to restrict continuing education credits for radiologic technologists to Category A courses.

(Comment 256). One comment stated that a limit should be placed on the number of times credit could be earned for teaching the same course. NMQAAC, when discussing this issue, recommended that no credit should be given for teaching. FDA recognizes, however, that a great amount of study and learning is required to successfully teach a course, especially the first time it is given. The agency will continue to permit personnel to earn credit towards the continuing education requirement by teaching, but has added a new provision that limits the times a particular course can be counted towards this requirement to once in any 3-year period (see § 900.12(a)(2)(iii)(B)). This is consistent with similar provisions for interpreting physicians and medical physicists.

(Comment 257). A number of comments on this section were based on misunderstandings. One comment expressed the belief that this requirement actually meant that an individual would have to earn 15 units every 2 calendar years in order to meet this requirement. Another comment, incorrectly assuming that implant imaging was a mammographic modality, assumed that 6 hours of implant imaging training would be required every 3 years. Other comments mistakenly concluded that 5 credits on implant imaging would be required every year, that the requirement to average 5 credits a year was being increased to 6, or that 5 credits were being required each and every year.

All of these comments opposed the requirement based on their misunderstandings. As FDA develops educational materials to help personnel understand how they may comply with the new regulations, special attention will be focused on correcting such misunderstandings. Changes in the wording of § 900.12(a)(2)(iii)(A) from the proposal are intended to emphasize that the basic continuing education requirement is to earn 15 credits over 3 years and to clarify options for calculating the time period to be used to demonstrate compliance with that requirement. The agency hopes that these changes will eliminate confusion about whether 5 units must be averaged per year or earned per year (the unit requirement is an average) and provide radiologic technologists and the facilities that employ them with some flexibility in maintaining and documenting compliance with this requirement. Both of the changes parallel similar changes made in the wording to the interpreting physician and medical physicist requirements.

Only two comments were received on proposed § 900.12(a)(2)(iii)(B) (now § 900.12(a)(2)(iii)(C)), which requires a technologist to have some continuing education for all modalities used by that technologist. One comment stated this was a ''great revision.'' The other expressed concerns about the availability of the training.

FDA believes that if a new mammographic modality is introduced, training will be available initially from the originators of the mammographic modality because those originators will have a high interest in ensuring that the mammographic modality is used properly. FDA acknowledges that training with a disappearing mammographic modality, like xeromammography, may be more difficult to obtain. However, FDA has concluded that the possibility of detriment to the public health that could result from personnel not maintaining their skills must override this concern.

(Comment 258). FDA received four comments on proposed § 900.12(a)(2)(iii)(C) (now § 900.12(a)(2)(iii)(D)), which describes requalification procedures for technologists who failed to meet continuing education requirements. One comment agreed with the provision and two comments went further to suggest that there should be some sort of penalty for not meeting the requirement on time. The authors apparently did not realize that the penalty was not being able to perform mammography except under direct supervision until the requalification was completed (see previous discussion related to interpreting physician). The fourth comment supported the requirement, but expressed concern about who would approve the training and keep the records of completion.

FDA has found the mechanisms used under the interim regulations for approving training, which involve the participation of professional groups, are adequate. These same professional groups ordinarily provide documentation of completion. Under the interim regulations, it has been the responsibility of the facility to obtain and maintain such records and this will continue under the final regulations.

(Comment 259). The three comments received on proposed § 900.12(a)(2)(iii)(D) (now § 900.12(a)(2)(iii)(E)) opposed the requirement that a technologist receive training in use of a mammographic modality for which she was not previously trained before using that modality. One comment stated that the requirement would be an undue hardship and two stated that it will be difficult to obtain the training. FDA believes that the value of being trained in the use of a mammographic modality before beginning to use it on patients overrides the hardship concern. As discussed earlier, FDA also believes that availability of training will not be a problem and that the definition of qualified instructor (§ 900.2(oo)) provides for an adequate number of teachers. The proposed requirement has been retained unchanged.

Continuing experience is the second of the general requirements intended to ensure that the technologists maintain their skills. As proposed, § 900.12(a)(2)(iv) required that technologists perform a minimum of 100 examinations during a 12-month period. This requirement was intended to parallel the continuing experience requirement for physicians.

(Comment 260). Eight comments supported a continuing experience requirement for technologists, explaining that a technologist's positioning skills improve with additional mammography examinations. Nine comments opposed the requirement. Several of these suggested alternative measures, such as a ''lengthy appraisal (at least 3 days * * *) * * *'' by the chief technologist and radiologists or a certification program similar to that used by the American Heart Association for CPR certification.

While these suggestions have merit, they are a form of proficiency testing and, as discussed elsewhere, large numbers of comments provided valid reasons to conclude that it is premature to require such testing.

(Comment 261). Another comment opposed the requirement on the grounds that ''if you can do a mammogram, you can do it, period.'' The author's basic assumption seems to be that you never forget how to perform mammography. FDA notes that the purpose of continuing experience requirements is to ensure that technologist skills are maintained at a level that is likely to produce accurate and reliable mammograms. In view of the complexity of the examination and changes in technology, FDA believes that the optimism expressed by this last comment is unwarranted.

