consumer complaint mechanism. The author supported the proposed requirement, but preferred the use of either ''consumer comment mechanism,'' or ''consumer feedback mechanism'' to encourage feedback on positive mammography experience(s).

FDA and members of NMQAAC agree that the term ''complaint'' has negative connotations and may not encourage well-deserved positive comments. The statute, however, requires FDA and NMQAAC to develop a mechanism for the investigation of ''consumer complaints.'' Consequently, FDA adhered to the terminology in the statute.

(Comment 574). FDA received seven comments requesting additional guidance and detail about consumer complaint procedures. Five comments suggested that guidance documents be made available for facilities to follow in generating their system for collecting and resolving complaints, including directions for consumers who wish to file a complaint with the facility's accreditation body. One comment suggested that FDA develop a standardized plan, with appropriate forms to review and evaluate each facility's consumer complaints. One comment supported the proposed definition of a serious complaint, but noted that most complaints deal with Medicare and insurance reimbursements, or lack thereof.

FDA agrees that additional information will be helpful and members of NMQAAC have also strongly recommended that guidance be developed. The agency plans to develop such documents for facilities and consumers.

In reference to discussions in the proposal about cultural considerations, one comment noted that facilities cannot reasonably be expected to develop complaint procedures for all possible language, ethnic, and literacy backgrounds. FDA agrees that to require facilities to make such provisions would pose an undue burden. However, the agency encourages facilities to design their complaint mechanism procedures to be responsive to the particular needs of consumers they serve.

(Comment 575). Fourteen comments stated that the required consumer complaint mechanism increases costs.

FDA believes that the requirements for the complaint mechanism are minimal. Preliminary estimates indicate that the costs for establishing and implementing a system are not significant and that many facilities already have such systems in place. In addition, costs of establishing and implementing such systems are likely to be outweighed by the benefits to the facility resulting from better patient relations, enhanced reputation, and avoidance of costs related to unresolved complaints that may lead to litigation.

(Comment 576). Several comments expressed concern that some consumer complaints could unfairly jeopardize facilities and particular employees. These comments hypothesized a variety of situations: A facility's certification could be threatened by an examinee bent on vengeance (for example, if a false negative mammogram and an error in interpretation constitute serious complaints); certain employees could be singled out any time a complaint is

referred to a higher authority (the accreditation body); the technologist could be falsely accused of a myriad of issues pertaining to patient care. Another comment interpreted the proposed regulation to mean that patients with complaints must be contacted for their opinion on whether the facility's solutions are acceptable to them.

FDA foresees some situations in which a facility's certification may be threatened as a result of consumer complaints. For example, if serious complaints have been continuously ignored or left unresolved by the accreditation body or the facility, subsequent FDA investigations may demonstrate that the facility is unable or unwilling to comply with the MQSA standards. The agency is confident, however, that most facilities will make a sincere and effective effort to respond to valid complaints and does not expect that it will be necessary to consider suspending or revoking certificates for this reason, except in rare cases. In reference to concerns about personnel being unjustly accused, FDA notes that technologists are not ordinarily designated as the individuals responsible for the facility's management and operation. To the extent consumer complaints lead to improvement in performance of individual personnel, the quality of mammography is improved at that facility. With respect to the need to contact consumers about resolution of complaints, the agency believes such communication is a necessary part of resolving a complaint. If consumers believe the facility's solutions are unacceptable, they may contact the accreditation body or FDA, who will try to resolve the issue on a case-by-case basis.

(Comment 577). Seven comments noted their objection to additional policies and procedures for a consumer complaint mechanism. One comment noted that a mandatory facility complaint mechanism is superfluous because effective resolution of patients' complaints is already a component of proper patient care. Another comment noted that each facility can develop its own consumer complaint plan without any guidelines from the MQSA. Fourteen comments suggested that FDA simply accept the policies and procedures for mammography consumer complaints that are currently in use at each facility. If no policy and procedures are in place, the facility should establish one.

FDA agrees that, for the majority of facilities, effective resolution of patient complaints is already a component of proper patient care. In fact, under the interim rules, facilities are required to post an address where complaints can be filed with accreditation bodies, and maintain records of all complaints registered at the facilities. The requirements in the final regulations, therefore, should present little additional burden. Those facilities that already have procedures in place are unlikely to have to make any significant changes. Only facilities that do not have a system in place will be required to make any significant investment of resources. As discussed above, procedures are likely to benefit both the public health and the individual facility.

(Comment 578). One comment suggested that the facility should have the option to ignore a consumer complaint. This comment stated that facilities should be encouraged to handle complaints, but not required to do so.

Under the final regulations, a facility must establish a written and documented system for collecting and resolving consumer complaints. That system may include varying degrees of responsiveness to different kinds of complaints. A complaint about the temperature of the waiting room may be handled differently than a complaint about failure to receive notification of examination results. There may be certain types of complaints under its system that a facility decides do not merit additional resources beyond a verbal acknowledgment or response. However, the system must include a mechanism to provide consumers with a way to register serious complaints with the accreditation body. The consumer can use that information to take serious complaints to the accreditation body and inform the accreditation body that the facility made no attempt to resolve the complaint.

(Comment 579). One comment applauded the consumer complaint mechanism in theory, but questioned the wisdom of permitting the facility to determine whether the complaint is serious. The comment stated that facilities should be required to record all complaints and provide all consumers with directions for filing complaints with the facility's accrediting and/or licensing body. FDA does not believe that the facility independently determines whether the complaint is serious because the definitions of ''serious complaint,'' ''serious adverse event,'' and ''adverse event'' (see § 900.2) are the basis for such decisionmaking. Also, if consumers are not satisfied with the complaint resolution, they may complain directly to the accreditation body. A facility's system may require that records be kept for all complaints and that consumers be provided with directions for filing all complaints with the accreditation body if they choose to do so. However, tracking and providing the consumer with instructions about how to file a complaint with the accreditation body are required under the regulations only for serious complaints.

Nine comments recommended that all complaints should be handled on an individual basis at each facility, and that recordkeeping should be based on the protocol for that facility. Two comments noted the additional amount of paperwork the consumer complaint mechanism would generate, and one of these noted the possibility that facilities would be open to liability because of this mechanism.

FDA agrees that all complaints should be handled at the facility if possible, and that recordkeeping procedures can vary with each facility and each complaint, so long as tracking and accreditation body notification are established for serious complaints. If satisfactory resolution of the complaint cannot be achieved at the facility level, however, the consumer must have the option of taking the complaint to another level. In response to the concern about generation of paperwork, FDA notes that the requirement to track complaints has been in effect under the interim regulations since 1993 without any feedback indicating excessive paperwork. As to concerns for additional liability, the agency and members of NMQAAC have both noted that records that are required to be tracked are more likely to help facilities document that they responded to and resolved complaints. In addition, effective consumer complaint mechanisms allow facilities to identify problems and improve the quality of their services.

(Comment 580). One comment advocated that some safeguard addressing confidentially should be implemented before this and similar recordkeeping requirements are retained in the final regulations. FDA notes that consumer complaints are part of patient records and will be handled by facilities with the same care as other records relative to patients. Accreditation bodies are required to protect nonpublic information they receive from facilities and will not further disclose such information. FDA's public information regulations prohibit disclosure of patient records or information that would identify individual patients.

(Comment 581). FDA did not propose a requirement that facilities post a sign that explains how to file consumer complaints, although NMQAAC members supported such a requirement. Nevertheless, the agency received 28 comments, all on a form letter, opposing any requirement for posting of the complaint process, particularly with respect to addressing complaints to the accreditation body. These comments argued that such a notice will confuse patients and send mixed messages (e.g., this is a certified facility, but here's how to complain). One comment noted that the consumer complaint mechanism needs to be more clearly articulated in order to determine a mechanism for posting. The comment expressed concerns about promoting dissatisfaction with the screening experience.

FDA notes that facilities can develop their own posting mechanism if they chose to do so. In these cases, the facility could use messages such as: ''We care about our patients. If you have comments and/or concerns, please direct them to (the name of the person in the facility who is responsible for complaints).'' FDA 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 patients.

9. Clinical Image Quality (§ 900.12(i))

This paragraph establishes that clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by the facility's accreditation body.

This requirement did not appear as a separate provision in the proposal but was added to the final regulations to emphasize that adequate clinical image quality is to be maintained by the facility on an ongoing basis and is not something to be achieved only at the time of accreditation. FDA recognizes that this requirement may appear unnecessary or redundant. The stated purpose of the MQSA, to establish national uniform minimum quality standards for mammography facilities, presumes that all facilities will produce adequate mammograms on a regular basis. Specific statutory provisions, such as those requiring random clinical image review by accreditation bodies and the establishment of quality assurance programs at each facility to ensure clarity of images, reflect the drafters' intent to ensure quality mammograms for every patient. In addition, the interim regulations issued by FDA and these final regulations establish and support the need for maintenance of adequate clinical image quality at all times. However, FDA's experience with implementation of the interim regulations, and the impression the agency has received from some of the public comments, suggests that some facilities may view clinical image quality as important only or primarily in connection with the accreditation process. The agency has concluded that this critical standard for quality mammography should be stated explicitly in order to emphasize its critical importance and eliminate any chance of misunderstanding.

10. Additional Mammography Review and Patient Notification (Proposed § 900.12(i) (Final § 900.12(j)))

This paragraph requires a facility to cooperate with FDA in the investigation of concerns about the quality of the mammography performed by that facility and in notification of patients or the public, should the investigation justify such notification. As the result of the addition of the new § 900.12(i), Clinical image quality, this paragraph is now § 900.12(j) in the final regulations. The provision has been modified from the original proposal to clarify that this type of review is different from those performed either for accreditation, reaccreditation, or for random clinical image review. Additional mammography review is to be used in those cases where FDA has reason to believe that mammography quality has been compromised and may present a serious risk to human health. Depending on the individual circumstances, this review may be an onsite evaluation or may be performed through the mail. Procedures for performing additional mammography review will be developed by the accreditation bodies and approved by FDA.

If the agency determines that any activity related to the provision of mammography at a facility presents a serious risk to human health, § 900.12(j)(2) requires a facility to notify patients, their designees, their physicians, or the public of actions that may be necessary to minimize the risk. Such notification may be warranted, e.g., in cases where diagnoses of possible malignancy may have been missed due to grossly inadequate performance on the part of the facility. Patients, their designees, health care professionals, or the public may have to be notified so that they may take appropriate remedial action. For example, affected patients may wish to repeat examinations at another facility or a member of the public may be able to contact an otherwise unreachable patient.

(Comment 582). While seven comments supported these requirements as originally proposed, the authors of 26 other comments were concerned about possible abuse of the provisions. These comments requested more information and clear guidelines on how ''serious risk to human health'' would be determined and how the regulation would be implemented. One comment stated that the entire section was not needed and should be deleted. The authors of 25 comments stated that this section sounded like a consent decree without an appeals process. The comments also stated that the intent of this section was unclear.

FDA notes that even comments that expressed concern generally supported the need to investigate and to take appropriate action at facilities where there is a serious risk to human health. In response to specific comments, the agency first notes that patient notification will not always be an appropriate corrective action, even in cases where mammography services have been inadequate. In some cases, patient notification could result in unnecessary patient anxiety, without providing the patient with any plan of action that the patient could take to minimize her risk. The agency recognizes the important consequences to the patients, the public, and the facility of pursuing patient notification and would not initiate such action without full consultation with the accreditation body and the facility and only following review of the additional mammography review performed by the accreditation body.

Although NMQAAC agreed that the agency should exercise this authority with respect to facilities that are performing poorly, members of NMQAAC were unable to reach a consensus on guidelines for initiating patient notification. FDA's experience under the interim regulations may reassure facilities and the public that patient notification is not requested unless FDA has evidence, including review of clinical images by the facility's accreditation body, that indicates there is a strong likelihood that a significant number of mammograms taken by the facility were inadequate. In any given situation, notification will only be appropriate where the benefits of providing notice to women, who may wish to repeat the exam, outweigh any resultant risks, such as patient anxiety or the possible disincentive for future mammography screening. Because of the number of variables involved in any particular situation, FDA believes that the decision as to when a facility has sufficiently

serious problems to warrant patient notification is best made on a case-by-case basis. In the past 2½ years, two facilities have instituted limited patient notification after an investigation by the accreditation body and FDA.

The intent of this section is to assure the public that in those cases of suspected compromised mammography quality, an investigation is performed, and depending on the results of that investigation, appropriate corrective action is taken. If patient notification is the corrective action recommended by the accreditation body and required by FDA, the facility will have every opportunity to participate in designing and implementing that notification. As with any adverse accreditation body or FDA action, the facility has the right to have a determination about patient notification reviewed and appealed within the agency. If the facility does not voluntarily come into compliance or take steps the agency has determined are necessary to ensure quality mammography at that facility, FDA can initiate suspension or revocation of the facility's certificate. In those circumstances, the facility is entitled to a hearing under part 16 of the agency's regulations (see § 900.14) and hearing decisions are subject to judicial review. Contrary to the opinion of many respondents, therefore, FDA's determination that patient notification is necessary is subject to review and appeal.

(Comment 583). One comment opposed this section, asserting that FDA already performs clinical image reviews by randomly notifying the facility that they have so many days to send in certain mammograms.

FDA notes that the author of this comment mistakenly believed that random clinical image review and additional mammography review were the same. As previously stated, these two reviews are performed differently and address different issues and problems. Random clinical image review is performed as an evaluation tool by accreditation bodies in an effort to audit their own performance, and the performance of facilities they accredit. Additional mammography review is to be performed only in those cases where FDA believes there has been a compromise of quality sufficient to pose a serious risk to human health.

(Comment 584). Two comments stated that FDA should ask the accreditation body to investigate questionable facilities, but that the type of evaluation and the final decision should be left up to the accreditation body.

FDA continues to work closely with the accreditation bodies to coordinate all activities, especially those related to image review and mammography quality. Accreditation bodies are critical in establishing processes and parameters for additional mammography review at any particular facility and may be the first entity to discover information that indicates such a review is necessary. Nevertheless, decisions about whether additional mammography review or patient notification are necessary ultimately must rest with the agency.

(Comment 585). One comment questioned why FDA would not start this process as soon as a facility fails accreditation due to clinical image review.

FDA responds that accreditation clinical image review is an evaluation of the ''best'' images that a facility can produce and is scored against the accreditation body's highest standard. Failure to achieve the high quality standard does not necessarily mean that the facility's average images are of a quality likely to result in the misdiagnosis of significant abnormalities.

It is FDA's view that failure of accreditation or reaccreditation clinical image review does not automatically indicate that the facility's overall quality level has been compromised to such an extent that there is a serious risk to human health. Unless there is other information indicating such a risk, the agency does not intend to apply § 900.12(j) to this circumstance. The initiation of additional mammography review under this section is primarily intended to protect the public in circumstances where there is reason to believe an accredited facility is practicing in a way that may cause serious harm.

M. Revocation of Accreditation, and Revocation of Accreditation Body Approval (§ 900.13)

This provision describes the procedures that FDA will follow in the event a facility's accreditation is revoked by its accreditation body (§ 900.13(a)). It also outlines the facility's responsibility if FDA withdraws approval of its accreditation body (§ 900.13(b)). No comments were received on § 900.13(b).

(Comment 586). One comment supported § 900.13(a) as written while another comment stated that this section is unclear, and asked whether a facility is allowed to conduct mammography without accreditation. Another comment suggested that no FDA certification should continue in force after an accreditation body has revoked the accreditation of a facility.

FDA issues certificates, and only FDA can determine when a certificate is no longer in effect. Loss of accreditation does not automatically mean the loss of certification. In certain unique circumstances, a facility may remain certified though it lacks accreditation. For example, a facility may be certified through a provisional certificate to perform mammography before it is accredited (42 U.S.C. 263b(c)(2)) or retain its certification for some period of time following FDA withdrawal of its accreditation body's approval (42 U.S.C. 263b(e)(2)). Under the MQSA, if an accreditation body revokes the accreditation of a facility, the certificate remains in effect until such time as may be determined by FDA (42 U.S.C. 263b(e)(5)). FDA interprets the statute to give the agency discretion to find that the certificate should no longer be in effect once accreditation has been lost or to permit the facility to continue to perform mammography for some period of time following loss of accreditation. The language in the final regulation has been amended to reflect this discretion.

After revocation of a facility's accreditation, FDA may conduct an investigation into the reasons for the revocation. Following the investigation, the agency may take whatever action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan that may permit the certificate to remain in effect while the facility seeks reaccreditation. (In the event that the investigation convinced the agency that revocation of accreditation was not justified, FDA would have discretion to continue the certificate in effect while the original accreditation body reinstated the facility or another entity provided accreditation). Anytime FDA determines that the revocation was justified and the certificate should not continue in effect, the facility that has lost its accreditation may no longer perform mammography. The final regulation has been amended to clarify that a facility whose certificate is no longer in effect must cease to practice mammography.

(Comment 587). Three comments concerning this provision appear to have confused revocation of accreditation with revocation of certification. One suggested making the accreditation bodies responsible for appeals of revoked certificates, and two described facilities that purportedly were unable to operate for 2 years as the result of revocation of their certificate due to a single flawed image or the recommendation of the facility's accreditation body.

