Federal Register

Tuesday
October 28, 1997

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 900

Quality Mammography Standards; Final Rule

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