(Comment 262). Proposed § 900.12(a)(2)(iv)(A) set the continuing experience requirement at the performance of at least 100 mammography examinations in a 12-month period. One comment stated that this was a ''very acceptable requirement,'' but two believed that it

should be higher. One of these recommended that the number should be the same as the 480 interpretations a year required of radiologists. Four comments supported the level of the requirement, but asked that the averaging period be longer than a year to allow technologists to be absent for longer periods and still be able to meet the requirement. Two of these comments noted that physicians are allowed a 24-month averaging period for their continuing experience. Ten other comments suggested that the number be lowered, with 50 or 75 a year being the most common suggestions.

FDA has concluded that the number of 100 per year, which was first suggested by NMQAAC in February 1994, and supported by them at their January 1997 meeting, is the most reasonable compromise between the need to establish a requirement sufficiently high to maintain skills and the need to avoid disqualifying large numbers of competent technologists. The agency notes that as few as two examinations per week will be sufficient to meet this requirement.

FDA does agree with the suggestion that the averaging period be lengthened to 24 months and the wording of the regulation has been changed to require the performance of 200 examinations in a 24-month period. A clarification of how to determine the 24-month period was also added, which parallels similar provisions for calculating such time periods for interpreting physicians and medical physicists.

(Comment 262a). Seventeen comments identified specific groups that they believed would have difficulty meeting this requirement. These included individuals, such as mammography supervisors, instructors, and technologists in sales, who had made career choices that would make it difficult for them to meet this requirement.

FDA understands the desire of these individuals to keep their options open in case they wish to return to the performance of examinations, but the agency believes that higher priority must be given to maintaining technologist proficiency. FDA also notes, as discussed later, that a requalification procedure has been provided for technologists in this situation.

(Comment 263). A related concern was expressed in the 13 comments that indicated technologists in rural hospitals would have difficulty meeting this experience requirement. As explained previously, FDA recognizes that rural facilities face special challenges but believes that it would be contrary to the MQSA goal of assuring women a uniform minimum level of quality of mammography nationwide to establish lesser standards for technologists practicing in rural areas.

As proposed, § 900.12(a)(2)(iv)(B) stated that technologists who fail to meet the continuing experience requirement can re-establish this qualification through the performance of 50 mammography examinations under direct supervision.

(Comment 264). Ten comments stated that this number of examinations was too many and suggested that it be reduced, with 30, 25, and 20 examinations all being proposed. Another comment urged that there be a penalty for failing to meet this requirement, apparently not realizing that the penalty was not being able to work independently until requalification was completed. One comment urged that proficiency testing be used instead of an experience requirement, while another was concerned about how the performance of these examinations would be documented.

As discussed above, FDA has reduced the number of examinations that have to be performed under direct supervision as part of the initial training from 50 to 25. The agency has no reason to require the requalification figure to be higher than the number of examinations for initial qualification. Accordingly, the agency has similarly reduced the requalification requirement from 50 to 25 examinations.

d. *Medical physicist (§ 900.12(a)(3))*

Section 900.12(a)(3) establishes the requirements that must be met by medical physicists who conduct surveys of mammography facilities and provide oversight of the facility quality assurance program. Initial qualifications, alternative initial qualifications, continuing qualifications, and the reestablishment of qualifications are all covered. No major changes have been made in the final regulations from what was proposed. Some changes have been made in the survey experience requirement and in the averaging time for the continuing qualifications requirement. The comments received on the final regulations in each of these areas are discussed in below in connection with the specific provisions.

(Comment 265). One comment stated that the proposed rule is very positive, ensuring that only properly trained and adequately qualified professionals perform medical physics surveys. Another comment concluded that the medical physicist qualifications were appropriate and reasonable.

The initial qualification requirements for medical physicists include board certifications or State licensure or approval; masters degree or higher in physical science with 20 semester hours in college or graduate level physics; 20 contact hours of training in mammography; and survey experience.

The proposed initial qualifications requirements generated a wide spectrum of comments. Views varied greatly on the value of State approval or licensure in ensuring that physicists were properly qualified to perform mammography services.

(Comment 266). Ten comments expressed doubt that State approval/licensure provided a sound basis for establishing competence. One comment recommended that the State approval option be deleted, while another suggested that State approval be accepted only after FDA investigation. One comment stated that State approval/licensure should be part of alternative criteria with additional appropriate training and experience requirements. Three comments argued that State approval or licensure should be specific to the State where the professional practice will occur, unless a State reciprocity mechanism is in place. One comment stated that the proposal was unclear as to whether State approval was sufficient or additional requirements would need to be met after October 1997. On the other hand, seven comments stated that State approval, like board certification, was adequate by itself and that additional requirements were not needed.

Five comments stated that board certification should be required for all medical physicists. Several other comments urged FDA not to accept board certification without requiring a special certificate for mammography. Two comments recommended deleting the master's degree requirement and argued that course work in college level physics and supervised experience should be adequate. One comment contended that the issues of degree, training, and curricula are unnecessarily complicated in the proposed regulation. Another comment stated that the requirement of board certification or State licensure unfairly excludes physicists who are otherwise well qualified to test mammography equipment on the basis of their actual experience in this field. One comment stated that these requirements are appropriate.