FDA does not have enough information about the specific cases referenced in the last comments to respond, except to note that an accreditation body does not have authority to revoke a certificate. In response to the first comment, the agency reiterates that suspension or revocation of accreditation is the responsibility of the accreditation body, and each accreditation body is required to have internal appeals procedures available to all the facilities it serves. Suspension of revocation of an MQSA certificate, however, is the responsibility of FDA. Such suspensions and revocations are governed by 42 U.S.C. 263b(i) and the regulation implementing that section in § 900.14. An accredited facility whose certificate FDA is seeking to suspend or revoke is generally entitled to a hearing before that action is taken in accordance with 42 U.S.C. 263b(i) and § 900.14. The agency wants to take this opportunity to clarify, however, that a facility whose certificate FDA determines to be no longer in effect because its accreditation has been revoked is not governed by 42 U.S.C. 263b(i) or § 900.14. In accordance with 42 U.S.C. 263b(e)(5), the certificate of a facility whose accreditation has been revoked remains in effect only until such time as determined by FDA. Although such a facility will be entitled to an opportunity for a timely hearing following a determination by FDA that the certificate is no longer in effect, it may not continue to practice mammography in the interim.

N. Suspension or Revocation of Certificates (§ 900.14)

This section sets forth the conditions under which FDA may suspend or revoke a facility's certificate.

(Comment 588). One comment supported this section as written, while another recommended that this section be revised to include the MQSA provision which authorizes States to conduct certification duties.

As noted earlier in this preamble, the subject of States as certifying bodies is beyond the scope of these regulations. Preparations are under way to draft regulations that will govern State agencies that wish to become certifying bodies.

(Comment 589). One comment recommended changing the word ''determines'' to ''believes.''

Suspension or revocation of a facility's certificate is an action against the facility that should be based on more than ''belief.'' FDA does not intend to take such action without making a determination that it is warranted.

Because there were so few comments on this section, it has been codified basically as proposed. The discussion in the preamble to the proposal at 61 FR 14877 through 14878 describes the provisions of this section in detail. FDA has added failure to provide information, reports, or records ''to the accreditation body'' as an additional grounds for suspension or revocation in § 900.14(a)(3). The agency has made this change to ensure that accreditation bodies have access to records, including clinical images, that are necessary for review. In many circumstances, the accreditation body's access to records is essential for it to fulfill its obligations under the statute and to advise FDA with respect to potential enforcement actons. A facility that refuses to supply such records makes it difficult, if not impossible, for the accreditation bodies and FDA to efficiently investigate or monitor mammography practices at that facility.

O. Appeals of Adverse Accreditation Decisions that Preclude Certification or Recertification (§ 900.15)

The title of this provision has been changed to better reflect the fact that it describes the procedures for appealing adverse accreditation decisions that preclude a facility from becoming certified or recertified.

(Comment 590). One comment supported this section as written, and another comment questioned whether a facility can submit additional information in its appeal to FDA, noting that ACR does not consider any additional information from a facility and bases its appeal findings on rereview of the films from the facility that were originally evaluated.

When appealing an adverse accreditation decision, FDA will consider and evaluate any information provided by the appealing facility that may bear on the outcome of the appeal, in accordance with the governing regulations identified in the next paragraph.

(Comment 591). One comment suggested adding ''or reaccredited'' in addition to, ''has failed to become accredited.''

FDA agrees that the addition of ''reaccredited'' would add clarity. Another comment recommended that there be a timeframe for appeals. The MQSA establishes that the procedures in 42 CFR part 498 are to be followed by FDA for appeals. These regulations contain the timeframes to be followed for appeals under the MQSA.

P. Appeals of Denials of Certification (§ 900.16)

The comments that requested clarification about the relationship between revoked accreditation and continued certification encouraged the agency to explicity address the issue of facilities that have received accreditation but are denied a certificate. FDA has added a new provision to clarify that the statute provides the agency with discretion to deny certification to a facility that has been accredited. As discussed previously in connection with the section on reviewing applications for certificates, FDA ordinarily will issue a certificate to a facility that has proof of accreditation by an approved accreditation body. This has been the agency's practice in the past and the agency intends to continue its reliance on the professional bodies that are expert in these reviews.

However, there may be situations when the agency has access to information that was not available to the accreditation body or when the agency has other reasons to disagree with that body's determination that the facility applying for a certificate will practice quality mammography. In these unusual circumstances, FDA has authority to deny a certificate. The new provision sets forth the grounds that FDA will use as the bases for such denials: A finding that the facility is not likely to comply with the quality standards; a finding that the facility is not likely to permit inspections or provide access to records and information in a timely fashion; or a finding that the facility was guilty of misrepresentation in obtaining accreditation. These grounds are parallel to those that are the statutory bases for suspension or revocation of a certificate. FDA believes that it is in the interest of public health to ensure that such facilities are not permitted to begin practicing mammography rather than automatically granting a certificate that the agency must later seek to revoke.

The new provision also provides appeal rights for facilities that are denied a certificate. These procedures are the same as those set forth for reconsideration and appeal of an adverse accreditation decision in § 900.15. The procedures are mandated by the statute under 42 U.S.C. 263b(d)(2) and include the right to request a formal hearing from the Departmental Appeals Board of the Department of Health and Human Services.

Q. Alternative Requirements (§ 900.18)

Section 900.18 establishes procedures for approval, extension, and withdrawal 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. The alternative requirement procedure allows the agency to permit the practice of mammography to benefit rapidly from improvements and advancements without the need to first go through the often lengthy process of amending the regulations. When added to the interim requirements through the amendments of September 30, 1994 (59 FR 49808), no public comments were received. This section was incorporated into the final regulations with only minor changes. A few comments were received.

1. General Comments on Alternative Requirements

(Comment 592). Two comments supported this section, one referring to it as a ''most sensible approach,'' but urged monitoring of the use of the alternatives after approval. A third comment suggested that manufacturers be required to provide documentation of approved alternatives to potential purchasers and that copies be available at the facility for review by the physicist and the inspector. A fourth comment urged removal of this section, stating that no variation in meeting the requirements should be allowed.

FDA believes that this process is needed to avoid the danger of discouraging advances in mammography and freezing technology at the present level. If the standards had to be amended to permit use of an advance in methods, training, or technology, the time required for the amendment might well discourage members of the public from attempting improvements. The agency does not believe that it is necessary to make the third comment a regulatory requirement. Manufacturers will find it difficult, if not impossible, to sell equipment that does not meet the requirements or an approved alternative. Because facilities will demand such documentation and will be required to produce it to pass surveys or inspections, FDA concludes there will be sufficient incentive to provide documentation without issuance of a regulation. The agency also notes that copies of applications, amendments, and extensions of alternative standards will be available to the public in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857. The Dockets Management Branch is open to the public between 9 a.m. and 4 p.m., Monday through Friday.

2. Approved Requests for Alternative Standard Notification (§ 900.18(d)(2)(ii))

(Comment 593). One comment recommended that the justification level for an alternative requirement in this paragraph should be changed from the benefit being so great that the time required (typically more than 1 year) for an amendment would be ''an unjustifiable risk to human health'' to a standard that established that the alternative requirement ''provides a benefit to human health.''

FDA believes that the criterion suggested by the comment could be too low for some ''benefits,'' and has retained the provision as proposed.

3. Summaries (§ 900.18(d)(3))

(Comment 594). One comment stated that the requirement for providing summaries of alternative standards to NMQAAC should be deleted because NMQAAC does not have authority to approve or reject actions of FDA in such matters.

FDA agrees that NMQAAC does not have approval authority in such matters, but it does have the responsibility to advise FDA on matters related to FDA's development and implementation of standards. Because the agency cannot gain the benefit of this advice on alternative requirements without informing NMQAAC about the alternatives, FDA does not accept this comment.

4. Applicability (§ 900.18(f))

This paragraph describes the applicability of an alternative requirement. The proposal limited the use of the alternative to the applicant, with the exception of alternative requirements approved for manufacturers of equipment, which would apply to all users of the equipment. Under the proposal, others desiring to make use of other alternative requirements would have to apply separately.

(Comment 595). Four comments stated that FDA should reserve the authority to extend any approval beyond the applicant. A fifth comment went further and advocated automatic extension of an approved alternative requirement to all interested parties. FDA originally placed the limitation on the approval of alternative requirements in order to assure itself that the conditions that prompted the approval of the original application also applied for other applicants.

In light of these comments and after further consideration, the agency has concluded that the limitation would impose an unnecessary resource burden on applicants and FDA. Such a burden is not warranted by the low probability that an approved alternative requirement should not be extended to other interested and similarly situated parties. However, because the program is relatively new and the circumstances that may trigger requests for alternatives are so varied, FDA has concluded that it should review the appropriateness of each possible extension instead of making it automatically approved as suggested in the fifth comment. Accordingly, § 900.18(f) has been revised to permit expansion of the approval of the alternative requirement to other entities, but only after FDA has determined that this would be an effective means of promoting the acceptance of measures to improve the quality of mammography.

5. Other Changes

FDA has also made a change in the administrative procedures included in § 900.18, realizing that the level of delegation of authority to approve alternative requirements may vary with time or organizational changes. Thus, the specific references to approval by the Director of DMQRP have been replaced by general references to approval by FDA.

R. Conforming Amendments

Conforming amendments were made to 21 CFR 16.1 to add §§ 900.7 and 900.14 to the list of provisions under which regulatory hearings are available.

IV. Environmental Impact

The agency had determined under 21 CFR 25.34(c) that this action as proposed is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866, under the Regulatory Flexibility Act (5 U.S.C. 601–612), and under the Unfunded Mandates Reform Act (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in Section 202) that agencies prepare an assessment of anticipated costs and benefits before enacting any rule that may result in an expenditure in any 1 year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 (adjusted annually for inflation).

The agency has conducted analyses of the final rule, and has determined that the rule is consistent with the principles set forth in the Executive Order and in these statutes. FDA's analysis, as summarized in the remainder of this section, demonstrates that the final rule constitutes an economically significant rule, as described in Executive Order 12866. The agency has further determined that the final rule may have a significant economic impact on a substantial number of small entities. This discussion, therefore, along with the other relevant sections of this preamble and the agency's final Economic Impact Analysis (available at the agency's Dockets Management Branch), constitute the agency's final regulatory flexibility analysis as required under the Regulatory Flexibility Act. Similarly, because this rule is expected to result in expenditures that exceed $100,000,000 in at least 1 year, these documents also comprise the agency's assessment of anticipated costs and benefits under the Unfunded Mandates Reform Act. The final economic impact analysis also includes all references.

FDA presented a summary of its preliminary economic analysis in the preamble to the proposed rule (61 FR 14856). That summary discussed the potential costs and benefits of the proposed rule and described the findings of a more detailed industry analysis conducted by FDA's contractor, the Eastern Research Group (ERG). In response, the agency received numerous comments that addressed economic issues. FDA has examined and evaluated the reasoning and data presented in these comments and has incorporated many of them into its revised analysis of the final rule. The following discussion provides a summary of these impacts and presents the agency's responses to the relevant public comments.

A. Incremental Costs

For its analysis of the incremental costs of the proposed regulation (''Cost and Benefit Analysis of Regulations Under the Mammography Quality Standards Act of 1992''; preliminary final; March 14, 1996), FDA relied on agency experts and technical consultants to develop a broad profile of mammography facilities and to identify the type and cost of the additional equipment and procedures that would be needed to bring the affected facilities into compliance. That analysis found that the proposed rule would impose annualized industry costs of approximately $61.4 million. Upon review of the resulting public comments, FDA has maintained the basic methodology for these estimates, but updated or otherwise revised a number of the input variables.

The full details of the cost estimates for these final regulations are presented in the agency's final Economic Impact Analysis, which is available for review at the Dockets Management Branch and at FDA's home page on the World Wide Web (www.fda.gov) the analysis addresses only those costs that would not have occurred in the absence of these final regulations. The estimates assume that at a minimum mammography facilities are already complying with the agency's current interim regulations and that a typical facility will comply with each requirement of the final regulation by selecting the least costly method of compliance. Current facility compliance levels for the industry were derived for early provisions of the final regulations from published data services or interviews with experts in mammography. The cost estimates are based on a facility cost model that analyzes the inputs to a mammographic examination (e.g., professional time, amortization of fixed equipment costs, variable costs of supplies) and derives the contribution of each activity to the average cost of conducting a mammographic screen. The required capital costs were developed from an industry wide inventory of existing equipment stock, which allowed FDA to estimate the percentage of equipment that will need to be modified or replaced. The compliance cost attributable to equipment requirements was calculated by including the value that this equipment will lose (based on years of remaining asset life) and the cost of retrofitting, if possible. The aggregate costs were modeled over a 10-year analysis period and allocated among the industry sectors based on facility screening volumes. This method allowed FDA to analyze the effect of compliance costs on small volume and large volume facilities.

The analysis projects that yearly expenditures for compliance by mammography facilities will range from a high of $156.2 million during the second year of implementation to $9.5 million during the tenth year, with the variation reflecting the phased implementation dates for the individual requirements. On an annualized basis (over the 10-year period at a 7 percent discount rate), the yearly costs will equal about $38.2 million. Over the full 10-year period, the combined expenditures and lost resources for the largest cost element (replacement of mammography units with units meeting technical or quality assurance standards) will total more than $241 million and contribute approximately $28.5 million in average annual costs (75 percent of the total average annual costs). The other major annual cost components include medical records and reports, $4.6 million; quality assurance systems, $3.4 million; personnel qualifications, $1.6 million; and consumer complaint mechanisms, $0.1 million.

B. Incremental Benefits

The benefits of the final regulations will result from improvements in mammography quality and include: (1) Additional life-years (or quality adjusted life-years (QALY's)) and reduced costs of cancer treatment gained by earlier stage identification of breast cancers, and (2) less anxiety and stress and reduced cost of followup diagnostic mammographic screens and other diagnostic procedures gained by fewer false abnormal screens. While data limitations preclude FDA from developing a precise estimate of the magnitude of these benefits, the agency has constructed an impact model that projects the expected health and cost outcomes under various scenarios of plausible mammography quality levels. This model, which forecasts breast cancer outcomes based on tumor stages at time of initial identification, is summarized below and fully described in the agency's aforementioned final Economic Impact Analysis.

1. Baseline Estimates

The patient population affected by the regulation includes all 79.3 million women age 30 or older. Applying age-specific cancer incidence rates to the number of women in each 10-year age cohort projects approximately 180,600 new breast cancer cases annually, of which about one-quarter may ultimately prove fatal.

About 90 percent of the 25 million mammography procedures performed each year are for screening procedures in asymptomatic patients. Thus, FDA's impact model assumes a base of 22.5 million annual screens and 2.5 million annual diagnostic (or subsequent) mammograms in symptomatic patients. Of the 22.5 million screens, approximately 5 million (22 percent) are for women over the age of 65 and 2.7 million (12 percent) are for women younger than 40. The remaining 14.8 million annual screens are distributed by size of each 10-year age category. The age-specific cancer incidence rates within each age cohort indicate that about 56,900 of the 22,500,000 annual screens are for women with breast cancer and 22,443,100 are for women without breast cancer.

Although the benefits of the rule derive from increases in the quality of mammography, the quality dimensions are very difficult to measure. Each mammogram is unique because each patient is unique and many factors contribute to quality, including those that are not affected by these regulations. While other measures have been suggested (e.g., cancer yield and PPV), FDA's impact model relies on a combination of sensitivity and specificity levels to represent average mammography quality. The sensitivity of any diagnostic test is the proportion of the tested, diseased population that is correctly identified as diseased. Thus, test sensitivity addresses the problem of false negatives. The specificity of a test measures the proportion of nondiseased patients who are correctly identified as not having the disease. Thus, test specificity addresses the problem of false positives.

If both sensitivity and specificity improve toward 100 percent, the proportion of ''incorrect'' mammograms decreases. Although improvements in one measure may come at the expense of decreases in the other, as certain technical changes can tradeoff sensitivity for specificity, FDA finds that the input changes required by this regulation will raise the national average of both measures. Thus, the agency's impact model measures quality improvement as the percent decrease (expressed as a percentage over the current level) in the number of incorrect diagnoses, both false positives and false negatives.

Estimates of the current national average levels of mammography sensitivity and specificity are approximate representations, because they reflect literature examinations based on different patient populations, time periods, and definitions. Current sensitivity measures in community settings have ranged from 53 percent to as high as 90 percent and specificity measures have reached as high as 99 percent. However, several studies indicate that mammography facilities in research/academic settings have sensitivity and specificity measures that exceed most ''typical, community facilities'' by 7 to 13 percent. Based on these studies, FDA's baseline estimates assume that current national levels of sensitivity and specificity average 80 percent and 90 percent, respectively. The calculations use age-specific rates, because breast tissue density varies by age of patient.

The estimated 80 percent sensitivity rate implies that while 45,400 of the estimated 56,900 annually screened women with breast cancer currently receive a true positive result, 11,500 receive a false negative result. Thus, FDA estimates that each year, mammography fails to identify breast cancers in an estimated 11,500 screened women. The agency's impact model, which relies on a distribution of identified cancers by development stage and SEER incidence rates for both screened and nonscreened populations, predicts that about 4,300 of these 11,500 women will die of breast cancer within 20 years. The model implies that perfect mammography would prevent about 1,200 of these fatalities. FDA recognizes that perfect mammographic screening is not yet technologically achievable, but the agency is convinced that mammography sensitivity rates can be significantly improved, thereby avoiding a substantial number of these premature deaths.

Economic literature includes many attempts to place a dollar value on mortality avoidance for the purpose of conducting cost/benefit analysis. A common methodology estimates society's willingness to pay to avoid the risk of a statistical death as evidenced by wage premiums necessary to attract employees to riskier occupations. These data contain considerable variability, but appear to average about $5 million per death avoided. Thus, for illustrative purposes, FDA's analysis assumes a $5 million value to represent the societal benefit of preventing a premature death. The value of a life-year was estimated at $368,000 and the value of a quality-adjusted life-year at $373,000.

FDA also believes that the improved mammography quality gained by the final regulations will significantly reduce the rate of false positive results. The above methodology indicates that 22,443,100 women without breast cancer are screened annually. Consequently, a baseline specificity measure of 90 percent implies that 20,184,600 will receive true negative results, but 2,258,500 others will receive false positive results. FDA estimated the cost of the anxiety and increased stress associated with these false positive screening results by assessing the contribution of psychological well-being to the overall quality of life.

The time between a patient notification of a positive screen result and the subsequent identification through a followup diagnostic mammogram was assumed to take about 1 month. The cost of enduring this anxiety was assumed to detract from the value of a quality-adjusted month value of $31,100, i.e., $373,000 ÷ 12. Research indicates that mental focus and psychological well-being affected by a major life crisis can contribute approximately 8 percent to the overall quality of life. Worries about health, illness, and well-being may account for approximately one-sixth of the stress that would constitute a major life crisis. To assess the potential effect, FDA's impact model assumes that 25 percent of those patients who receive false positive results would be willing to pay about $415 ($31,100 x .08 x .167) to avoid the stress and anxiety of a false positive mammogram.

FDA also found that cancer treatment costs vary by stage of detection, from annual costs of $18,900 for the earliest stage to $50,000 for the latest stage. Other components of FDA's model address patient noncompliance with screening results due to fear or denial. Diagnostic mammography readings were assumed to follow positive initial screens, and additional followup diagnostic procedures were assumed to follow positive diagnostic results and to identify lesions that were present without screening. Based on limited data, FDA's model assumes that a small number of those patients with positive screens do not seek further treatment. Figure 1 illustrates the model components and baseline estimates.

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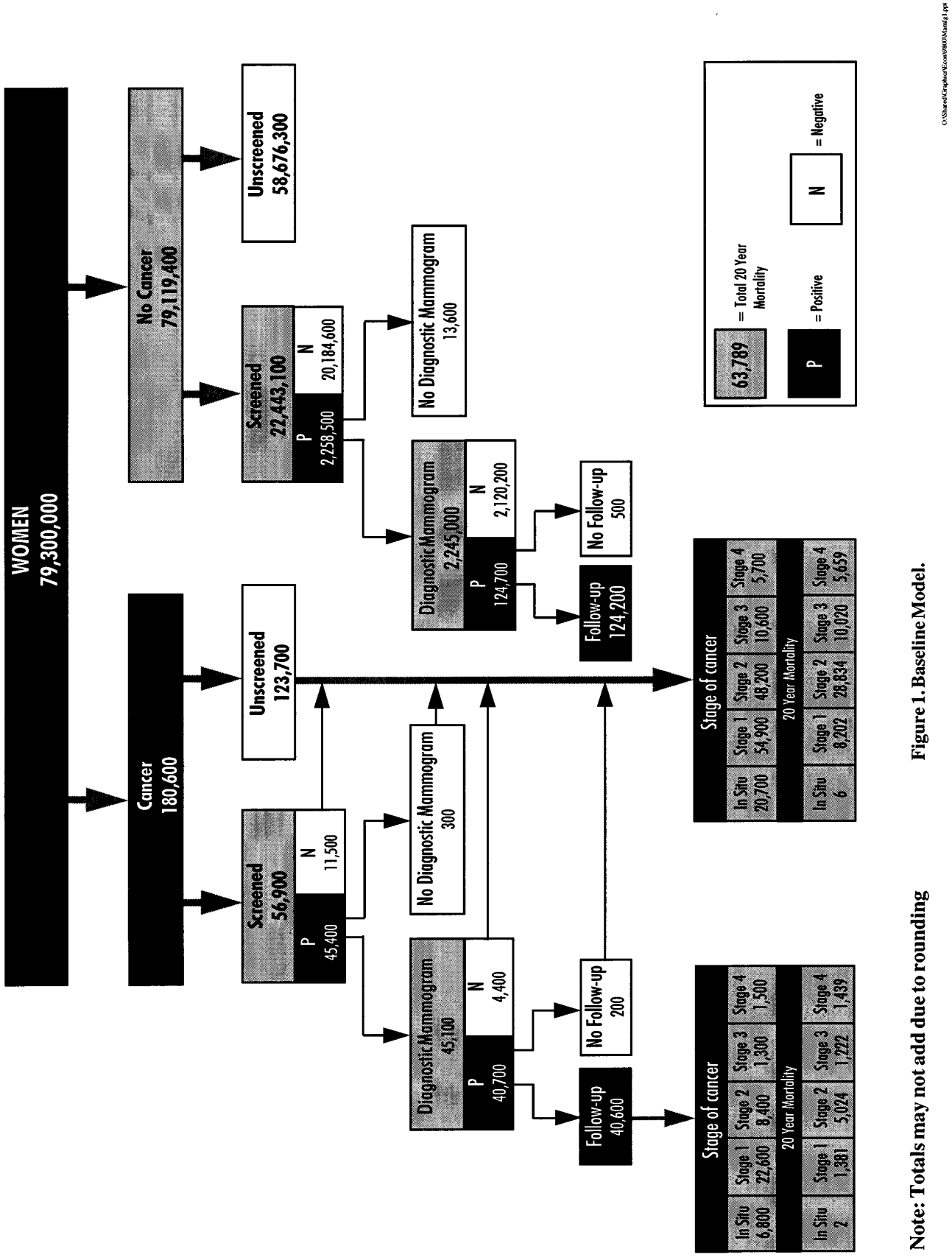

Figure 1. Baseline Model.

Note: Totals may not add due to rounding

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2. Regulatory Impacts

The agency also finds that the impact of these regulations could affect the demand for mammography. One study found a price elasticity of approximately -0.2 for outpatient well care. As the rules will likely raise mammography prices as well as costs, FDA incorporated this price elasticity into its impact model. On the other hand, improved mammography quality will have a positive effect on mammography demand. Assuming that the demand for mammography for a subset of potential patients exhibits a unitary elasticity with respect to quality, FDA's impact model finds that a 5 percent increase in mammography quality would roughly offset the above price-induced decline in demand, with the net change less than .03 percent.

Because of the difficulty in assessing the impact of the regulations on mammography quality, no public comments attempted to quantify the likely health outcomes. Similarly, FDA cannot predict the precise magnitude of the quality improvement that will be generated by these final regulations. FDA believes, however, that the mammography quality improvements will be substantial and that gains as small as 5 percent (i.e., reducing the proportion of incorrect procedures by 5 percent by increasing average sensitivity levels from 80 percent to 81 percent, and specificity levels from 90 to 90.5 percent) would produce substantial net benefits. The results of this analysis are shown in figure 2. For example, when compared to the baseline data (figure 1), the number of earlier cancers detected due to a 5 percent improvement in mammography sensitivity would prevent about 75 women per year from dying of breast cancer within a 20-year period. At $5 million per life saved, the discounted value of this outcome is about $234 million per year. Alternatively, the model shows that a 5 percent quality improvement would bring an annual increase of about 410 discounted QALY's valued at $153 million. Thus, FDA estimates the benefit of avoiding these premature mortalities as ranging from $153 to $233 million per year.

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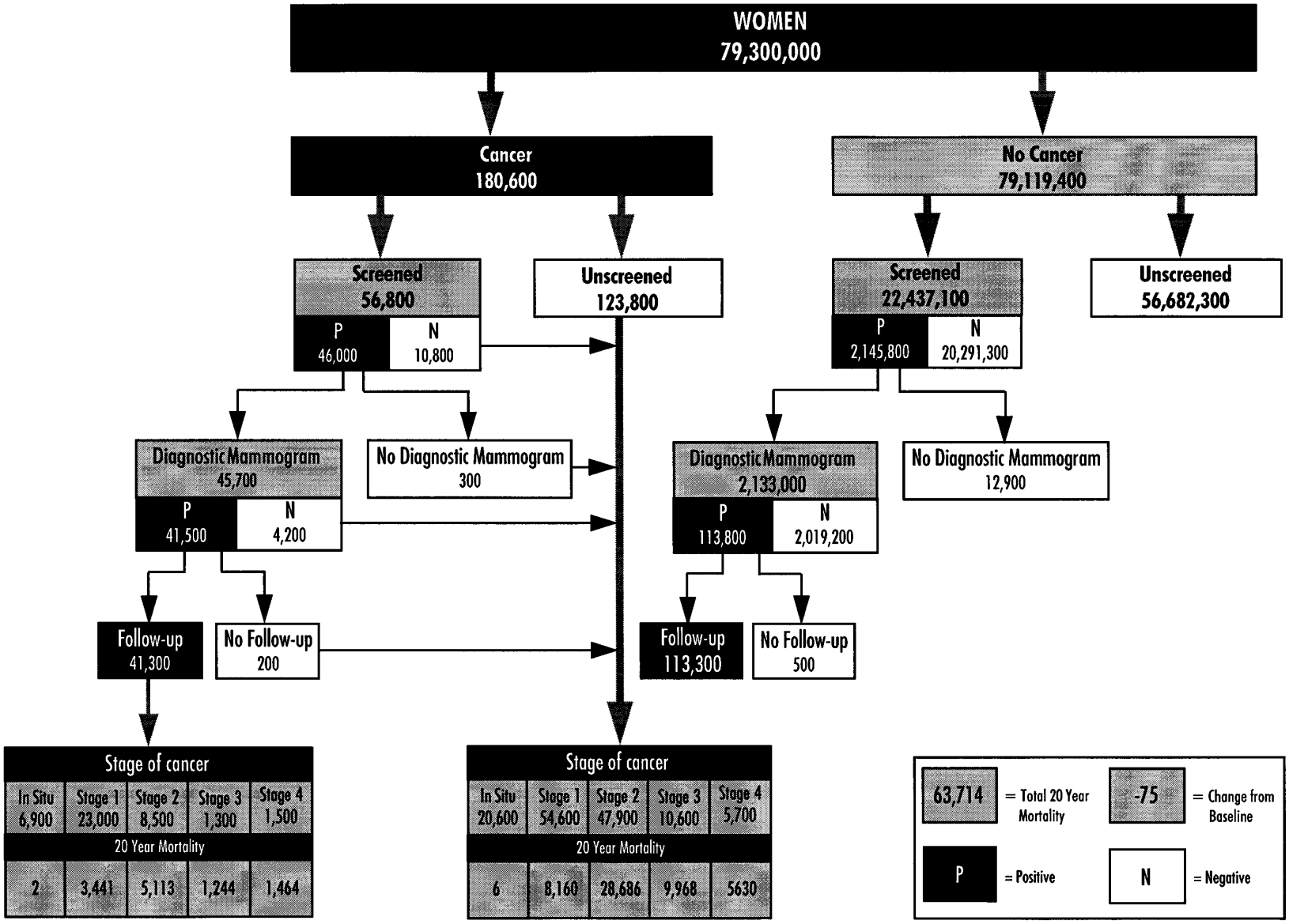

Note: Totals may not add due to rounding

Figure 2. Model with 5-percent quality improvement, and final rule compliance costs.

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A 5 percent quality improvement would also decrease cancer treatment costs by about $1.9 million. In addition, the reduction in false positives would produce less anxiety and stress valued at $12.7 million, and reduced diagnostic costs of $14.5 million. In total, quality improvements of 5 percent would generate annual benefits of from $182 to $263 million, far exceeding the expected annual compliance costs of $38.2 million. From a cost-effectiveness perspective, the cost per QALY would amount to about $20,000. Even if the overall quality improvement were only 2 percent, the estimated annual benefits of the final regulation exceed the estimated annual compliance costs.

C. Small Business Impact

According to the Small Business Administration, any doctor's office, clinic, or hospital with $5 million or less in revenue is considered small. In addition, any not-for-profit enterprise that is independently owned and operated and not dominant in its field is considered small. On this basis, mammography is offered in about 4,800 small doctor's offices or clinics and 5,000 small hospitals, comprising up to 98 percent of all mammography facilities.

FDA recognizes that the nature of these regulations may have a disproportionate effect on very small volume mammography facilities, as fixed costs of compliance for equipment improvements are likely to increase the cost per mammogram for low volume facilities relatively more than for high volume facilities. The cost of a mammogram is expected to increase by 3.4 percent in an average facility and by 4.2 percent in the smallest 10 percent of facilities. However, total revenues are also likely to increase. Overall, the annual net revenues attributable to mammography (gross revenues minus gross costs) are estimated to decline by approximately $1,000 in the smallest 10 percent of facilities, whereas the larger facilities may experience net revenue gains. ERG judged that these smallest facilities would have an increased vulnerability for closure. These results are fully described in the agency's final Economic Impact Analysis.

FDA also examined the effect on small businesses of alternative implementation schedules for this proposal. For example, one alternative would have required an even more elaborate equipment upgrade, effective immediately upon issuance of the regulations. The agency rejected this alternative becauseit would have placed an unnecessary burden on the industry, costing more than $120 million annually. By eliminating some specifications that were marginal to ensuring mammography quality, and phasing in certain requirements to allow for normal replacement of current equipment, the agency substantially reduced the cost of compliance. FDA also considered postponing the implementation of the final equipment requirements by an additional year. This alternative would have reduced the annual compliance costs by $7.1 million, but delay the impact on quality improvements. The final implementation schedule was selected as a reasonable balance between compliance costs and quality improvements. FDA also considered providing an exemption for small facilities in shortage areas, but concluded that the importance of mammography quality made this tradeoff unacceptable, and that a primary objective of MQSA was to ensure quality for all patients. The agency's final Economic Impact Analysis includes a discussion of several additional alternatives.

D. Total Impact of the MQSA

The total compliance costs for all of the regulations implementing the MQSA are the sum of the costs for the interim rules already in place, as well as for the final regulations as estimated above. Thus, to assess the total costs of the MQSA, FDA also estimated the costs of complying with the interim regulations.

Interim regulations implementing the MQSA required facilities to be accredited by an FDA-approved body as a first step towards receiving a certificate. FDA approved the ACR and the States of Iowa, Arkansas, and California to accredit facilities. The standards used by these bodies to accredit facilities were developed by FDA, but are largely based on the standards previously used by the ACR in their voluntary accreditation program. Because the ACR was the only national accreditation body and had already accredited approximately half of the mammography facilities in the country in its voluntary program, the majority of unaccredited facilities applied to the ACR for accreditation in order to continue to provide mammography services. On being notified by the ACR or one of the State bodies that a facility was accredited, FDA issued a certificate to the facility.

Approximately 5,500 facilities had not fully completed the accreditation and certification process by October 1, 1994 and approximately 1,000 accredited facilities were assumed to incur low levels of compliance cost. FDA estimated the costs of compliance with the interim rule by dividing these 6,500 facilities (5,500 unaccredited and 1,000 accredited) into groups with low, moderate, and high levels of noncompliance. Approximately 4,500 of these facilities had completed the accreditation and certification process by the end of the 6-month period of the provisional certificates or required minor improvements to achieve accreditation. These facilities were assumed to have low levels on noncompliance. Approximately 1,500 were able to complete the accreditation and certification process by the end of a 90-day extension of their 6-month provisional certificate. These facilities were assumed to have a moderate level of noncompliance. The remaining approximately 500 facilities were assumed to have a high level of noncompliance.

Discussions with expert consultants and operators of mammography facilities indicated that a low level of noncompliance would typically include minor recordkeeping and personnel training deficiencies. A moderate noncompliance level would typically include (beyond the low level) some quality assurance deficiencies and equipment requiring retrofit. Finally, facilities with high levels of noncompliance would incur costs for replacement of a mammography unit (in addition to ''moderate'' costs less retrofit). Based on this methodology, FDA estimates the annual costs of the interim rule at about $23.4 million. Adding the additional $38.2 million cost attributable to the final rules indicates that the total annual compliance costs of the MQSA are about $61.6 million.

The benefits of the interim rules result from their impact on mammography quality. A poll of industry experts indicated that the interim rules may have improved mammography quality by between 2 and 10 percent. Other reports have estimated that based on 1992 levels of quality, typical community quality levels may have been as much as 13 percent below the quality levels found in academic or research centers. FDA agrees that post-interim levels of quality may be approximately 10 percent lower than those found in typical academic settings, which implies a relative quality gain of 3 percent due to the interim regulations. FDA also found that, given average annual compliance costs of $23.4 million for the interim regulations, a 3.1 percent quality improvement would account for the current level of mammography use (all else being equal). Thus, FDA estimates that the interim regulations have

resulted in an approximate 3 percent increase in mammography quality. With this assumption, FDA's impact model calculates that the overall annual benefits of the interim rule range from $108 to $155 million, including the annual gain of about 44 lives and 242 discounted QALY's.

E. Conclusions

In summary, the final regulations will generate mammography quality increases above those already achieved by the interim regulations. As shown in the summary table, the annual costs of compliance with these final regulations are estimated at $38.2 million. Expected benefits will accrue as a result of fewer breast cancer fatalities due to the earlier detection of lesions and the avoidance of unnecessary surgery. While the magnitude of the expected quality increases are uncertain, an improvement of 5 percent in mammography sensitivity and specificity would result in annual benefits valued at from $178 to $257 million. With respect to all of the MQSA requirements, the annual compliance costs of the combined interim and final regulations equal about $61.5 million, and the annual benefits (assuming total quality increases of 8 percent) range from $284 to $408 million.