FDA considered all of the comments received concerning initial qualifications requirements for medical physicists. Because the MQSA expressly establishes State approval or licensure

as an alternative pathway (42 U.S.C. 263b(f)(1)(E)(i)), FDA could not eliminate this route for initial qualification, even if the agency believed it was desirable to do so. The agency is aware that not all States have adequate minimum qualifications standards. Concern has also been expressed that some board certified physicists do not have adequate experience with mammography equipment. Therefore, as proposed, FDA added additional educational and experience requirements for all physicists, regardless of which initial route they follow to become qualified under the MQSA. These additional requirements are: (1) For initial qualification, masters degree or higher in physical science, with a minimum 20 semester hours or equivalent in college or graduate level physics, 20 contact hours of training in mammography, and experience of surveying 1 facility and 10 units; and (2) for alternative initial qualification, bachelors degree or higher in physical science, with a minimum 40 semester hours or equivalent in college or graduate level physics, 40 contact hours of training in mammography, and experience of surveying 1 facility and 20 units.

(Comment 267). A number of comments suggested that additional subjects, such as mathematics, biology, nuclear physics, and radiologic technology should be added as acceptable fields in which the degree may be obtained. Some comments wanted the reference to physical science to be changed to medical physics. One comment stated that physicists who are not board certified should be required to demonstrate a stronger educational background than currently required. In response to the agency's discussions in the preamble section of the proposal about the possibility of requiring all 20 semester hours in imaging physics (61 FR 14905), two comments stated that such a requirement would not be appropriate because the mammography equipment evaluation would require more than training in imaging and limiting 20 semester hours to imaging physics would not provide the physicist with the education needed to adapt to constant changes in technology.

The agency has decided to keep the requirement of physical science as the field in which the degree must be obtained and believes that its definition of physical science (§ 900.2(jj)) sufficiently covers the wide range of subfields that can provide adequate initial training to enable an individual with 20 semester hours of physics to understand the basics of mammography physics. The agency believes that this would not be the case if other fields, such as biology, were added to the definition.

(Comment 268). Sixteen comments stated that board-certified physicists should not have to demonstrate compliance with the additional educational requirements of § 900.12(a)(3)(i)(B)(*1*) in the proposed regulations, but should demonstrate experience conducting mammography surveys. Because the MQSA establishes board certification and State licensure/approval as equivalent pathways for qualifying medical physicists, FDA has not issued different additional qualifications for each of these groups. Accordingly, the agency has retained this requirement as proposed. However, if a designated board confirms that its certification in an accepted speciality always requires the minimum of a masters degree in physical science with at least 20 semester hours in physics, the agency may not have to verify the degree and semester hour requirements during annual inspections for those physicists certified by that board.

Another initial requirement is that physicists have 20 contact hours of documented training in mammography. Several comments requested further clarification of contact hours. Some comments urged FDA to accept self attestations of contact hours for experienced physicists who have worked in the field for a long time but do not have any documented contact hours. Ten comments stated that, if the medical physicist is board certified, the contact hours requirement should not apply.

After considering these comments and consulting with NMQAAC, FDA has retained contact hour requirements for all physicists, regardless of which initial route they followed to become qualified. FDA will accept self attestation of any contact hours received before October 1994. The agency has also provided a more detailed description of contact hours in § 900.2(m).

Under the proposal, an additional initial requirement was that medical physicists shall have the experience of surveying at least 5 facilities and 10 units.

(Comment 269). About one hundred comments opposed the requirement for multiple facility surveys for in-house physicists and stated that in-house physicists who are employed by hospitals and medical schools are often contractually prohibited from performing surveys at outside facilities. Several of these comments suggested that FDA should instead base its requirement on number of unit surveys.

In response to these comments, the agency has revised this requirement so that physicists qualified under § 900.12(a)(3)(I) will be required to have initial experience of one facility and ten unit surveys. FDA did not eliminate the facility requirement entirely because the agency strongly believes that having experience with complete surveys of facilities, including oversight of all QC records, is necessary. Evaluations of units only cannot provide a medical physicist with the same experience and knowledge as the survey of a facility. Although the amended regulation does not mandate survey experience with more than one facility, the agency encourages all physicists to perform additional facility surveys when possible to expand their experience. FDA believes that it is also advisable to gain familiarity with a number of different mammography units because much of the educational benefit is lost if the same unit is surveyed repeatedly to meet the experience requirement. In order to address this concern to some degree, the regulation now provides that no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

The initial experience requirement also stated that, after the effective date of these regulations, the initial survey experience must be acquired under the direct supervision of a qualified medical physicist.

(Comment 270). One comment stated that direct supervision would be very difficult to arrange. Another suggested requiring two surveys under direct supervision and the rest under indirect supervision. The comment stated that indirect supervision with telephone consultation and advice is more valuable than the direct supervision.

FDA has retained this requirement because the agency and NMQAAC consider it important that new physicists entering the field acquire initial experience in conducting mammography surveys under the direct supervision of a qualified medical physicist, who can correct any mistakes made during the learning process before they pose to a threat to patients. Because this provision does not take effect until the effective date of the regulations, the agency believes that it will not disrupt the availability of experienced medical physicists.

Alternative initial qualifications were established in § 900.12(a)(3)(ii) to provide a way to permit medical physicists who have been successfully providing mammography physics services for some time, but who lack a masters degree, to continue to practice

without lowering quality standards in any manner that would jeopardize public health. In general, in order to qualify by this alternative qualification route, an individual must have qualified under § 900.12(a)(3) of the interim regulations and maintained his or her licensure, approval, or certification requirement as required under the interim regulations. The physicist using this alternative route is also required to have a bachelors degree or higher in physical science, with at least 10 semester hours or equivalent in college level physics, 40 contact hours of training in mammography, and survey experience of 10 facilities and 20 units.