TABLE 1.—SUMMARY OF ECONOMIC IMPACTS (MILLION $)

	Interim Rule[1]	Final Rule[2]	Total[3]
Compliance Costs	23.4	38.2	61.6
Benefits	108.2–153.8	181.7–262.7	289.9–416.5
Diagnostic Cost Decreases	9.0	14.5	23.5
Treatment Cost Decreases	1.1	1.9	3.0
Anxiety Cost Decreases	7.8	12.7	20.5
Value of Lives Extended	90.3–135.9	152.6–233.6	242.9–369.5

[1]Assumes 3 percent increase in mammography quality
[2]Assumes 5 percent increase in mammography quality
[3]Assumes 8 percent increase in mammography quality

F. Responses to Comments on the Impact Analysis of the Proposed Regulation

1. Cost Analysis

FDA published a preliminary impact analysis in association with the final regulations on April 3, 1996. Public comments were invited on the methodology and projections included in that analysis.

One comment disagreed with the cost-benefit analysis and stated that the imposition of additional costs would adversely affect public health because fewer women will be able to receive the benefits of mammography.

FDA agrees that additional costs with no concurrent quality improvement may adversely affect mammography access. FDA also recognizes that access without quality is of no public benefit. FDA believes, however, that the assurance of quality resulting from these regulations will overcome any possible negative impacts. This belief is supported by a CDC study on mammography utilization that showed a continued increase in screening mammography examinations under the MQSA interim rules (Ref. 4).

One comment stated that most CEU classes for technologists cost between $75.00 and $100.00 for 6 to 8 credits, and require additional travel expenses. FDA agrees with the estimate provided by this comment. FDA estimated that the cost per hour of technologist's CEU would cost approximately $16.00 per credit hour and used this estimate in its impact analysis. This estimate was based on input from consultants and is within the range presented by this comment.

Numerous comments stated that the **Federal Register** notice for the proposed rule lacked sufficient methodological detail and should have included the cost of each requirement and the per facility or per procedure cost.

FDA agrees that the summary of impacts included in the **Federal Register** did not include detailed methodologies, discussions of assumptions, and sources of data. Nevertheless, as is required, FDA had provided a clear explanation of the calculations used for the cost/benefit analysis in the Full Regulatory Impact Analysis which was available for review at the Dockets Management Branch. Similarly, the agency's final Economic Impact Analysis, which provides substantial detail on the cost estimates is available at the same location that document can also be retrieved from FDA's home page on the World Wide Web (www.fda.gov).

A number of comments asserted that the equipment requirements would mandate the replacement of most mammography units and would increase the cost of these replacement units and that these costs were underestimated by FDA. One comment calculated the cost of replacing 15,000 mammography units, priced at $70,000, at more than $1 billion. The comment also calculated the cost of replacing 5,000 processors (½ of total), priced at $15,000, at $75 million.

FDA disagrees with the assumption that all mammography units in the country (which actually number about 12,000 instead of 15,000) or even most units will have to be replaced in order to meet the final rules. The Economic Impact Analysis that accompanies this final rule includes a detailed discussion on the estimation of the replacement costs. FDA has estimated the costs of the equipment requirements of the proposed rule by estimating replacement and retrofit costs through contacts with mammography equipment manufacturers. For replacements, the analysis considers the lost useful life of the machine. FDA also solicited input on compliance costs from mammography unit manufacturers and project consultants. These manufacturers indicated that not all mammography units would require replacement or retrofit and that prices for the new units would be identical to current prices. Based upon these sources of information, FDA estimated the total costs related to the equipment requirements of the proposed regulations to be approximately $270 million or $35 million in average annual costs (over the 10-year analysis period at a 7 percent discount rate). The agency notes that, after consideration of the public comments and other information, a number of equipment requirements, including those related to processors, were deleted before these regulations were issued. The impact of those deletions was to reduce the total estimated expenditure of meeting the equipment requirements in lost resources to $241 million and the average annual costs over the 10-year analysis period to $28.5 million.

One comment stated that phasing in equipment requirements 5 and 10 years after the effective date of the regulations would significantly increase costs if facilities are required to replace the unit in 5 years and then again in 10 years.

FDA believes that this comment stems from a misinterpretation of the proposal. FDA did not expect facilities to replace units every 5 years. Input on the equipment requirements from manufacturers indicated units would be available almost immediately after the regulations were published that would be able to meet the 5- and 10-year requirements. Thus, if a unit had to be replaced to meet an immediate requirement, a new unit could be selected that would meet the 5- and 10-year requirements as well. The facility would not need to purchase additional replacement units ''every 5 years.'' FDA's purpose in phasing in some requirements 5 and 10 years in the future was to provide time for facilities whose units met the immediate requirements but not the 5- or 10-year requirements to replace those units on their regular replacement schedule. This would decrease the burden by allowing machines to be replaced as they reach the end of their useful life. However, for reasons discussed in the responses to the comments on the equipment requirements, most of the 5-year requirements and all of the 10-year requirements were removed before these final regulations were issued.

Two comments expressed concern that the cost requirements for training every technologist to perform weekly or daily phantom checks were not considered in the impact analysis of the proposed regulations. Another comment estimated that the cost of performing the daily phantom tests for 240 days per year at $0.80 per sheet of film would be an additional $192.00 per unit. Using the estimated 10,800 certified units this would mean an additional cost of $2,073,600 per year.

FDA notes that the weekly phantom tests are identical to those currently being performed monthly under the interim regulations. No additional training costs will be incurred beyond those already included in the cost estimates of the interim regulations. FDA did not include any cost requirements for training to perform the daily phantom checks or for performance of the test because the agency did not propose such a test but merely requested public comment on its possible value. As previously discussed, FDA concluded from the public comments that further studies would be needed to confirm the value of such a test before it was made a regulatory requirement. Because it was not made a regulatory requirement, no costs either for training in its performance or performing the test needed to be included in these cost estimates.

A number of comments stated that FDA underestimated costs by not considering all of the factors that will contribute to increased provider and consumer cost.

FDA's Economic Impact Analysis has attempted to consider all of the factors that will contribute to increased costs from compliance with the final rule. This analysis is available through the Dockets Management Office, as well as the World Wide Web. As these comments did not identify the factors believed to have been overlooked, the agency is unable to give a more specific response.

Numerous comments asserted that the cost of lay notification would significantly increase the costs of mammography. These comments estimated that the cost ranged from $0.78 to $15.00 per notification.

For the proposed rule, FDA used a methodology to estimate the cost of patient notification that is similar to that described in the comments. The Economic Impact Analysis presented an estimate of $0.94 per written notification including 2.5 minutes of an office staff worker's time and cost of postage. However, this proposed requirement was removed from the final rule before it was codified, so these estimated costs will not occur.

A number of comments stated that the increased costs to comply with the final rule will result in facility closings (especially for small-volume facilities and rural facilities) and loss of access. One comment also stated that FDA has not adequately justified the cost of the regulation in the face of reducing access to low income populations.

FDA agrees that it is possible that increased costs of conducting mammography due to these regulations may cause some facilities to close if those facilities are currently not offering high quality mammography. However, FDA disagrees that such an impact has not been adequately explored. FDA has attempted to identify areas of potential access problems and believes that very few patients would be adversely affected if, as is anticipated, few, if any, facilities close as a result of the burdens of the final regulations. When facilities do close, alternate facilities are usually expected to be available within a reasonable distance. The agency also notes that the GAO study cited earlier found that the interim regulations, which had a similar cost impact, had little impact on access. FDA agrees that access for low income women is a potential problem, but does not believe that these regulations will greatly increase this problem. Nevertheless, FDA will monitor this potential outcome to ensure that any adverse impact on underserved populations is minimized.

One comment stated that costs were underestimated because only the incremental costs of nonvoluntary compliance were identified.

FDA disagrees with this comment. The quality standards contained in these regulations reflect standards of good practice, so it would not be surprising to find that many facilities were already complying with them before the regulations went into effect. Where voluntary compliance with regulatory requirements existed prior to implementation of the rule, costs were not included in the agency's Economic Impact Analysis because they are due to the facility's own desire to achieve quality mammography and not to the regulations. FDA agrees that if compliance costs occur only as a result of or in anticipation of a regulation and would be discontinued in its absence, such costs should be considered. However, FDA believes that most mammography facilities did not anticipate the specific regulatory requirements of this rule, and so any past actions to improve quality at their facilities were independent actions on their part.

Several comments noted that the proposal included only costs associated with the proposed regulations and not the interim rule. They stated that the costs and benefits of the entire MQSA should be estimated.

FDA agrees with these comments and has included estimates of the interim impacts for these final regulations.

One comment noted that costs may be understated because FDA assumed the lowest compliance cost. This comment stated that because some facilities would incur higher costs, the overall costs were underestimated.

FDA disagrees with this comment. The agency assumed that each facility would adopt a least-cost compliance strategy, which is standard economic methodology for analysis of regulations as required by Executive Order 12866. While some facilities would have higher costs, other facilities would have lower (or no) costs. Thus, the least-cost method of compliance for the average facility is a reasonable method of estimating industry wide costs. It is possible that this comment misunderstood the methodology used to estimate costs.

One comment stated that FDA has not adequately accounted for decreases in mammography usage due to expected cost increases.

FDA has attempted to address this issue for the final regulations. FDA agrees that cost increases are likely to decrease mammography use, all else being equal, but that perceived increases in mammography quality are likely to offset any negative impact. This issue is discussed above in B.2 and in the Economic Impact Analysis that accompanies the final rule.

One comment asserted that FDA's costs were ''unrealistic,'' rely only on consultant opinion and are, therefore, unreliable.

FDA disagrees with this comment. Cost estimates were derived from an extensive process of site-visits and expert input and no alternative data were included with this comment. The agency's cost methodology is fully detailed in the Economic Impact Analysis.

Several comments noted that specific activities were underestimated. FDA cannot respond to these comments because no supporting data were supplied.

2. Benefits Analysis

A number of comments maintained that FDA overstated the expected improvement in avoiding cancer deaths from the final regulation and that the benefit estimates should be based on scientific literature.

FDA believes that quality improvements in mammography will result in health gains, of which reductions in breast cancer mortality are a major contributor. FDA has attempted to assess the potential quality gains from the requirement of the final rule by reviewing relevant literature and through contact with experts in mammography quality. The Economic Impact Analysis that accompanied the proposed regulations included a detailed and referenced description of the benefits estimate. Similarly, the analysis of impacts for the final regulations include, a comprehensive description of the methodology.

One comment maintained that the final rule was a waste of money because the ACR program has already accomplished a goal of ''reasonably achievable mammographic quality.''

FDA disagrees with this comment. While voluntary accreditation by ACR did much to improve quality in participating facilities, the agency notes that, at the time of passage of the MQSA, less than half of the mammography facilities in the country had sought voluntary accreditation. The MQSA and its implementing regulations have led to the establishment of a uniform minimum set of quality standards to be met by all mammography facilities, including standards in areas not previously covered by the ACR program, and have provided increased assurance that these standards continue to be met between the times of accreditation. As shown in the above impact analysis, the agency believes that the benefits achieved more than compensate for the additional costs.

One comment stated that there has been a significant improvement in the quality of mammography performed under the interim regulations and further maintained that this quality improvement will continue under the final regulations.

FDA agrees with this comment. Quality improvements attributable to the interim regulations are estimated in conjunction with those attributable to the final regulations.

Several comments stated that because sensitivity is defined as the number of true positives divided by the number of true positives plus false negatives, a gain in sensitivity rate would have no effect on the false positive rate.

FDA agrees with these comments. FDA believes that both false negatives and false positives would be reduced by the quality improvements expected from these regulations. Thus, FDA believes that expected quality improvements would be likely to improve both sensitivity and specificity of screening mammography examinations. FDA notes that a typographical error in the analysis of impacts accompanying the proposed regulations may have contributed to these comments.

One comment stated that the discussion on sensitivity confuses the notion that there are inherent tradeoffs between sensitivity and specificity with the mathematical reality that this is not necessarily the case. The respondent believed also that this error may be due to confusing sensitivity with PPV.

FDA recognizes that the sensitivity and the PPV of a diagnostic test are not identical. Nonetheless, FDA believes that sensitivity and specificity provide reasonable quality measures for evaluating these final regulations.

Several comments stated that there is an error in the benefits analysis where it states, ''a five percent gain in sensitivity measurements of 80 percent would indicate a revised sensitivity level of 81 percent (a reduction of the rate of false positives from 20 to 19 percent).'' The comments stated that 5 percent gain to 80 is 84 not 81.

FDA agrees that the description of the impact was not well stated. A 5 percent quality improvement is defined in FDA's analysis as a 5 percent reduction in inaccurate testing results. Thus, if 20 percent of the diseased, screened population are currently not identified, a 5 percent quality improvement would see 19 percent not identified. The 5 percent is actually a 5 percent reduction in the complement of sensitivity.

Numerous comments asserted that the estimated willingness to pay to avoid a statistical loss of life of $5 million was too high and was unsupported.

FDA disagrees with these comments. For illustrative purposes, FDA has quantified the decreased breast cancer mortality potentially resulting from the rule using an average value of $5.0 million per each avoided death. This value is the implied value of society's willingness to pay to avoid the likelihood of an additional death as derived from economic literature, as referenced in the full Economic Impact Analysis. The methodology used to estimate this value is based on wage-premiums necessary to induce workers to accept riskier occupations and is a commonly used approach for estimating the value that society appears to be willing to pay to avoid a statistical death.

Several comments questioned the probability of expected benefits accruing from improvements in specificity. The comments identified this as the area where the greatest cost savings could be realized, and underlined this area as one which should be a target for improvement by the MQSA. Relatively small improvements in specificity could markedly reduce the numbers of false positive results nationwide, resulting in less diagnostic testing.

FDA agrees with these comments. These cost savings were addressed for the proposed regulations and are addressed for these final regulations.

One comment stated that raising the sensitivity of a test results in an increase in the false positives rather than a decrease.

FDA disagrees. The agency finds that quality improvements made to comply with the final rule are likely to improve sensitivity and/or specificity by raising the typical community receiver operating characteristic curve toward the optimum level. That is, quality improvements due to these regulations would change the entire relationship between sensitivity and specificity by improving the production function of mammography. As a result, both measures would be improved by these regulations.

One comment questioned the use of identified cancer stages used in the benefit analysis and noted that there is controversy associated with the impact of ductal carcinoma in situ on health outcomes.

FDA agrees with this comment and adjusted the benefit analysis for the final regulations.

One comment asserted that benefits were overstated because the general trend in mammography was toward higher quality even in the absence of the regulations.

FDA disagrees that the beneficial impact of these regulations has been overstated. Current trends in mammography quality are accounted for in baseline conditions.

Several comments noted areas of potential benefit that were not accounted for in the analysis that accompanied the proposal. These areas include the benefit of increased assurance to patients, the benefits of increased diagnostic quality, and reductions in treatment costs for identified cancers.

FDA agrees with these comments and has included these categories in this final analysis.

One comment stated that references for the benefit analysis were not available. FDA notes that references were included with the Economic Impact Analysis that accompanied the proposed regulations.

One comment noted that the affected population would change over time and that FDA has assumed a static population.

FDA agrees with this comment. FDA notes, however, that forecasting changes in future populations would likely increase the expected benefits because of the age distribution changes expected as the baby boom generation moves into ages of greater risk from breast cancer.

Several comments questioned the assumptions used in FDA's benefit estimation model.

FDA agrees that several of the key assumptions are uncertain. Nevertheless, the agency believes that the absence of scientific certainty does not preclude the development of preamble projections based on reasonably supported amplifying assumptions. The Economic Impact Analysis for these final rules provides sensitivity analyses that demonstrate the effects of modifying a number of these variables.

VI. Paperwork Reduction Act of 1995

A. Information Collection Provisions in the Final Rule

This final rule contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The following title, description, and respondent description of the information collection provisions are shown with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Reporting and Recordkeeping Requirements for Mammography Facilities.

Description: The final rule collects information from accrediting bodies and mammography facilities. Under the final rule, each accreditation body is required to submit applications and establish a quality assurance program. Each mammography facility is required to establish and maintain a medical reporting and recordkeeping system, a medical outcomes audit program, a consumer complaint mechanism, and records documenting personnel qualifications.

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

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

FDA estimates the burden of this collection of information as follows:

Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facilities; General Facility Requirements

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3	6	1	6	60	360		
900.3(b)(3)	10	1	10	60	600	$50	
900.3(c)	4	0.14	0.56	15	8.4		
900.3(e)	1	0.2	0.2	1	0.2		
900.3(f)(2)	1	0.2	0.2	200	40		
900.4(c) and (d)[1]	834	1	834	1	834		
900.4(e)[2]	10,000	1	10,000	8	80,000		
900.4(f)[3]	1,000	1	1,000	14.5	14,500		
900.4(h)[4]	6	1	750	6	4,500		
900.4(i)(2)	1	1	1	1	1		
900.6(c)(1)	1	1	1	1	1		
900.11(b)(2)	25	1	25	2	50		
900.11(b)(3)	5	1	5	.5	2.5		
900.11(c)	10,000	0.0050	50	20	1,000		$1,000
900.12(c)(2)	100	1	100	5	500		
900.12(j)(1)	10	1	10	1	10		
900.12(j)(2)	1	1	1	50	50		
900.15(d)(3)(ii)	10,000	0.0020	20	2	40		$100
900.18(c)	10,000	0.0005	6	2	12		$60

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN—Continued

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.18(e)	10	0.1000	1	1	1		$10
TOTAL					102,510	$50	$1,170

[1]Formerly § 900.4(b) under the interim rule.
[2]Formerly § 900.4(d) under the interim rule.
[3]Formerly § 900.4(e) under the interim rule.
[4]Formerly § 900.4(g) under the interim rule.

Requirements for Accreditation Bodies of Mammography Facilities and Quality Standards and Certification Requirements for Mammography Facility Requirements; General Facility Requirements and Personnel Requirements

TABLE 3.—ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)[1]	10,000	1	10,000	1	10,000	
900.11(b)(1)[2]	1,000	1	1,000	1	1,000	
900.12(c)(4)[3]	10,000	1	10,000	1	10,000	
900.12(e)(13)	6,000	52	312,000	0.125	39,000	
900.12(f)	10,000	1	10,000	1	10,000	
900.12(h)	10,000	2	20,000	0.5	10,000	$20,000
TOTAL					82,000	$20,000

[1]Formerly § 900.4(f) under the interim rule.
[2]Formerly § 900.11(c)(1) under the interim rule.
[3]Formerly § 900.12(e)(1) under the interim rule.

Most of this burden is not new, but rather results from requirements continued from the interim rule. FDA estimated the annual burden for reporting and recordkeeping requirements under the interim rule to be 120,944 hours (58 FR 67562 and 67569). The additional requirements contained in these final rules will add 63,566 burden hours to this estimate, resulting in an estimated total annual burden of 184,510 hours.

The burden estimate for this final rule differs from the proposed rule in several respects (see 61 FR 14865 to 14868). First, FDA revised § 900.12(c)(2), which proposed written notification of examination results to all mammography patients. The final rule requires that each facility maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. This revision resulted in the removal of proposed § 900.12(c)(2)(i) from the paperwork burden estimates. Second, FDA revised § 900.12(d)(2), which proposed the specific documentation to be maintained by each facility as part of its quality assurance program. This revision included removing §§ 900.12(d)(2)(i), 900.12(d)(2)(ii) and 900.12(d)(2)(iii) from the final rule and combining §§ 900.12(d)(2) and 900.12(d)(2)(iv) from the proposed rule into § 900.12(d)(2) for the final rule. This revision is reflected in these estimates of the recordkeeping burden. Third, FDA added several reporting and recordkeeping burden estimates that are not new to the final rule, but whose impact was overlooked in the burden estimate for the proposed rule. Also, FDA renumbered some of the provisions for the final rule, due to removal or additions of other provisions; these revisions had no effect on the paperwork burden estimates. The following sections concerning paperwork burden were renumbered: § 900.4(a)(7) in the proposed rule is § 900.4(a)(6) in the final rule, and §§ 900.12(f)(2) and 900.12(f)(4) in the proposed rule are §§ 900.12(f)(1) and 900.12(f)(3) in the final rule, respectively.

B. Comments on the Paperwork Reduction Act Statement

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act, FDA provided an opportunity for public comment on the information collection provisions of the proposed rule (April 3, 1996). A small number of comments addressed FDA's Paperwork Reduction Act statement. In general, these comments asserted that FDA had underestimated burden or had not considered all of the reporting and recordkeeping requirements.

One comment stated that FDA's Paperwork Reduction Act statement underestimated the time burden on mammography facilities for recordkeeping and reporting. The comment further stated that FDA's estimate of 23,553 hours, which translated into less than 2.5 hours per facility (based on an estimated 10,000 mammography facilities in the United States), was low. The comment asserted that FDA underestimated or ignored the incremental burden on facilities from the interim rule to the final rule. The comment further stated that at least one person at each mammography facility

must understand the final rule. The author of the comment estimated this task at 10 hours per person at each of the estimated 10,000 mammography facilities.

FDA disagrees with this statement in general, but upon review of the burden estimates under the proposed rule FDA has revised some of the time estimates. For example, FDA has added hours to cover § 900.12(e)(3)(13), infection control, because its burden was overlooked under the paperwork burden analysis of the proposed rule.

FDA also agrees that someone in the mammography facility will have to understand the final rule and that it will take some time to develop this understanding. The agency believes, however, that the time estimate suggested by the comment is far too high. This belief is based upon three considerations. First, the basic framework of the requirements has not significantly changed from the interim rule. Many of the additional details in the final rule are taken from policies developed under the interim rule, with which the facilities are already familiar. Because of this overlap, the time required to understand the final rule is less than it would be if they were entirely new. Second, the recordkeeping and reporting burdens are estimated on an annual basis; therefore, each estimate is stated as an average time per year. Whatever burden there would be in understanding the new regulations would be primarily a one-time burden. If an individual spends x hours the first year developing an understanding of the regulations, the time required in the second and subsequent years will be much less than x because the person will already be familiar with them. The average time per year for understanding the regulations thus would be only a small fraction of x. Third, in compliance with the Paperwork Reduction Act, it is the time burden for reporting and recordkeeping that is being estimated. Thus, only the time required to understand the new reporting and recordkeeping requirements, not to understand the total requirements, would properly be included in these estimates. The combined effect of these three factors, the agency believes, reduces the time burden for understanding the requirements that should be included in these estimates significantly. The burden for understanding each requirement has been included in the individual burden estimates for that requirement.

One comment stated that FDA had not estimated any burden for compliance with proposed § 900.12(f), which requires each facility to implement a medical outcomes audit. The author of the comment estimated that the burden of such a requirement would require at least 10 hours of an interpreting physician's time at each of the estimated 10,000 mammography facilities. Several other comments also stated that proposed § 900.12(f) was an undue burden on freestanding facilities. The comments discussed the difficulty in tracking down and obtaining all biopsy and consultation outcomes. One comment noted the lack of evidence that outcome measurement contributes to improved care.

FDA understands the difficulty with tracking outcomes data but such data are critical in assessing the quality of mammography at facilities. FDA also notes that most of the requirements in § 900.12(f) do not require any additional reporting or recordkeeping burden beyond what was required under the interim rule.

One comment also asserted that FDA had failed to include the time burden for proposed § 900.12(g), which adds requirements for mammography of patients with breast implants. The comment stated that FDA should have estimated the time burden related to scheduling patients with implants, documenting patients with implants, and requiring the presence of an appropriately trained interpreting physician onsite during mammography of women with implants. The author of the comment estimated that the above would require an additional 10 to 20 hours of reporting and recordkeeping at each mammography facility.

As discussed previously, FDA has changed the proposed requirement that each facility should inquire whether a patient has an implant at the time of scheduling to a requirement in the final rule that each facility shall inquire as to whether the woman has an implant prior to the examination. The final rule also eliminated the requirement that an interpreting physician be present. Even under the proposal, the additional recordkeeping time would have been minimal and the revision in the final rule gives the facility flexibility in determining when and how the information is collected for the patient's record. All facilities maintain patient records with information such as address, telephone number, insurance information, and medical history. The additional time to ask a yes or no question on implants and record the answer is negligible.

Another comment stated that FDA had failed to estimate the additional requirements and documentation associated with personnel requirements in proposed § 900.12(a). The comment estimated that additional documentation requirements would necessitate at least 5 hours of additional time for approximately 1,000 medical physicists, and approximately ¼ hour for each mammography facility.

FDA acknowledges that § 900.12(a) contains some increases in the required level of personnel training and experience from the interim rule. However, FDA did not include any recordkeeping burden estimates for the personnel requirements under either the interim or final rules because the agency believes that it is usual and customary practice for mammography facilities to keep records of the qualifications of their employees.

Although this position makes moot the question of the amount of time required for recordkeeping related to these requirements, FDA would like to note that there are factors that the author of the comment may not have been aware of that make the estimates in the comment excessive. Most changes in the personnel qualifications are only increases in the amounts of the interim requirements. In such cases there is no additional recordkeeping burden. It requires no more effort, for example, under the final rule, to keep a letter in a doctor's records indicating that he or she had 3 months of training in mammography during residency that it did, under the interim rule, to keep a letter indicating he or she had 2 months of such training.

For most of the new personnel requirements in the final rule, such as the continuing experience requirements for technologists and physicists, the information that bears on whether these requirements are met often already exists in the form of various work records. All that is needed is to place a copy or summary in each person's file.

The remaining new standard establishes an initial requirement of a minimum level of education and training for medical physicists. FDA believes that the majority of physicists providing services to mammography facilities will have exceeded this level in meeting the requirement that the medical physicist be board-certified, State licensed, or State approved, which was retained from the interim rule. In such cases, the agency intends to minimize the burden by accepting the documentation of board approval, State licensure, or State approval (in States whose standards for approval exceed the minimum level) as adequate evidence that the second requirement is also met.

Physicists approved by States that require a level of qualification for approval lower than that in the second

requirement will have to provide additional documentation but the time required is likely to be significantly less than the 5 hours estimated in the comment. More importantly, as this is an initial requirement, it will be a one time burden. To be compared with the other burden estimates, it must be averaged over the physicists's entire career, which could be 30 years or longer.

Again, because keeping records of personnel qualifications is usual and customary practice, FDA has not included this in the burden estimates. The agency notes, however, for the reasons discussed above, that the comment greatly overestimates the time required for the new recordkeeping.

One comment stated that virtually all of the requirements in the proposed rule duplicate requirements of accreditation bodies and noted that FDA inspectors require much of the same personnel documentation required by the ACR.

FDA notes that the author of the comment has misunderstood the nature of the accreditation system required under the MQSA. The requirements of the FDA-approved accreditation bodies are not established by those bodies but rather are FDA-established quality standards that the accreditation bodies, as a condition of their approval, must ensure are met by the facilities they accredit. Thus, there is only one set of requirements, not two or more duplicate sets, and the actions identified in the comment are mandated by the legislation in order to increase the likelihood that quality mammography will be consistently achieved.

Several comments asserted that the proposed rule would create an unnecessary amount of paperwork that would ultimately take away from time with patients. One comment asserted that the reporting requirements would necessitate a computer system and additional clerical support.

FDA has attempted to limit the paperwork burden to only those recordkeeping and reporting requirements necessary to ensure that facilities meet minimum quality standards. As discussed above, FDA has also reduced the paperwork burden of the final rule by removing several reporting and recordkeeping requirements from the final rule. The agency believes that the paperwork impact, as estimated in Tables 1 and 2, is not unreasonable in view of the benefits to be gained from the quality standards that made the recordkeeping and reporting necessary.

A number of comments asserted that proposed § 900.12(c)(2), which would have required written notification of mammographic examination results to all mammography patients, would cost time and postage expenses and would generate much paperwork. Some comments asserted that this practice would be redundant for patients with referring physicians who could explain the results.

FDA has revised § 900.12(c)(2) to require that each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. FDA has allowed for increased flexibility in the notification of patients by allowing written or other notification by either the mammography facility or the referring physician. FDA believes that some form of patient notification is a standard of good practice that is currently followed voluntarily by virtually all mammography facilities, so the burden of this requirement will fall only on those few facilities who are not currently meeting such a standard. The flexibility of notification method allowed under the revision of § 900.12(c)(2) will make the burden minimal even for these facilities.

Several comments asserted that proposed § 900.12(h), which requires the development of a consumer complaint mechanism, was unnecessary. The comments stated that all complaints should be handled on an individual basis at each facility according to the protocol of that facility. One comment asserted that the proposed rule would be very costly in terms of staff time and materials.

This comment has misinterpreted the requirements of § 900.12(h), which gives facilities the flexibility to develop their own consumer complaint mechanism in the manner they feel most appropriate. The requirement that each facility must maintain records of each serious complaint over the last 3 years should be of minimal burden to facilities and would only necessitate a file including the appropriate correspondence by the complainant, facility, and accrediting body. Many facilities already have some form of consumer complaint mechanism and would not incur significant additional burden by meeting the requirements of the final rule.

One comment agreed with proposed § 900.12(c)(4)(ii), which states that facilities must transfer mammographic films and records to other facilities or the patient at the patient's request, but stated that it was not economical or practical to copy films for the sake of keeping them in the patient's medical record.

FDA notes that § 900.12(c)(4)(ii) does not require that a facility maintain copies of a patient's medical records if the patient has asked to have them transferred elsewhere. The facility is free to determine for itself whether it is desirable to copy films for its own records.

Several comments stated that proposed § 900.4(c), which requires clinical image review as part of the accreditation and reaccreditation process, would be extremely costly and time-consuming. This burden includes the time and expense of choosing the images and having them copied and mailed. Another comment supported clinical image review as the best approach for a performance-based standard, but also stated that it would be costly and time-consuming.

FDA notes that Congress specifically required clinical image review as part of the accreditation and reaccreditation process (42 U.S.C. 263b((e)(1)(B)(i)), because clinical image review is necessary to ensure high quality mammography. While it may appear that the complexity of the process, and thus of the burden, has increased due to the increased detail in the final rule, these details are presently being followed as policy by the accreditation bodies so, in fact, there is no additional burden. The agency further notes that facilities are not required to copy the films before sending them for review. Only original films are reviewed and these are returned to the facility after the review is complete.

Several comments stated that § 900.12(e)(13), requiring facilities to establish an infection control procedure including documentation after each cleaning, would create needless paperwork and would not affect quality assurance.

FDA has included an additional paperwork burden estimate for this requirement in the final rule. Under § 900.12(e)(13), facilities are required to establish and comply with a system for cleaning and disinfecting equipment as needed. Although there is no evidence that blood-borne pathogens have been transmitted from patient to patient during mammography, there is a theoretical possibility of such a transmission. That agency believes the time required is justified to ease concerns about such a possibility, concerns that in some cases may cause patients to refuse to undergo mammography examinations and thus possibly lose the life-saving benefit of early detection of breast cancer.

The information collection provisions of this final rule have been submitted to OMB for review. Prior to the effective date of this rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve,

modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Appendix

Excerpts from Chapter 4 of AHCPR's "Quality Determinants of Mammography;" Guidelines for Communicating Test Results

As noted previously, FDA recommends that mammography facilities utilize the AHCPR'S guidelines in ''Quality Determinants of Mammography'' with respect to written notification of results to patients. The pertinent information from Chapter 4 of those guidelines is reprinted here for ease of reference. The symbol [R] indicates that the AHCPR document provides an additional reference or references at that point.

COMMUNICATING RESULTS

RECOMMENDATION: The referring health care provider and the interpreting physician should be sensitive, supportive, and appropriate in communicating results, as well as prompt and accurate. (B)

STRONG RECOMMENDATION: An appropriate professional at the mammography facility, usually an interpreting physician, should send the woman's health care provider a written report documenting the specific findings, follow up recommendations, and the name of the interpreting physician. The facility should directly telephone the referring provider if the result is suspicious for cancer. (B)

STRONG RECOMMENDATION: The mammography facility personnel should give the woman written notification of the results of her mammography and other breast imaging, either on site or by mail. The results should be in simple language, document the name of the interpreting physician, be given in a timely fashion, and include further steps to be taken. (B)

RECOMMENDATION: If a facility accepts women who have no health care provider, facility personnel should give the woman a list of qualified providers who are willing to provide care. The name, address, and phone number of the provider chosen should be recorded, if possible (C).

STRONG RECOMMENDATION: The facility personnel should directly telephone the woman who has no health care provider if the result is suspicious for cancer (B).

Many women believe that mammography results are normal if they are not contacted after their examination. This impression that ''no news is good news'' can have serious adverse consequences for women with an abnormal examination. The interpreting physician, the referring health care provider, and the woman are all responsible for ensuring that mammography results are communicated in an effective and timely manner and that recommendations are carried out. Timely communication is necessary whether results are normal or abnormal (Table 3).

An increasing number of mammography facilities have begun to report both normal and abnormal results directly to the woman. This can be accomplished without disrupting the woman's relationship with her referring provider. Studies have shown that direct communication of results to the woman by the mammography facility produces a dramatic improvement in compliance with follow recommendations [R]. Traditional communication procedures, where the facility communicates only with the referring provider, result in inadequate compliance with follow up recommendations [R].

Problems in communicating abnormal results have included confusion concerning the appropriate steps to be taken; inappropriate or insensitive communication, resulting in avoidable anxiety and confusion; delay in receipt of results; and failure to communicate results to the woman at all—for example, when reports are misfiled or filed unread. These problems have caused delays in diagnosis and treatment, with consequences that include limited treatment options and death [R]. Providing results directly to the woman is a sound risk-management procedure, reducing the prospect of medicolegal complications for both the interpreting physician and the referring health care provider [R].

TABLE 3.—REPORTING OF RESULTS BY MAMMOGRAPHY FACILITY

Outcome of Mammography Examination and Recommendation for Followup	Communication to Women—Oral (Onsite or by Telephone)	Communication to Women—Write (Onsite or Sent by Mail)	Phone Communication to Health Care Provider in Addition to Standard Report	Always Necessary Written Report to Health Care Provider
Normal	Optional	Strongly Recommended	None	Strongly Recommended
Abnormal: schedule additional imaging and/or ultrasonography	Recommended[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
a) On line[1]	Optional[2]	Strongly recommended[2]	Recommended[3]	Strongly recommended
b) Off line[1]				
Abnormal: short-interval followup	Optional	Strongly recommended	Optional	Strongly recommended
Abnormal: Biopsy	Optional strongly recommended for self-referred women	Strongly recommended[4]	Strongly recommended	Strongly recommended

[1] For an online study, the interpreting physician is present and reads the mammogram while the patient is there. For an offline study, the mammogram may be read after the woman leaves so the interpreting physician does not have to be present.

[2] For any patient for whom additional views or ultrasonography are recommended, a telephone call or discussion onsite with the patient may precede the written letter when the studies are to be performed immediately or within 2 days at that mammography facility. However, the results of the original and additional studies must be provided to the woman in writing.

[3] A telephone call from the mammography facility to the woman's designated physician or other health care provider is recommended. For self-referred patients, the telephone call should be made to the woman herself.

[4] For any patient without a direct referral, the mammography facility may wish to send the letter via registered or certified mail.

NOTE: Strong recommendations deal with elements of mammography that the panel considers essential to good practice. Recommendations deal with elements of mammography that the panel considers attainable in most but not all cases. Options are statements of a less compelling nature that cannot be justified as recommendations.