(Comment 271). Several comments opposed the alternative pathway for initial qualifications and considered the proposed educational requirements for these medical physicists to be inadequate. On the other hand, a larger number of comments shared FDA's concern for existing medical physics service providers and the facilities they serve. These comments supported this alternative qualifications route and recommended that experienced individuals who have previously qualified and who meet continuing education and experience qualifications should be allowed to continue to practice. Five comments stated that the alternative initial qualifications should be a permanent option. One comment claimed that the proposed alternative qualifications criteria were too restrictive to permit many State licensed physicists to qualify.

A number of comments suggested increasing the requirement of semester hours of college level physics for this alternative route from the proposed number of 10. Some comments suggested that the credit hours requirement for this alternative route be increased from 10 to 15 or 20 hours by including subjects such as biology, radiation biology, radiation science, and chemistry. Other comments expressed concern that this college level physics requirement would bar a number of presently qualified physicists from continuing to provide mammography services. Two comments stated that the requirement for semester hours in physics should be removed, and that physicists qualified under the current interim regulations by the State licensure or approval process should not have to meet additional educational requirements. One comment stated that 10 hours of physics is reasonable. Another comment stressed that formal training in physical science is necessary and stated that this standard should not be weakened.

In the preamble to the final regulations, the agency explained its reasons for proposing the alternative initial qualifications route for physicists with bachelors degrees who are currently performing mammography physics services under the interim rule (62 FR 14905). Based upon discussions with NMQAAC and the Conference of Radiation Control Program Director's Task Force on Medical Physics Criteria, the agency proposed the requirements for course work in physics, contact hours, and experience included in this alternative route. The agency believes that the combination of all these requirements provides adequate protection for the public health, while permitting most practicing physicists to continue to provide mammography services under the final rule.

Moreover, the agency considered it to be unfair to individual physicists and potentially detrimental to facilities and the public to exclude many currently practicing physicists by withdrawing the alternative initial qualifications route or by increasing the educational credit hours requirement for these individuals in the absence of evidence that such physicists are providing inadequate services. The agency was concerned that such an exclusion could cause a possible shortage in the availability of physics services for some period of time.

Several comments supported the views expressed in the preamble to the proposed rule. In addition, the agency's experience and data gathered from its inspection data base affirm that many currently practicing medical physicists with bachelors degrees, adequate course work in physics, and substantial experience are performing quality medical physics surveys in mammography facilities with care and competence.

The agency continues to believe that it is very important to have at least 10 semester hours in college or graduate level physics. The other subjects, suggested by some comments, will not necessarily provide an individual with the necessary background and training to understand the basics of mammography physics. However, because at least a bachelors degree in physical science is also part of the educational requirement, the credit hours in other related subjects, suggested by the comments, may be associated with fulfilling the degree requirement. Although the agency believes that a minimum of 10 hours of course work in physics is necessary to gain proper physics background, it also believes that requiring more credit hours in physics, as some comments and some members of NMQAAC suggested, will exclude individuals other than physics minors or majors or those with graduate degrees. For these reasons and those previously stated in the proposed rule (61 FR 14905), the agency has retained, as proposed, the minimum requirement of a bachelors degree with no less than 10 semester hours or equivalent courses in physics in its final rule on alternative initial qualifications.

The agency agrees, however, that enhanced educational qualifications are necessary in order for physicists entering the field in the future to have the required background to understand the technology of the future as it becomes increasingly intricate. As previously proposed, therefore, FDA is limiting the use of this alternative pathway to only those physicists who have met its requirements by the effective date of the final regulations.

(Comment 272). Several comments opposed the contact hours requirement, while some supported it.

The agency has previously stated its justification for retaining this requirement for initial qualification route. For the same reason, the agency will retain the requirement for the alternative route.

(Comment 272a). A large number of comments stated that the proposed initial experience requirement of 10 facilities and 20 unit surveys for the alternative route in § 900.12(a)(3)(ii)(B)(*3*) would be impossible to achieve for many in-house physicists and suggested eliminating the reference to the number of facilities.

In order to be consistent with the initial requirements for physicists under § 900.12(a)(3)(i)(B)(*3*), the agency has revised § 900.12(a)(3)(ii)(B)(*3*) to change the required initial experience from conducting surveys of at least 10 mammography facilities and 20 units to conducting one facility and 20 unit surveys. Again, no more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

(Comment 272b). Two comments stated that the experience component under the alternative initial requirement should have to be fulfilled under the direct supervision of a qualified medical physicist, as required under § 900.12(a)(3)(i)(B)(*3*). Another comment suggested changing the effective date of this regulation to the effective date of this section because there is more than one effective date in these regulations.

The agency points out that § 900.12(a)(3)(i)(B)(*3*), which will take effect 18 months after these regulations

are published, will affect only new medical physicists entering the field. Because § 900.12(a)(3)(ii)(B) establishes that the alternative pathway is only available until the effective date of the final rules, the direct supervision requirement does not apply to the individuals qualified through the alternative pathway, because no one will enter the field through that pathway following the effective date of the rules. In response to the comments about varying effective dates in the proposed rule, FDA points out that, except for some of the equipment standards and equipment QC tests, all sections of the final rule will be effective 18 months after publication. This is clearly stated in the final rule.

The continuing qualifications requirements for medical physicists have two components: § 900.12(a)(3)(iii)(A) continuing education, which requires the physicist to earn 15 units over 3 years; and § 900.12(a)(3)(iii)(B) continuing experience, which requires the physicist to survey 2 facilities and 6 units over 24 months.

(Comment 273). One comment questioned FDA's authority to require continuing education at all.

In response, FDA observes that the MQSA is designed to provide the government with authority to issue and enforce standards to ensure safety and accuracy of mammography in the United States. The section of the statute relating to quality standards lists a variety of requirements for each group of personnel associated with mammography practice. Although only the requirements relating to interpreting physicians expressly includes a reference to continuing education, these requirements are not an exclusive or limited list of standards to be established by the agency. They represent only the minimum requirements that Congress mandated that the Secretary must ''include'' among those issued to ensure safety and effectiveness of mammography (42 U.S.C. 263b(f)(1)). Just as FDA has determined that continuing education is necessary to maintain the skills and expertise of radiological technologists, the agency has concluded that continuing education requirements are also essential for medical physicists, who play a critical role in guaranteeing the safe operation of equipment and effective quality assurance systems.

(Comment 274). One comment stated that these requirements are appropriate. Two comments asserted that self training by reading and studying should qualify. Other comments asked that continuing education units be better defined. Another comment stated that the language was too prescriptive. One comment stated that most medical physicists would have completed rather than taught continuing education units and another opposed giving repeated credit for a course taught several times. One comment maintained that no CME has been available for those who have tested Xerox systems for the last 5 years, and that such courses are unlikely to be available in the future.

FDA notes that the final rule establishes that the units earned through teaching of a specific course can only be counted once towards the 15 education units requirement. A new definition for continuing education unit or credit has been added in § 900.2(l). The agency will accept only the continuing education credits offered by professional organizations whose training is shown to be relevant and acceptable for medical physicists. Language clarifying the options for calculating the 3-year period has also been added. The agency understands that sufficient training opportunities may not be available in xeroxmammography. However, because only 0.5 percent or less of the facilities use xeromammography, the agency believes that the majority of physicists, if not all, will need only continuing education related to screen-film mammography. When other mammographic modalities, such as digital mammography, become available, medical physicists will need continuing education in those areas. The agency believes that such training will be increasingly more available as the technologies develop. The agency advises the facilities that use xeromammography to contact the manufacturer of this system to provide or arrange for training in xeromammography.

(Comment 275). One comment recommended that the second and subsequent 3-year periods begin to run from the original date that the physicist was required to meet the continuing experience qualification.

FDA decided to use a floating 3-year period for all mammography personnel, instead of a fixed 3-year period as suggested by the comment, for two reasons. First, as explained previously, a fixed period actually allows an individual to go much longer without continuing education than the length of the period itself. With a 3-year fixed period, for example, if an individual received training near the beginning of one period and near the end of the next period, he or she would go nearly 6 years without continuing education, which is entirely too long in a changing field such as mammography. Second, because inspections are annual, if an inspector found that an individual had not met the continuing education requirement during the previous fixed period, that individual might have provided services to the facility for almost a year before the failure was discovered. Depending upon the circumstances, the actions needed to correct the consequences of using the services of a noncompliant individual could require a considerable amount of time and money on the part of the facility.

(Comment 276). Two comments stated that persons providing continuing education should meet the qualifications of a medical physicist as described in the proposed regulations and that the instructors should be in active practice.

FDA disagrees. The agency believes that many scientists, university professors, and equipment manufacturers can provide training in different aspects of mammography physics.

(Comment 277). Another comment claimed that it is excessively bureaucratic to require that a physicist send a copy of his or her CME to include in the operating manuals, as was insisted upon by an inspector at their facility.

FDA believes that the author of the comment misunderstood the reason why the information on CME was required to be sent to the facility. The reason was not for inclusion in the facility's operating manual but to enable the facility to demonstrate that its medical physicist met the continuing education requirement. All interpreting physicians, radiologic technologists, and medical physicists providing services to mammography facilities have to document that they meet the continuing education requirement.

(Comment 278). One comment stated that there should be some penalty for failing to meet the continuing education requirements.

The consequences of failure to maintain these requirements is the inability to work independently as a medical physicist. As stated with respect to other mammography personnel, the agency believes this penalty is the most effective means to guarantee that physicists maintain qualifications and to protect the public health.

Under the proposal, FDA would require medical physicists to maintain their skills through the survey of at least 3 mammography facilities a year.

(Comment 279). More than 50 comments opposed this requirement. As

expressed in related comments, in-house physicists may be contractually prohibited from surveying outside facilities. Many of these comments suggested deleting the reference to the number of facilities.

In response to these comments and in order to establish consistency with revisions to the initial experience requirement discussed above, FDA has revised the proposed continuing experience requirement. The requirement will be for surveys of two facilities and six units in a 24-month period. The same facility can be surveyed twice. However, as with the initial experience requirement, no more than one evaluation of a specific unit within a period of 60 days may be counted towards the requirement. In addition, while the same facility may be surveyed twice within this 24-month period by an individual physicist in order to meet this requirement, the two surveys by this physicist must be at least 10 months apart. This restriction does not prohibit the facility from having surveys more frequently than once every 10 months, if it wishes to do so out of quality concerns or for other reasons. The restriction only limits the number of surveys of that facility that an individual physicist can use to meet his or her continuing experience requirement. The reduction in the number of facilities will address the concerns that were raised about in-house physicists.