Communicating normal results directly to the woman as soon as possible eliminates anxiety, reinforces the woman's role as a responsible participant in the process, reminds the woman of the importance of regular screening, and is a quality assurance safeguard. Effective communication is most crucial when results are abnormal and additional imaging or other follow up is required. If findings are abnormal, the written results should detail steps the woman should take next.

Any written communication must have language that is carefully constructed to impart results without causing undue anxiety, to promote a relationship between the woman and a health care provider, and to encourage the woman to take the next step. [Note—the AHCPR publication provides several examples of letters for communicating results directly to women.]

Mammography facilities may accept self-requesting and self-referred women for mammography. Interpreting physicians have additional responsibilities for ensuring the effective communication of results for these women.

- Self-requesting woman. This woman comes for mammography on her own initiative but is able to name a personal physician or health care provider. Whether the woman is having screening or diagnostic mammography, the interpreting physician should document that the designated provider accepts responsibility for the woman's breast care before sending out the mammography report. In cases where the provider declines to accept the mammography report from the mammography facility, the facility should treat the woman as if she were self-referred.
- Self-referred woman. This is a woman who comes for mammography but has no personal health care provider or for whom the provider declines responsibility. Whether the woman is having screening or diagnostic mammography, the interpreting physician assumes responsibility for the woman's breast care, including education, physical examination, and communication of mammography results directly to the patient in understandable language. Mammography facility personnel should give the woman a list of qualified providers. If the woman chooses a provider from a list provided by the mammography facility, the interpreting physician should ensure that the chosen clinician will assume responsibility for the woman's breast care. Although self-referral has improved access to mammography, it has increased the responsibilities of the interpreting physician and created more possibilities for failure to communicate abnormal results.

STRONG RECOMMENDATION: At the time of the examination, mammography facility personnel should inform all women of the time period in which they will receive their results and of the possibility that prior films may need to be obtained. The woman should also be instructed to call the mammography facility or her health care provider if she does not receive her results within the stated time period. The facility should report results to the woman's provider and to the woman within the shortest practical time period. (B)

RECOMMENDATION: The facility should use its best efforts to send a report to the referring health care provider and to send results to the woman as soon as possible, usually within 10 business days. The reporting period should not exceed 30 days. (B)

STRONG RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires needle or open biopsy to the referring (or designated) health care provider's office in a timely manner. (B)

RECOMMENDATION: The interpreting physician or designee should telephone the results of an abnormal examination that requires additional views and/or ultrasonography in a timely manner to the referring (or designated) health care provider's office. (B)

OPTIONAL: The interpreting physician or the referring (or designated) health care provider may telephone the woman directly to explain abnormal findings, their significance, and recommended next steps. (B)

Mammography facility personnel should telephone the referring or designated health care provider because the written report may not reach the provider or may not arrive in time for the provider to respond to questions from the patient. A telephone call also enables the provider to ask questions about the report and to discuss follow up options with the interpreting physician [R].

When mammography results are abnormal, a telephone call to the woman's designated health care provider before a report is sent may identify and resolve any vagueness in the provider-patient status. For a self-requesting woman with an abnormal finding, this call will significantly reduce the chance that she will slip through the cracks.

If the woman does not have a provider or if the provider declines to accept the report, the interpreting physician or designee should call the woman directly to explain the result and the recommended next steps. This telephone communication is in addition to the written report and should offer the option to have the results explained in person. Information should not be left on an answering machine or given to another individual without the woman's express prior permission. Particularly for the woman without a referring provider, the mammography facility may choose to send written notification of abnormal results by certified mail or with return receipt requested. Mammography facility personnel should document the communication to the referring provider or the woman in the woman's medical record. Recommended reporting is outlined on Table 3.''

Chapter 6 of the AHCPR document also provides more information on the communication responsibilities of the interpreting physician.

VII. References

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

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

2. AHCPR, ''Quality Determinants of Mammography,'' AHCPR Pub. No. 95–0632, October, 1994.

3. U.S. GAO, ''Mammography Services Initial Impact of New Federal Law Has Been Positive,'' GAO/HEHS–96–17, October, 1995.

4. Linver, M. N., J. R. Osuch, R. J. Brenner, and R. A. Smith, ''The Mammography Audit: A Primer for the Mammography Quality Standards Act (MQSA),'' *American Journal of Radiology*, 1995; 165:19–25.

5. CDC, ''Use of Mammography Services by Women Aged ≤ 65 Years Enrolled in Medicare—United States, 1995–1993,'' 1995; 44:777–781.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

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, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 900 are amended as follows:

PART 16—REGULATORY HEARINGS BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 is revised to read as follows:

Authority: 21 U.S.C. 41–40, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201–262, 263b, 364; 15 U.S.C. 1451–1461, 28 U.S.C. 2112.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding entries for §§ 900.7 and 900.14 to read as follows:

§ 716.1 Scope.

* * * * *

(b) * * *

(2) Regulatory provisions:

* * * * *

§ 900.7, relating to approval, reapproval, or withdrawal of approval of mammography accreditation bodies or rejection of a proposed fee for accreditation.

§ 900.14, relating to suspension or revocation of a mammography certificate.

* * * * *

3. 21 CFR Part 900 is revised to read as follows:

PART 900—MAMMOGRAPHY

Subpart A—Accreditation

Sec.

Subpart B—Quality Standards and Certification

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

Subpart A—Accreditation

§ 900.1 Scope.

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

§ 900.2 Definitions.

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

(a) *Accreditation body* or *body* means an entity that has been approved by FDA under § 900.3(d) to accredit mammography facilities.

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

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

(1) Poor image quality;

(2) Failure to send mammography reports within 30 days to the referring physician or in a timely manner to the self-referred patient; and

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

(d) *Air kerma* means kerma in a given mass of air. The unit used to measure the quantity of air kerma is the Gray (Gy). For X-rays with energies less than 300 kiloelectronvolts (keV), 1 Gy = 100 radian (rad) = 114 roentgens (R) of exposure.

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

(f) *Calendar quarter* means any one of the following time periods during a given year: January 1 through March 31, April 1 through June 30, July 1 through September 30, or October 1 through December 31.

(g) *Category I* means medical educational activities that have been designated as Category I by the Accreditation Council for Continuing Medical Education (ACCME), the American Osteopathic Association (AOA), a state medical society, or an equivalent organization.

(h) *Certificate* means the certificate described in § 900.11(a).

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

(j) *Clinical image* means a mammogram.

(k) *Consumer* means an individual who chooses to comment or complain in reference to a mammography examination, including the patient or representative of the patient (e.g., family member or referring physician).

(l) *Continuing education unit* or *continuing education credit* means one contact hour of training.

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

(n) *Direct instruction* means:

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

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

(o) *Direct supervision* means that:

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

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

(p) *Established operating level* means the value of a particular quality assurance parameter that has been established as an acceptable normal level by the facility's quality assurance program.

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

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

(s) *FDA* means the Food and Drug Administration.

(t) *Interim regulations* means the regulations entitled ''Requirements for Accrediting Bodies of Mammography Facilities'' (58 FR 67558–67565) and ''Quality Standards and Certification Requirements for Mammography Facilities'' (58 FR 67565–67572), published by FDA on December 21, 1993, and amended on September 30, 1994 (59 FR 49808–49813). These regulations established the standards that had to be met by mammography facilities in order to lawfully operate between October 1, 1994, and April 28, 1999.

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

(v) *Kerma* means the sum of the initial energies of all the charged particles liberated by uncharged ionizing particles in a material of given mass.

(w) *Laterality* means the designation of either the right or left breast.

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

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

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

(aa) *Mammography* means radiography of the breast, but, for the purposes of this part, does not include:

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

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

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

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

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

(ee) *Mean optical density* means the average of the optical densities measured using phantom thicknesses of 2, 4, and 6 centimeters with values of kilovolt peak (kVp) clinically appropriate for those thicknesses.

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

(gg) *MQSA* means the Mammography Quality Standards Act.

(hh) *Multi-reading* means two or more physicians, at least one of whom is an interpreting physician, interpreting the same mammogram.

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

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

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

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

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

(nn) *Provisional certificate* means the provisional certificate described in § 900.11(b)(2).

(oo) *Qualified instructor* means an individual whose training and experience adequately prepares him or her to carry out specified training assignments. Interpreting physicians, radiologic technologists, or medical physicists who meet the requirements of § 900.12(a) would be considered qualified instructors in their respective areas of mammography. Other examples of individuals who may be qualified instructors for the purpose of providing training to meet the regulations of this part include, but are not limited to, instructors in a post-high school training institution and manufacturer's representatives.

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

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

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

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

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

(uu) *Standard breast* means a 4.2 centimeter (cm) thick compressed breast consisting of 50 percent glandular and 50 percent adipose tissue.

(vv) *Survey* means an onsite physics consultation and evaluation of a facility quality assurance program performed by a medical physicist.

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

(xx) *Traceable to a national standard* means an instrument is calibrated at either the National Institute of Standards and Technology (NIST) or at a calibration laboratory that participates in a proficiency program with NIST at least once every 2 years and the results of the proficiency test conducted within 24 months of calibration show agreement within ± 3 percent of the national standard in the mammography energy range.

§ 900.3 Application for approval as an accreditation body.

(a) *Eligibility.* Private nonprofit organizations or State agencies capable of meeting the requirements of this subpart A may apply for approval as accreditation bodies.

(b) *Application for initial approval.* (1) An applicant seeking initial FDA approval as an accreditation body shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiology Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, marked Attn: Mammography Standards Branch, of its desire to be approved as an accreditation body and of its requested scope of authority.

(2) Following receipt of the request, FDA will provide the applicant with additional information to aid in submission of an application for approval as an accreditation body.

(3) The applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant and, if the applicant is not a State agency, evidence of nonprofit status (i.e., of fulfilling Internal Revenue Service requirements as a nonprofit organization);

(ii) Detailed description of the accreditation standards the applicant will require facilities to meet and a discussion substantiating their equivalence to FDA standards required under § 900.12;

(iii) Detailed description of the applicant's accreditation review and decisionmaking process, including:

(A) Procedures for performing accreditation and reaccreditation clinical image review in accordance with § 900.4(c), random clinical image reviews in accordance with § 900.4(f), and additional mammography review in accordance with § 900.12(j);

(B) Procedures for performing phantom image review;

(C) Procedures for assessing mammography equipment evaluations and surveys;

(D) Procedures for initiating and performing onsite visits to facilities;

(E) Procedures for assessing facility personnel qualifications;

(F) Copies of the accreditation application forms, guidelines, instructions, and other materials the applicant will send to facilities during the accreditation process, including an accreditation history form that requires each facility to provide a complete history of prior accreditation activities and a statement that all information and data submitted in the application is true and accurate, and that no material fact has been omitted;

(G) Policies and procedures for notifying facilities of deficiencies;

(H) Procedures for monitoring corrections of deficiencies by facilities;

(I) Policies and procedures for suspending or revoking a facility's accreditation;

(J) Policies and procedures that will ensure processing of accreditation applications and renewals within a timeframe approved by FDA and assurances that the body will adhere to such policies and procedures; and

(K) A description of the applicant's appeals process for facilities contesting adverse accreditation status decisions.

(iv) Education, experience, and training requirements for the applicant's professional staff, including reviewers of clinical or phantom images;

(v) Description of the applicant's electronic data management and analysis system with respect to accreditation review and decision processes and the applicant's ability to provide electronic data in a format compatible with FDA data systems;

(vi) Resource analysis that demonstrates that the applicant's staffing, funding, and other resources are adequate to perform the required accreditation activities;

(vii) Fee schedules with supporting cost data;

(viii) Statement of policies and procedures established to avoid conflicts of interest or the appearance of conflicts of interest by the applicant's board members, commissioners, professional personnel (including reviewers of clinical and phantom images), consultants, administrative personnel, and other representatives of the applicant;

(ix) Statement of policies and procedures established to protect confidential information the applicant will collect or receive in its role as an accreditation body;

(x) Disclosure of any specific brand of imaging system or component, measuring device, software package, or other commercial product used in mammography that the applicant develops, sells, or distributes;

(xi) Description of the applicant's consumer complaint mechanism;

(xii) Satisfactory assurances that the applicant shall comply with the requirements of § 900.4; and

(xiii) Any other information as may be required by FDA.

(c) *Application for renewal of approval.* An approved accreditation body that intends to continue to serve as an accreditation body beyond its current term shall apply to FDA for renewal or notify FDA of its plans not to apply for renewal in accordance with the following procedures and schedule:

(1) At least 9 months before the date of expiration of a body's approval, the body shall inform FDA, at the address given in § 900.3(b)(1), of its intent to seek renewal.

(2) FDA will notify the applicant of the relevant information, materials, and supporting documentation required under § 900.3(b)(3) that the applicant shall submit as part of the renewal procedure.

(3) At least 6 months before the date of expiration of a body's approval, the applicant shall furnish to FDA, at the address in § 900.3(b)(1), three copies of a renewal application containing the information, materials, and supporting documentation requested by FDA in accordance with § 900.3(c)(2).

(4) No later than July 28, 1998 any accreditation body approved under the interim regulations published in the **Federal Register** of December 21, 1993 (58 FR 67558), that desires to continue to serve as an accreditation body under the final regulations shall apply for renewal of approval in accordance with the procedures set forth in paragraphs (c)(1) through (c)(3) of this section.

(5) Any accreditation body that does not plan to renew its approval shall so notify FDA at the address given in paragraph (b)(1) of this section at least 9 months before the expiration of the body's term of approval.

(d) *Rulings on applications for initial and renewed approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the accreditation standards the applicant will require facilities to meet are substantially the same as the quality standards published under subpart B of this part.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be rectified within a specified time period. If the deficiencies are not rectified to FDA's satisfaction within the specified time period, the application for approval as an accreditation body may be rejected.

(3) FDA shall notify the applicant whether the application has been approved or denied. That notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(6) If FDA does not reach a final decision on a renewal application in accordance with this paragraph before the expiration of an accreditation body's current term of approval, the approval will be deemed extended until the agency reaches a final decision on the application, unless an accreditation body does not rectify deficiencies in the application within the specified time period, as required in paragraph (d)(2) of this section.

(e) *Relinquishment of authority.* An accreditation body that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA, at the address in § 900.3(b)(1), at least 9 months before relinquishing such authority.

(f) *Transfer of records.* An accreditation body that does not apply for renewal of accreditation body approval, is denied such approval by FDA, or relinquishes its accreditation authority and duties before expiration of its term of approval, shall:

(1) Transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

(2) Notify, in a manner and time period approved by FDA, all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

(g) *Scope of authority.* An accreditation body's term of approval is for a period not to exceed 7 years. FDA may limit the scope of accreditation authority.

§ 900.4 Standards for accreditation bodies.

(a) *Code of conduct and general responsibilities.* The accreditation body shall accept the following responsibilities in order to ensure safe and accurate mammography at the facilities it accredits and shall perform these responsibilities in a manner that ensures the integrity and impartiality of accreditation body actions.

(1)(i) When an accreditation body receives or discovers information that suggests inadequate image quality, or upon request by FDA, the accreditation body shall review a facility's clinical images or other aspects of a facility's practice to assist FDA in determining whether or not the facility's practice poses a serious risk to human health. Such reviews are in addition to the evaluation an accreditation body performs as part of the initial accreditation or renewal process for facilities.

(ii) If review by the accreditation body demonstrates that a problem does exist with respect to image quality or other aspects of a facility's compliance with quality standards, or upon request by FDA, the accreditation body shall require or monitor corrective actions, or suspend or revoke accreditation of the facility.

(2) The accreditation body shall inform FDA as soon as possible but in no case longer than 2 business days after becoming aware of equipment or practices that pose a serious risk to human health.

(3) The accreditation body shall establish and administer a quality assurance (QA) program that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section. Such quality assurance program shall:

(i) Include requirements for clinical image review and phantom image review;

(ii) Ensure that clinical and phantom images are evaluated consistently and accurately; and

(iii) Specify the methods and frequency of training and evaluation for clinical and phantom image reviewers, and the bases and procedures for removal of such reviewers.

(4) The accreditation body shall establish measures that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the body's behalf. Such individuals who review clinical or phantom images under the provisions of paragraphs (c) and (d) of this section or who visit facilities under the provisions of paragraph (f) of this section shall not review clinical or phantom images from or visit a facility with which such individuals maintain a financial relationship, or when it would otherwise be a conflict of interest for them to do so, or when they have a bias in favor of or against the facility.

(5) The accreditation body may require specific equipment performance or design characteristics that FDA has approved. However, no accreditation body shall require, either explicitly or implicitly, the use of any specific brand of imaging system or component, measuring device, software package, or other commercial product as a condition for accreditation by the body, unless FDA determines that it is in the best interest of public health to do so.

(i) Any representation, actual or implied, either orally, in sales literature, or in any other form of representation, that the purchase or use of a particular product brand is required in order for any facility to be accredited or certified under § 900.11(b), is prohibited, unless FDA approves such representation.

(ii) Unless FDA has approved the exclusive use and promotion of a particular commercial product in accordance with this section, all products produced, distributed, or sold by an accreditation body or an organization that has a financial or other relationship with the accreditation body that may be a conflict of interest or have the appearance of a conflict of interest with the body's accreditation functions, shall bear a disclaimer stating that the purchase or use of such products is not required for accreditation or certification of any facility under § 900.11(b). Any representations about such products shall include a similar disclaimer.

(6) When an accreditation body denies accreditation to a facility, the accreditation body shall notify the facility in writing and explain the bases for its decision. The notification shall also describe the appeals process available from the accreditation body for the facility to contest the decision.