In order to be consistent with the equivalent physician and technologist requirements, the continuing experience requirement for physicists is now based upon a 24-month period. This will now make it more feasible for physicists who are out of the field for a time, e.g., on maternity or sabbatical leave, to maintain their qualifications. The requirement has also been amended to explain options for identifying the 24 months that will be used to determine compliance. This change parallels similar changes in the requirements for radiological technologists and interpreting physicians and is intended to provide personnel and facilities with additional flexibility for monitoring compliance with these standards.

Section 900.12(a)(3)(iii)(C) requires physicists to be trained to do surveys of a mammographic modality for which they have not previously received training before independently doing surveys of such units.

(Comment 280). A number of comments correctly pointed out that the reference to mammographic ''examinations'' should actually be to mammographic ''surveys'' or ''evaluations.''

FDA has corrected this error by replacing the word examination with survey.

(Comment 281). Several comments opposed the requirement for 8 hours of training in a new mammographic modality prior to doing a survey of such a modality. One comment expressed concern that this will keep physicists from surveying new modalities. Another comment suggested that length and degree of training be commensurate with the specifics of the new modality. Two comments stated that the requirement overestimated the complexity of new modalities and undervalues the physicist's capability of adapting to new modalities in medical imaging. One comment stated that this rule is unnecessary because a qualified physicist will be able follow guidelines developed by ACR and AAPM when a new modality, such as digital mammography, begins to be used by the facilities. One comment stated that 8 hours of training in a nonscreen-film modality would be difficult to complete, while another comment stated that only expert instrument manufacturers would be qualified to provide such training.

The agency continues to believe that the proposed requirement of 8 hours of training in a new mammographic modality before a medical physicist may begin performing surveys independently in that type of modality is reasonable and necessary. Training prior to practice using a new mammographic modality is required for all critical personnel (interpreting physicians, radiologic technologists, and medical physicists) because FDA has determined that the benefits to patients from such prior training outweighs the cost to individuals and facilities. The agency recognizes that training in a new modality may not be widely available and agrees with comments that have observed that equipment manufacturers would and should be able provide such training. The agency will encourage manufacturers of a new mammographic modality, such as digital mammography, to provide or arrange for such training when the modality is commercially marketed.

Section 900.12(a)(3)(iv) describes measures medical physicists may take to reestablish their qualifications if they have failed to meet their continuing qualifications requirements.

(Comment 282). Two comments stated that the surveys of facilities and units required for reestablishing qualifications should be consistent with the experience requirement for initial qualifications. The authors believed that, if a medical physicist is not actively involved in mammography facility surveys for an extended period of time, performing the proposed three surveys may not be enough to regain the required expertise. They recommended that the requirement for requalifying be increased to five supervised surveys. One comment supported the qualification's supervision requirements. Another comment questioned why physicists are not allowed to perform surveys without the supervision of a qualified physicist, while such supervision is not required for physicians and technologists.

The agency notes that this provision has been amended to be consistent with similar provisions relating to physicians and technologists. In order to reestablish qualifications, physicists must perform facility and unit surveys to bring their total up to the required survey of 2 facilities and 6 units in the previous 2 years. This change also makes the requirements for continuing experience qualification more consistent with the experience requirements for initial qualification, as suggested by some comments. Any survey performed by a physicist to bring his or her total up to the requirement must be under the direct supervision of a qualified medical physicist. Contrary to the assumption in one of the comments, physicians and technologists who fail to meet their continuing experience requirement are also required to reestablish their qualifications under direct supervision and cannot resume working independently until the requalification is complete.

e. *Retention of personnel records (§ 900.12(a)(4))*

The provision on retention of personnel records § 900.12(a)(4) is intended to describe the personnel records that must be kept by the facility to establish that their personnel meet the MQSA requirements and to indicate how long such records should be kept.

(Comment 283). Ten comments disagreed with the proposal by FDA to allow records to be discarded following the next annual inspection and the resolution of any personnel problems discovered during that inspection. These comments urged that records be required to be kept for longer periods, with ''as long as the person is employed at the facility'' being the maximum suggestion. Four more comments suggested that FDA also establish requirements for how long records of staff members who have left the facility should be kept. One comment noted that the list of the people for whom records were required in the proposal included darkroom personnel and pointed out there were no specified qualifications for such individuals. Two

comments suggested that, if mammography is performed at various sites under the same ownership, the records be kept only at one site and be sent to the separate facilities as needed. Finally, one comment expressed the opinion that keeping personnel records was an unnecessary burden, but made no suggestions as to how personnel qualifications could be verified without documentation.

FDA has made a number of changes in this requirement in response to the comments. First, to address the concern about inclusion of darkroom personnel, the list of activities performed at a facility has been replaced with a reference to those personnel for whom quality standards have been issued. The wording was further changed to clarify that, as long as an individual is employed at a facility in one of these capacities, records must be available to show that the individual meets all qualifications. Records for individuals who have left the facility may be discarded after the next inspection has occurred and FDA has determined if the individual met the requirements. Although nothing in the MQSA or these final regulations precludes the facility from retaining these records for longer periods of time, FDA does not expect to have further need to review such records following the subsequent inspection. In response to comments suggesting that multi-site facilities retain personnel records in a central location, FDA notes that such a practice would be permitted but is not required under the final rule. Because the MQSA inspections are typically announced in advance, a facility could store its records at one site and bring them to the other sites as needed for review during the inspections there.

2. Equipment (§ 900.12(b))

The requirements were intended to establish specifications to ensure that each facility would have equipment that is capable of producing quality mammograms. FDA made a number of significant changes in the equipment requirements that were proposed. These changes include removing several of the requirements proposed for phase-in 5 and 10 years after the publication of the final rule and moving several requirements from § 900.12(b) to the quality assurance paragraph in § 900.12(e). Most of the test procedures that would have been required under the proposal have also been deleted. Each of these changes will be discussed below.

a. *General comments on equipment*

(Comment 284). A number of comments raised issues that did not address specific provisions proposed under § 900.12(b), but were directed generally toward the entire package of regulations governing equipment. These included two comments that expressed a blanket support for the regulations proposed under § 900.12(b).

One comment stated that it would be useful to have a better delineation of responsibility for ensuring that units meet particular standards under the MQSA. The comment recommended that the facility medical physicist be designated as the individual responsible to ensure that a facility's equipment is in compliance.

FDA believes responsibility for compliance with all the MQSA requirements rests ultimately with the facility. Within the scope of each facility's individual operations, responsibility can be apportioned as the facility wishes, so long as this is consistent with the regulations. The suggestion made by the comment is not inconsistent with the regulations. Under § 900.12(d)(1)(iv), the medical physicist is designated as the individual responsible to oversee the QC requirements, though no provisions specifically require routine QC testing to be performed by the medical physicist.

(Comment 285). Three comments suggested that FDA cannot anticipate future changes in mammographic equipment technology sufficiently well to be able to determine all appropriate requirements in this area over this extended timeframe. One of these recommended that FDA review the equipment requirements on a continuing basis to recommend and propose modifications that are recognized to promote quality mammography. One comment suggested that FDA simply require all mammography X-ray units to be replaced every 8 to 10 years in order to keep facilities upgraded with standardized equipment.

FDA agrees that it cannot anticipate all changes in mammography equipment over the next 10 years and has not attempted to do so. In the proposed regulations, FDA simply incorporated specifications of current equipment that experts had deemed desirable for quality mammography systems. The goal of the proposal was to ensure that, 10 years in the future, each facility would be using equipment that was considered state-of-the-art in today's market. FDA approached this goal by phasing-in the requirements over various time periods. Equipment requirements considered most fundamental to the delivery of quality mammography would be required first, followed by those specifications considered useful but which, because of cost impact, could be delayed for a period of 5 years. The third phase under the proposal included ''nice to have'' features that are not absolutely necessary to the production of quality mammograms and would not be required until the end of a 10-year period. However, based on the uncertainty surrounding the need for the phase three requirements, consultation with NMQAAC and industry representatives, assessment of the costs associated with some of the proposed 5-year phase-in requirements, and consideration of the public comments, FDA has determined that this goal is inconsistent with efforts to keep the costs associated with the delivery of mammography services at a manageable level. The agency has, therefore, decided to eliminate many of the requirements that had been proposed for both 5- and 10-year phase-in. FDA has previously stated that it plans to periodically review the regulations for necessary revisions in response to new technology and remains committed to that effort. The agency intends to and will revisit these areas in the future to reassess the need for additional regulations.

Although the revised equipment standards do not mandate that each facility have all the equipment features the agency originally had proposed, FDA believes the final regulations establish basic requirements that ensure that every facility meets the baseline equipment standards necessary to perform safe and accurate mammography. In response to the comment that recommended requiring new equipment every 8 to 10 years, FDA does not believe that the costs associated with the arbitrary replacement of mammography equipment every 8 years to 10 years is justifiable. In addition, the agency notes, too, that the alternate standards provisions, included in the regulations under § 900.18, provide the flexibility needed to ensure that new and innovative advancements reach the market without unnecessary delay.

(Comment 286). Two comments recommended that all detailed testing procedures be eliminated from § 900.12(b) to allow flexibility for qualified medical physicists to determine the appropriate testing methodology.

FDA has, in large part, adopted this approach in the final regulations. In doing so, the agency has placed responsibility on the medical physicists to be able to justify the procedures that they utilize to perform testing of equipment in any particular facility.

(Comment 287). One comment suggested that the X-ray tube companies are ''planning for early tube retirement so they can replace the tubes frequently at high cost to the facilities.'' The comment asked FDA to address this issue immediately in an effort to keep mammography costs down.

FDA does not control the pricing of equipment in the marketplace. The agency is, however, interested in equipment problems that may indicate a unit does not meet its specifications and/or aspects of compliance that it is certified as meeting. Specific information about manufacturers should be submitted to the Office of Compliance in FDA's Center for Devices and Radiological Health, 2094 Gaither Rd., Rockville, MD 20850.

(Comment 288). One comment suggested that there should be a lock-out and/or alarm mechanism preventing a mammography technologist from exposing the patient to radiation without placing film in the equipment. Another comment suggested a requirement for an interlock to prevent a second exposure until the cassette is changed, and two more comments recommended a requirement for an interlock to ensure the presence of a cassette in the bucky/film holder. These comments noted that such incidents have occurred, needlessly exposing patients to radiation multiple times because the technologist forgot to insert or change the film.

Although FDA is aware that some manufacturers include interlocks that ensure the presence of a cassette or that cassettes are changed after each exposure on their equipment, FDA is not considering such requirements at this time. FDA believes that, unlike equipment performance, this is an aspect of the mammography process that is within the complete control of the technologist and that the technologist must assume responsibility for preparing the system for each exposure. In facilities where more than one technologist uses the equipment, a check list of items should be followed and this should most certainly be one of the items on the list. If the technologists adequately follow standard procedures, incidents such as those described in the comments can be prevented without incurring the considerable expense involved in requiring the suggested interlocks.