(7) No accreditation body may establish requirements that preclude facilities from being accredited under § 900.11(b) by any other accreditation body, or require accreditation by itself under MQSA if another accreditation body is available to a facility.

(8) The accreditation body shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted under § 900.3(d).

(9) An accreditation body shall establish procedures to protect confidential information it collects or receives in its role as an accreditation body.

(i) Nonpublic information collected from facilities for the purpose of carrying out accreditation body responsibilities shall not be used for any other purpose or disclosed, other than to FDA or its duly designated representatives, including State agencies, without the consent of the facility;

(ii) Nonpublic information that FDA or its duly designated representatives, including State agencies, share with the accreditation body concerning a facility that is accredited or undergoing accreditation by that body shall not be further disclosed except with the written permission of FDA.

(b) *Monitoring facility compliance with quality standards.* (1) The accreditation body shall require that each facility it accredits meet standards for the performance of quality mammography that are substantially the same as those in this subpart and in subpart B of this part.

(2) The accreditation body shall notify a facility regarding equipment, personnel, and other aspects of the facility's practice that do not meet such standards and advise the facility that such equipment, personnel, or other aspects of the practice should not be used by the facility for activities within the scope of part 900.

(3) The accreditation body shall specify the actions that facilities shall take to correct deficiencies in equipment, personnel, and other aspects of the practice to ensure facility compliance with applicable standards.

(4) If deficiencies cannot be corrected to ensure compliance with standards or if a facility is unwilling to take corrective actions, the accreditation body shall immediately so notify FDA, and shall suspend or revoke the facility's accreditation in accordance with the policies and procedures described under § 900.3(b)(3)(iii)(I).

(c) *Clinical image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review clinical images from each facility accredited by the body at least once every 3 years.

(2) Requirements for clinical image attributes. The accreditation body shall use the following attributes for all clinical image reviews, unless FDA has approved other attributes:

(i) Positioning. Sufficient breast tissue shall be imaged to ensure that cancers are not likely to be missed because of inadequate positioning.

(ii) Compression. Compression shall be applied in a manner that minimizes the potential obscuring effect of overlying breast tissue and motion artifact.

(iii) Exposure level. Exposure level shall be adequate to visualize breast structures. Images shall be neither underexposed nor overexposed.

(iv) Contrast. Image contrast shall permit differentiation of subtle tissue density differences.

(v) Sharpness. Margins of normal breast structures shall be distinct and not blurred.

(vi) Noise. Noise in the image shall not obscure breast structures or suggest the appearance of structures not actually present.

(vii) Artifacts. Artifacts due to lint, processing, scratches, and other factors external to the breast shall not obscure breast structures or suggest the appearance of structures not actually present.

(viii) Examination identification. Each image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(A) Name of the patient and an additional patient identifier.

(B) Date of examination.

(C) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section shall be used to identify view and laterality.

(D) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(E) Technologist identification.

(F) Cassette/screen identification.

(G) Mammography unit identification, if there is more than one unit in the facility.

(3) Scoring of clinical images. Accreditation bodies shall establish and administer a system for scoring clinical images using all attributes specified in paragraphs (c)(2)(i) through (c)(2)(viii) of this section or an alternative system that FDA has approved in accordance with § 900.3(d) or paragraph (a)(8) of this section. The scoring system shall include an evaluation for each attribute.

(i) The accreditation body shall establish and employ criteria for acceptable and nonacceptable results for each of the 8 attributes as well as an overall pass-fail system for clinical image review that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(ii) All clinical images submitted by a facility to the accreditation body shall be reviewed independently by two or more clinical image reviewers.

(4) Selection of clinical images for review. Unless otherwise specified by FDA, the accreditation body shall require that for each mammography unit in the facility:

(i) The facility shall submit craniocaudal (CC) and mediolateral oblique (MLO) views from two mammographic examinations that the facility produced during a time period specified by the accreditation body;

(ii) Clinical images submitted from one such mammographic examination for each unit shall be of dense breasts (predominance of glandular tissue) and the other shall be of fat-replaced breasts (predominance of adipose tissue);

(iii) All clinical images submitted shall be images that the facility's interpreting physician(s) interpreted as negative or benign.

(iv) If the facility has no clinical images meeting the requirements in paragraphs (c)(4)(i) through (c)(4)(iii) of this section, it shall so notify the accreditation body, which shall specify alternative clinical image selection methods that do not compromise care of the patient.

(5) Clinical image reviewers. Accreditation bodies shall ensure that all of their clinical image reviewers:

(i) Meet the interpreting physician requirements specified in § 900.12(a)(1);

(ii) Are trained and evaluated in the clinical image review process, for the types of clinical images to be evaluated by a clinical image reviewer, by the accreditation body before designation as clinical image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any clinical image and provide information to the facility for use in improving the attributes for which significant deficiencies were identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security and return to the facility of all clinical images received and to ensure completion of all clinical image reviews by the body in a timely manner. The accreditation body shall return all clinical images to the facility within 60 days of their receipt by the body, with the following exceptions:

(i) If the clinical images are needed earlier by the facility for clinical purposes, the accreditation body shall cooperate with the facility to accommodate such needs.

(ii) If a clinical image reviewer identifies a suspicious abnormality on an image submitted for clinical image review, the accreditation body shall ensure that this information is provided to the facility and that the clinical images are returned to the facility. Both shall occur no later than 10 business days after identification of the suspected abnormality.

(7) Notification of unsatisfactory image quality. If the accreditation body determines that the clinical images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(d) *Phantom image review for accreditation and reaccreditation.* (1) Frequency of review. The accreditation body shall review phantom images from each facility accredited by the body at least once every 3 years.

(2) Requirements for the phantom used. The accreditation body shall require that each facility submit for review phantom images that the facility produced using a phantom and methods of use specified by the body and approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section.

(3) Scoring phantom images. The accreditation body shall use a system for scoring phantom images that has been approved by FDA in accordance with § 900.3(b) and (d) or paragraph (a)(8) of this section.

(4) Phantom images selected for review. For each mammography unit in the facility, the accreditation body shall require the facility to submit phantom images that the facility produced during a time period specified by the body.

(5) Phantom image reviewers. Accreditation bodies shall ensure that all of their phantom image reviewers:

(i) Meet the requirements specified in § 900.12(a)(3) or alternative requirements established by the accreditation body and approved by FDA in accordance with § 900.3 or paragraph (a)(8) of this section;

(ii) Are trained and evaluated in the phantom image review process, for the types of phantom images to be evaluated by a phantom image reviewer, by the accreditation body before designation as phantom image reviewers and periodically thereafter; and

(iii) Clearly document their findings and reasons for assigning a particular score to any phantom image and provide information to the facility for use in improving its phantom image quality with regard to the significant deficiencies identified.

(6) Image management. The accreditation body's QA program shall include a tracking system to ensure the security of all phantom images received and to ensure completion of all phantom image reviews by the body in a timely manner. All phantom images that result in a failure of accreditation shall be returned to the facility.

(7) Notification measures for unsatisfactory image quality. If the accreditation body determines that the phantom images received from a facility are of unsatisfactory quality, the body shall notify the facility of the nature of the problem and its possible causes.

(e) *Reports of mammography equipment evaluation, surveys, and quality control.* The following requirements apply to all facility equipment covered by the provisions of subparts A and B:

(1) The accreditation body shall require every facility applying for accreditation to submit:

(i) With its initial accreditation application, a mammography equipment evaluation that was performed by a medical physicist no earlier than 6 months before the date of application for accreditation by the facility. Such evaluation shall demonstrate compliance of the facility's equipment with the requirements in § 900.12(e).

(ii) Prior to accreditation, a survey that was performed no earlier than 6 months before the date of application for accreditation by the facility. Such survey shall assess the facility's compliance with the facility standards referenced in paragraph (b) of this section.

(2) The accreditation body shall require that all facilities undergo an annual survey to ensure continued compliance with the standards referenced in paragraph (b) of this section and to provide continued oversight of facilities' quality control programs as they relate to such standards. The accreditation body shall require for all facilities that:

(i) Such surveys be conducted annually;

(ii) Facilities take reasonable steps to ensure that they receive reports of such surveys within 30 days of survey completion; and

(iii) Facilities submit the results of such surveys and any other information that the body may require to the body at least annually.

(3) The accreditation body shall review and analyze the information required in this section and use it to identify necessary corrective measures for facilities and to determine whether facilities should remain accredited by the body.

(f) *Accreditation Body Onsite Visits and Random Clinical Image Reviews.* The accreditation body shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body for accreditation. The accreditation body shall submit annually to FDA, at the address given in § 900.3(b)(1), 3 copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

(1) Onsite visits. (i) Sample size. Annually, each accreditation body shall visit at least 5 percent of the facilities it accredits. However, a minimum of 5 facilities shall be visited, and visits to no more than 50 facilities are required, unless problems identified in paragraph (f)(1)(i)(B) of this section indicate a need to visit more than 50 facilities.

(A) At least 50 percent of the facilities visited shall be selected randomly.

(B) Other facilities visited shall be selected based on problems identified through State or FDA inspections, serious complaints received from consumers or others, a previous history of noncompliance, or any other information in the possession of the accreditation body, inspectors, or FDA.

(C) Before, during, or after any facility visit, the accreditation body may require that the facility submit to the body for review clinical images, phantom images, or any other information relevant to applicable standards in this subpart and in subpart B of this part.

(ii) Visit plan. The accreditation body shall conduct facility onsite visits according to a visit plan that has been approved by FDA in accordance with § 900.3(d) or paragraph (a)(8) of this section, unless otherwise directed by FDA in particular circumstances. At a minimum, such a plan shall provide for:

(A) Assessment of overall clinical image QA activities of the facility;

(B) Review of facility documentation to determine if appropriate mammography reports are sent to patients and physicians as required;

(C) Selection of a sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner specified by the accreditation body and approved by FDA that does not compromise care of the patient as a result of the absence of the selected images from the facility;

(D) Verification that the facility has a medical audit system in place and is correlating films and pathology reports for positive cases;

(E) Verification that personnel specified by the facility are the ones actually performing designated personnel functions;

(F) Verification that equipment specified by the facility is the equipment that is actually being used to perform designated equipment functions;

(G) Verification that a consumer complaint mechanism is in place and that the facility is following its procedures; and

(H) Review of all factors related to previously identified concerns or concerns identified during that visit.

(2) Clinical image review for random sample of facilities. (i) Sample size. In addition to conducting clinical image reviews for accreditation and reaccreditation for all facilities, the accreditation body shall conduct clinical image reviews annually for a randomly selected sample as specified by FDA, but to include at least 3 percent of the facilities the body accredits. Accreditation bodies may count toward this random sample requirement all facilities selected randomly for the onsite visits described in paragraph (f)(1)(i)(A) of this section. Accreditation bodies shall not count toward the random sample requirement any facilities described in paragraph (f)(1)(i)(B) of this section that were selected for a visit because of previously identified concerns.

(ii) Random clinical image review. In performing clinical image reviews of the random sample of facilities, accreditation bodies shall evaluate the same attributes as those in paragraph (c) of this section for review of clinical images for accreditation and reaccreditation.

(iii) Accreditation bodies should not schedule random clinical image reviews at facilities that have received notification of the need to begin the accreditation renewal process or that have completed the accreditation renewal process within the previous 6 months.

(iv) Selection of the random sample of clinical images for clinical image review by the accreditation body. Clinical images shall be selected in a manner, specified by the accreditation body and approved by FDA under § 900.3(d) or paragraph (a)(8) of this section, that does not compromise care of the patient as a result of the absence of the selected images from the facility.

(g) *Consumer complaint mechanism.* The accreditation body shall develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility. Such system shall have been approved by FDA in accordance with§ 900.3(d) or paragraph (a)(8) of this section. Accordingly, all accreditation bodies shall:

(1) Provide a mechanism for all facilities it accredits to file serious unresolved complaints with the accreditation body;

(2) Maintain a record of every serious unresolved complaint received by the body on all facilities it accredits for a period of at least 3 years from the date of receipt of each such complaint;

(h) *Reporting and recordkeeping.* All reports to FDA specified in paragraphs (h)(1) through (h)(4) of this section shall be prepared and submitted in a format

and medium prescribed by FDA and shall be submitted to a location and according to a schedule specified by FDA. The accreditation body shall:

(1) Collect and submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated, in a manner and at a time specified by FDA.

(2) Accept applications containing the information required in 42 U.S.C. 263b(c)(2) for provisional certificates and in § 900.11(b)(3) for extension of provisional certificates, on behalf of FDA, and notify FDA of the receipt of such information;

(3) Submit to FDA the name, identifying information, and other information relevant to 42 U.S.C. 263b and specified by FDA for any facility for which the accreditation body denies, suspends, or revokes accreditation, and the reason(s) for such action;

(4) Submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them;

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

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

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

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

§ 900.5 Evaluation.

FDA shall evaluate annually the performance of each accreditation body. Such evaluation shall include an assessment of the reports of FDA or State inspections of facilities accredited by the body as well as any additional information deemed relevant by FDA that has been provided by the accreditation body or other sources or has been required by FDA as part of its oversight initiatives. The evaluation shall include a determination of whether there are major deficiencies in the accreditation body's performance that, if not corrected, would warrant withdrawal of the approval of the accreditation body under the provisions of § 900.6.

§ 900.6 Withdrawal of approval.

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

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

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

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

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

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

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

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

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

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

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

(4) FDA may refuse to accept an application from a former accreditation body whose approval was withdrawn because of fraud or willful disregard of public health.

§ 900.7 Hearings.

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

(b) A facility that has been denied accreditation is entitled to an appeals process from the accreditation body. The appeals process shall be specified in writing by the accreditation body and shall have been approved by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

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

§§ 900.8–900.9 [Reserved]

Subpart B—Quality Standards and Certification

§ 900.10 Applicability.

The provisions of subpart B are applicable to all facilities under the regulatory jurisdiction of the United States that provide mammography

services, with the exception of the Department of Veterans Affairs.

§ 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 this subpart. 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 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 designated by FDA, the agency may 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) A new facility beginning operation after October 1, 1994, is eligible to apply for a provisional certificate. 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) Following the agency's receipt of the accreditation body's decision that a facility has submitted the required information, FDA may issue a provisional certificate to a facility upon determination that the facility has satisfied the requirements of § 900.11(b)(2)(i). 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 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) The accreditation body shall forward the request, with its recommendation, to FDA within 2 business days after receipt.

(iii) FDA may 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).

(iv) 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 suspended or revoked by FDA, may apply to have the certificate reinstated so that the facility may be considered to be a new facility and thereby be eligible for a provisional certificate.

(1) Unless prohibited from reinstatement under § 900.11(c)(4), a facility applying for reinstatement shall:

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

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

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

(B) Name of previous owner/lessor;

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

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

(iii) Justify application for reinstatement of accreditation by submitting to the accreditation body or other entity 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 may issue a provisional certificate to the facility if:

(i) The accreditation body or other entity 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 certification.

(4) If a facility's certificate was revoked on the basis of an act described in 41 U.S.C. 263b(i)(1), no person who owned or operated that facility at the time the act occurred may own or operate a mammography facility within 2 years of the date of revocation.

§ 900.12 Quality standards.

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

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

(i) Initial qualifications. Unless the exemption in paragraph (a)(1)(iii)(A) of this section applies, before beginning to interpret mammograms independently, the interpreting physician shall:

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

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

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

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

representative of the training institution; and

(D) Unless the exemption in paragraph (a)(1)(iii)(B) of this section applies, have interpreted or multi-read at least 240 mammographic examinations within the 6-month period immediately prior to the date that the physician qualifies as an interpreting physician. This interpretation or multi-reading shall be under the direct supervision of an interpreting physician.

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

(A) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have interpreted or multi-read at least 960 mammographic examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in-between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(1)(i) of this section were completed, the interpreting physician shall have taught or completed at least 15 category I continuing medical education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period. This training shall include at least six category I continuing medical education credits in each mammographic modality used by the interpreting physician in his or her practice; and

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

(D) Units earned through teaching a specific course can be counted only once towards the 15 required by paragraph (a)(1)(ii)(B) of this section, even if the course is taught multiple times during the previous 36 months.

(iii) Exemptions. (A) Those physicians who qualified as interpreting physicians under paragraph (a)(1) of this section of FDA's interim regulations prior to April 28, 1999 are considered to have met the initial requirements of paragraph (a)(1)(i) of this section. They may continue to interpret mammograms provided they continue to meet the licensure requirement of paragraph (a)(1)(i)(A) of this section and the continuing experience and education requirements of paragraph (a)(1)(ii) of this section.

(B) Physicians who have interpreted or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician in any 6-month period during the last 2 years of a diagnostic radiology residency and who become appropriately board certified at the first allowable time, as defined by an eligible certifying body, are otherwise exempt from paragraph (a)(1)(i)(D) of this section.

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

(A) Interpreting physicians who fail to meet the continuing experience requirements of paragraph (a)(1)(ii)(A) of this section shall:

(*1*) Interpret or multi-read at least 240 mammographic examinations under the direct supervision of an interpreting physician, or

(*2*) Interpret or multi-read a sufficient number of mammographic examinations, under the direct supervision of an interpreting physician, to bring the physician's total up to 960 examinations for the prior 24 months, whichever is less.

(*3*) The interpretations required under paragraph (a)(1)(iv)(A)(*1*) or (a)(1)(iv)(A)(*2*) of this section shall be done within the 6 months immediately prior to resuming independent interpretation.

(B) Interpreting physicians who fail to meet the continuing education requirements of paragraph (a)(1)(ii)(B) of this section shall obtain a sufficient number of additional category I continuing medical education credits in mammography to bring their total up to the required 15 credits in the previous 36 months before resuming independent interpretation.

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

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

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

(ii) Mammography requirements. Have, prior to April 28, 1999 qualified as a radiologic technologist under paragraph (a)(2) of this section or completed at least 40 contact hours of documented training specific to mammography under the supervision of a qualified instructor. The hours of documented training shall include, but not necessarily be limited to:

(A) Training in breast anatomy and physiology, positioning and compression, quality assurance/quality control techniques, imaging of patients with breast implants;

(B) The performance of a minimum of 25 examinations under the direct supervision of an individual qualified under paragraph (a)(2) of this section; and

(C) At least 8 hours of training in each mammography modality to be used by the technologist in performing mammography exams; and

(iii) Continuing education requirements. (A) Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed, the radiologic technologist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility will choose one of these dates to determine the 36-month period.

(B) Units earned through teaching a specific course can be counted only once towards the 15 required in paragraph (a)(2)(iii)(A) of this section, even if the course is taught multiple times during the previous 36 months.

(C) At least six of the continuing education units required in paragraph (a)(2)(iii)(A) of this section shall be related to each mammographic modality used by the technologist.

(D) Requalification. Radiologic technologists who fail to meet the continuing education requirements of paragraph (a)(2)(iii)(A) of this section shall obtain a sufficient number of

continuing education units in mammography to bring their 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.

(E) Before a radiologic technologist may begin independently performing mammographic examinations using a mammographic 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) Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraphs (a)(2)(i) and (a)(2)(ii) of this section were completed or of October 28, 1997 whichever is later, the radiologic technologist shall have performed a minimum of 200 mammography examinations during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in between the two. The facility will choose one of these dates to determine the 24-month period.

(B) Requalification. Radiologic technologists who fail to meet the continuing experience requirements of paragraph (a)(2)(iv)(A) of this section shall perform a minimum of 25 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 paragraph (e) of this section 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 survey; and

(B)(*1*) Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate 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 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999 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 paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and

(B) Prior to the April 28, 1999 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 undergraduate or graduate level physics,

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

(*3*) Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.

(iii) Continuing qualifications. (A) Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.

(B) Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of October 28, 1997 whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA inspection or the last day of the calendar quarter or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period on a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(C) Before a medical physicist may begin independently performing mammographic surveys of a new mammographic modality, that is, a mammographic 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 of the new mammographic 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 sufficient number of surveys under the direct supervision of a medical physicist who meets the qualifications of paragraphs (a)(3)(i) and (a)(3)(iii) of this section to bring their total surveys up to the required two facilities and six units in the previous 24 months. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(4) *Retention of personnel records.* Facilities shall maintain records to document the qualifications of all personnel who worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. These records must be available for review by the MQSA inspectors. Records of personnel no longer employed by the facility 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.

(b) *Equipment.* Regulations published under §§ 1020.30, 1020.31, and 900.12(e) of this chapter that are relevant to equipment performance should also be consulted for a more complete understanding of the equipment performance requirements.

(1) *Prohibited equipment.* Radiographic equipment designed for general purpose or special nonmammography procedures shall not be used for mammography. This prohibition 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) The assembly shall be capable of being fixed in any position where it is designed to operate. Once fixed in any such position, it shall not undergo unintended motion.

(ii) The mechanism ensuring compliance with paragraph (b)(3)(i) of this section shall not fail in the event of power interruption.

(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 from between the source and image receptor.

(5) *Beam limitation and light fields.* (i) All systems shall have beam-limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor.

(ii) For any mammography system with a light beam that passes through the X-ray beam-limiting device, the light shall provide an average illumination of not less than 160 lux (15 foot candles) at 100 cm or the maximum source-image receptor distance (SID), whichever is less.

(6) *Magnification.* (i) Systems used to perform noninterventional problem solving procedures shall have radiographic magnification capability available for use by the operator.

(ii) Systems used for magnification procedures shall provide, at a minimum, at least one magnification valve within the range of 1.4 to 2.0.

(7) *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 and/or focal spot is selected by a system algorithm that is based on the exposure or on a test exposure, the system shall display, after the exposure, the target material and/or focal spot actually used during the exposure.

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

(i) Application of compression. Effective October 28, 1999 each system shall provide:

(A) An initial power-driven compression activated by hands-free controls operable from both sides of the patient; and

(B) Fine adjustment compression controls operable from both sides of the patient.

(ii) Compression paddle. (A) Systems shall be equipped with different sized compression paddles that match the sizes of all full-field image receptors provided for the system. 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)(8)(ii)(D) and (b)(8)(ii)(E) of this section.

(B) Except as provided in paragraph (b)(8)(ii)(C) of this section, 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 when compression is applied.

(C) Equipment intended by the manufacturer's design to not be flat and parallel to the breast support table during compression shall meet the manufacturer's design specifications and maintenance requirements.

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

(E) The chest wall edge may be bent upward to allow for patient comfort but shall not appear on the image.

(9) *Technique factor selection and display.* (i) Manual selection of milliampere seconds (mAs) or at least one of its component parts (milliapere (mA) and/or time) shall be available.

(ii) The technique factors (peak tube potential in kilovolt (kV) and either tube current in mA and exposure time in seconds or the product of tube current and exposure time in mAs) to be used during an exposure shall be indicated before the exposure begins, except when automatic exposure controls (AEC) are used, in which case the technique factors that are set prior to the exposure shall be indicated.

(iii) Following AEC mode use, the system shall indicate the actual kilovoltage peak (kVp) and mAs used during the exposure. The mAs may be displayed as mA and time.

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

(ii) The positioning or selection of the 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 X-ray input surface of the breast compression paddle.

(B) The selected position of the detector shall be clearly indicated.

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

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

(12) *Intensifying screens.* The facility shall use intensifying screens for mammography that have been designated by the screen manufacturer as appropriate for mammography and shall use film that is matched to the screen's spectral output as specified by the manufacturer.

(13) *Film processing solutions.* For processing mammography films, the facility shall use chemical solutions that

are capable of developing the films used by the facility in a manner equivalent to the minimum requirements specified by the film manufacturer.

(14) *Lighting.* The facility shall make special lights for film illumination, i.e., hot-lights, capable of producing light levels greater than that provided by the view box, available to the interpreting physicians.

(15) *Film masking devices.* Facilities shall ensure that film masking devices that can limit the illuminated area to a region equal to or smaller than the exposed portion of the film are available to all interpreting physicians interpreting for the facility.

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

(i) The name of the patient and an additional patient identifier;

(ii) Date of examination;

(iii) The name of the interpreting physician who interpreted the mammogram;

(iv) 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;

(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;

(v) In cases where no final assessment category can be assigned due to incomplete work-up, ''Incomplete: Need 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

(vi) 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, even if the assessment is negative or benign.

(2) *Communication of mammography results to the patient.* Each facility shall maintain a system to ensure that the results of each mammographic examination are communicated to the patient in a timely manner. If assessments are ''Suspicious'' or ''Highly suggestive of malignancy'' and the patient has not named a health care provider, the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

(i) As soon as possible, but no later than 30 days from the date of the mammography examination, patients 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 a written notification of results in lay terms.

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

(3) *Communication of mammography results to health care providers.* When the patient has a referring health care provider or the patient 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 as soon as possible, or if the health care provider is unavailable, to a responsible designee of the health care provider.

(4) *Recordkeeping.* Each facility that performs mammograms:

(i) Shall (except as provided in paragraph (c)(3)(ii) of this section) maintain mammography films and reports in a permanent medical record of the patient for a period of not less than 5 years, or not less than 10 years if no additional mammograms of the patient are performed at the facility, or a longer period if mandated by State or local law; and

(ii) Shall upon request or on behalf of, by the patient, permanently or temporarily transfer the original mammograms and copies of the patient's reports to a medical institution, or to a physician or health care provider of the patient, or to the patient directly;

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

(5) *Mammographic image identification.* Each mammographic image shall have the following information indicated on it in a permanent, legible, and unambiguous manner and placed so as not to obscure anatomic structures:

(i) Name of patient and an additional patient identifier.

(ii) Date of examination.

(iii) View and laterality. This information shall be placed on the image in a position near the axilla. Standardized codes specified by the accreditation body and approved by FDA in accordance with § 900.3(b) or § 900.4(a)(8) shall be used to identify view and laterality.

(iv) Facility name and location. At a minimum, the location shall include the city, State, and zip code of the facility.

(v) Technologist identification.

(vi) Cassette/screen identification.

(vii) Mammography unit identification, if there is more than one unit in the facility.

(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 allowed 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:

(A) Follow the facility procedures for corrective action when the images they are asked to interpret are of poor quality, and

(B) Participate in the facility's medical outcomes audit program.

(iii) Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment

evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.

(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 a quality control technologist(s). The tasks are to be performed by the quality control technologist or by other personnel qualified to perform the tasks. When other personnel are utilized for these tasks, the quality control technologist shall ensure that the tasks are completed in such a way as to meet the requirements of paragraph (e) of this section.

(2) *Quality assurance records.* The lead interpreting physician, quality control technologist, and medical physicist shall ensure that records concerning employee qualifications to meet assigned quality assurance tasks, mammography technique and procedures, quality control (including monitoring data, problems detected by analysis of that data, corrective actions, and the effectiveness of the corrective actions), safety, and protection are properly maintained and updated. These quality control records shall be kept for each test specified in paragraphs (e) and (f) of this section until the next annual inspection has been completed and FDA has determined that the facility is in compliance with the quality assurance requirements or until the test has been performed two additional times at the required frequency, whichever is longer.

(e) *Quality assurance—equipment*—(1) *Daily quality control tests.* Film processors used to develop mammograms shall be adjusted and maintained to meet the technical development specifications for the mammography film in use. A processor performance test shall be performed on each day that examinations are performed before any clinical films are processed 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 + 0.03 of the established operating level.

(ii) The mid-density shall be within + 0.15 of the established operating level.

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

(2) *Weekly quality control tests.* Facilities with screen-film systems shall perform an image quality evaluation test, using an FDA-approved phantom, 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 + 0.20 from the established operating level.

(iii) The phantom image shall achieve at least the minimum score established by the accreditation body and accepted by FDA in accordance with § 900.3(d) or § 900.4(a)(8).

(iv) The density difference between the background of the phantom and an added test object, used to assess image contrast, shall be measured and shall not vary by more than ± 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. Any corrective actions shall be recorded and the results of these corrective actions shall be assessed.

(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 emulsion side up. If the darkroom has a safelight used for mammography film, it shall be on during this test.

(ii) Screen-film contact. Testing for screen-film contact shall be conducted using 40 mesh copper screen. All cassettes used in the facility for mammography shall be tested.

(iii) Compression device performance. (A) A compression force of at least 111 newtons (25 pounds) shall be provided.

(B) Effective October 28, 1999 the maximum compression force for the initial power drive shall be between 111 newtons (25 pounds) and 209 newtons (47 pounds).

(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 ± 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement 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 ± 0.30 of the average under phototimed conditions can be produced.

(B) After October 28, 1999 the AEC shall be capable of maintaining film optical density (OD) within ± 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.

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

(ii) Kilovoltage peak (kVp) accuracy and reproducibility. (A) The kVp shall be accurate within + 5 percent of the indicated or selected kVp at:

(*1*) The lowest clinical kVp that can be measured by a kVp test device;

(*2*) The most commonly used clinical kVp;

(*3*) The highest available clinical kVp, 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) Focal spot condition. Until October 28, 1999 focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 1999 facilities shall evaluate focal spot condition only by determining the system resolution.

(A) System Resolution. (*1*) Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.

(*2*) The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall

edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.

(*3*) When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.

(*4*) When more than one SID is provided, the test shall be performed at SID most commonly used clinically.

(*5*) Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.

(B) Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1.

TABLE 1

Focal Spot Tolerance Limit		
Nominal Focal Spot Size (mm)	Maximum Measured Dimensions	
	Width(mm)	Length(mm)
0.10	0.15	0.15
0.15	0.23	0.23
0.20	0.30	0.30
0.30	0.45	0.65
0.40	0.60	0.85
0.60	0.90	1.30

(iv) Beam quality and half-value layer (HVL). The HVL shall meet the specifications of § 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.

TABLE 2

X-ray Tube Voltage (kilovolt peak) and Minimum HVL		
Designed Operating Range (kV)	Measured Operating Voltage (kV)	Minimum HVL (millimeters of aluminum)
Below 50	20	0.20
	25	0.25
	30	0.30

(v) Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma 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 standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.

(vii) X-ray field/light field/image receptor/compression paddle alignment. (A) All systems shall have beam-limiting devices that allow the useful X-ray beam to extend to or beyond the edges of the image receptor but by no more than 2 percent of the SID at the chest wall side.

(B) If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any 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 surface shall not exceed 2 percent of the SID.

(C) 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 when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.

(viii) Uniformity of screen speed. Uniformity of screen speed 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 sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.

(x) Radiation output. (A) The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 1999 the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.

(B) The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.

(xi) Decompression. 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 be tested to confirm that it provides:

(A) An override capability to allow maintenance of compression;

(B) A continuous display of the override status; and

(C) A manual emergency compression release that can be activated in the event of power or automatic release failure.

(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 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 nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.

(ii) If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:

(A) Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in paragraphs (e)(1), (e)(2), (e)(4)(ii), (e)(4)(iii), (e)(5)(i), (e)(5)(iii), (e)(5)(v), (e)(5)(vi), (e)(6), or (e)(7) of this section;

(B) Within 30 days of the test date for all other tests described in paragraph (e) of this section.

(9) *Surveys.* (i) At least 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 described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described 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, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. 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 or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

(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 air kerma measuring instruments.* Instruments used by medical physicists in their annual survey to measure the air kerma or air kerma rate from a mammography unit shall be calibrated at least once every 2 years and each time the instrument is repaired. The instrument calibration must be traceable to a national standard and calibrated with an accuracy of + 6 percent (95 percent confidence level) in the mammography energy range.

(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.

(f) *Quality assurance-mammography medical outcomes audit.* Each facility shall establish and maintain a mammography medical outcomes audit program to followup positive mammographic assessments and to correlate pathology results with the interpreting physician's findings. 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 to collect and review outcome data for all mammograms performed, including followup on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. Analysis of these outcome data shall be made individually and collectively for all interpreting physicians at the facility. In addition, any cases of breast cancer among women imaged at the facility that subsequently become known to the facility shall prompt the facility to initiate followup on surgical and/or pathology results and review of the

mammograms taken prior to the diagnosis of a malignancy.

(2) *Frequency of audit analysis.* The facility's first audit analysis shall be initiated no later than 12 months after the date the facility becomes certified, or 12 months after April 28, 1999 whichever date is the latest. This audit analysis shall be completed within an additional 12 months to permit completion of diagnostic procedures and data collection. Subsequent audit analyses will be conducted at least once every 12 months.

(3) *Reviewing interpreting physician.* Each facility shall designate at least one interpreting physician to review the medical outcomes audit data at least once every 12 months. This individual shall record the dates of the audit period(s) and shall be responsible for analyzing results based on this audit. This individual shall also be responsible for documenting the results, notifying other interpreting physicians of their results and the facility aggregate results. If followup actions are taken, the reviewing interpreting physician shall also be responsible for documenting the nature of the followup.

(g) *Mammographic procedure and techniques for mammography of patients with breast implants.* (1) Each facility shall have a procedure to inquire whether or not the patient has breast implants prior to the actual mammographic exam.

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

(h) *Consumer compliant 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 serious complaints 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) *Clinical image quality.* Clinical images produced by any certified facility must continue to comply with the standards for clinical image quality established by that facility's accreditation body.

(j) *Additional mammography review and patient notification.* (1) If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

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

§ 900.13 Revocation of accreditation and revocation ofaccreditation 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. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

(b) *Withdrawal of FDA approval of an accreditation body.* (1) If FDA withdraws 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 the withdrawal of approval, 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 withdrawal 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.

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, 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 or the accreditation body 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 this 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 paragraph (d) of this section;

(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.

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

(a) The appeals procedures described in this section are available only for adverse accreditation or reaccreditation 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 or reaccredited, 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 or reaccreditation 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 in 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 (DMQRP), 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 request reconsideration by 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 three 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 basis 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.

§ 900.16 Appeals of denials of certification.

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a faciity that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

§ 900.17 [Reserved]

§ 900.18 Alternative requirements for § 900.12 quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuing 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 (HFZ–240), Center for Devices and Radiological Health, 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 ensure 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) FDA 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 shall 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 shall 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 shall be assigned an identifying number.

(2) Notice of an approved request for an alternative standard or any amendment or extension thereof shall 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 shall 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, shall 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 shall be available for public disclosure in the Dockets Management Branch, excluding patient 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 ensure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

(f) *Applicability of the alternative standards.* (1) Except as provided in paragraphs (f)(2) and (f)(3) of this section, 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. Other entities interested in similar or identical approvals must file their own application following the procedures of paragraph (c) of this section.

(2) When an alternative standard is approved for a manufacturer of equipment, any facility using that equipment will also be covered by the alternative standard.

(3) The agency may extend the alternative standard to other entities when FDA determines that expansion of the approval of the alternative standard would be an effective means of promoting the acceptance of measures to improve the quality of mammography. All such determinations will be publicized by appropriate means.

(g) *Withdrawal of approval of alternative requirements.* FDA shall amend or withdraw approval of an alternative standard whenever the agency 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 FDA determines that such action is necessary to prevent an imminent health hazard.

Dated: September 25, 1997.

Michael A. Friedman,

Lead Deputy Commissioner for the Food and Drug Administration.

Donna E. Shalala,

Secretary of Health and Human Services.

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