(Comment 289). One comment asked the agency to consider requiring special grounding devices to protect operators and patients. The comment also suggested a prohibition against carpeting in the mammography room, and a requirement for the use of static mats around the mammography machine.

Although these items might be desirable they do not impact the quality of the mammography image and are beyond the scope of these regulations.

(Comment 290). One comment suggested that a requirement establishing a maximum distance from the surface of the patient support to the sensitive part of the image receptor should be incorporated in § 900.12(b).

FDA is not aware, and the comment did not offer evidence to show, that this represents a problem for current mammography systems. Accordingly, the agency is not planning to regulate this aspect of equipment performance.

(Comment 291). One comment suggested that the maximum allowable photo-timed exposure for mammography applications should be specified. The comment stated that the backup limit of 2,000 mA's (from 21 CFR 1020.31(a)(3)(iii) in the *Performance Standards for Diagnostic X-ray systems and their major components*) was clearly selected based on prior technology, i.e., much slower screen-film systems or, perhaps, industrial X-ray film where exposures were typically on the order of 5,000 milli Roentgen (mR) for an average breast.

FDA notes that the regulations under 21 CFR 1020.31 presently set a limit of 2,000 mA's for automatic exposure control equipment when operating with a peak tube potential under 51 kVp. This regulation is not specific to mammography, but applies to any diagnostic X-ray equipment operating with a peak tube potential under 51 kVp. In previous draft regulations presented to NMQAAC, a lower value of 600 mA's was proposed for mammography systems. The committee was of the opinion that 600 mA's was too low and FDA planned to increase the value to 800 mA's. In the meantime, FDA received comments from industry pointing out that some systems have variable SID capability. This variability in current equipment undermines an approach that relies on the maximum mA's concept because the mA's required at a longer SID may be significantly greater than that required at a shorter SID, although the dose delivered might remain constant. Because FDA was faced with setting dose limits for the termination of the exposure or unnecessarily limiting equipment SID, the agency decided that the maximum allowable photo-timed exposure should not be prescribed in the regulations at this time. This decision was presented to NMQAAC, which had no comment. FDA may revisit this area in future proposals.

(Comment 292). One comment noted that the time between exposure of the film and photographic processing is critical because the latent image on all film decays with time.

FDA had considered this aspect of the imaging process for regulation but, based on comments from the public and NMQAAC, decided not to propose requirements at this time. This area may be revisited in the future when more is understood about the requirements and practices in the mobile mammography community, where film processing often must be delayed for a significant period of time after exposure.

(Comment 293). Several comments recommended that FDA set standards for batch variability of film, stating that this variability is often greater than that proposed for the equipment standards.

FDA recognizes that the variability of film may be a potential problem but believes that facilities can control this, to a significant degree, through their purchasing specifications and selection of suppliers. FDA will monitor this problem closely to determine if future regulation is required.

(Comment 294). Twenty-five comments recommended that FDA include requirements for the viewbox and/or the viewing conditions for the physician and technologist.

FDA agrees such standards would be beneficial, but does not believe that enough is known, at this time, to set appropriate specifications for viewing conditions. The guidelines recommended by ACR are excellent and the agency encourages facilities to follow them. FDA will consider this subject for future regulation and all relevant comments will be reconsidered at that time.

(Comment 295). Thirty-nine comments expressed concern that the cost of some or all of the equipment regulations would cause facilities to close and thereby restrict access for patients. Many of these comments urged that the equipment requirements should be made to apply to manufacturers of equipment for items manufactured after the specified effective date of the regulations. A related comment suggested that the current interim rule, which requires only that equipment be specifically designed for mammography, is working well and that further regulation proposed under § 900.12(b) will serve only to stifle invention, add cost, and ''overly rigidify'' this important aspect of providing the highest quality mammography services at the lowest cost to the public.

FDA can understand why the last comment believes the interim regulations are far less extensive than what was proposed. The interim regulations address the equipment aspect of mammography quality directly by listing four criteria that all X-ray systems used for mammography must satisfy: (1) The X-ray equipment must be specifically designed for mammography; (2) it must be certified to meet the performance standards in 21 CFR 1020.30; (3) it must have a removable grid; and (4) it must have a compression device. In addition, however, the interim regulations required each facility to undergo an annual survey in accordance with the standards specified in the 1992 or 1994 ACR QC manuals (see § 900.12(d) and (e) of the interim regulations). These manuals outline extensive requirements for the equipment associated with the mammography process. In the final regulations, FDA has not referenced these manuals although NMQAAC strongly advised their continued use and has instead included specific requirements that were part of the ACR standards under final regulations at § 900.12(b) and (e). Although they appear as new regulations, many of these new provisions merely restate requirements that previously had been referenced through the ACR manuals but are now reformatted as regulation.

FDA is also concerned about all costs associated with the regulations under the MQSA, including those incurred by the purchase, upgrade, and repair of equipment. However, FDA's authority under the MQSA relates to the user of the equipment rather than the manufacturer. Under authority granted to FDA by provisions of the act (which incorporates the Radiation Control for Health and Safety Act of 1968), FDA is pursuing a parallel path to generate standards for new equipment under § 1020.30. This process will take some time and regulations on new equipment only gradually affect the installed base. The agency concluded that regulations directed at new equipment only, and not the installed base, would have inappropriately delayed the benefits of the improvements provided by the new equipment for millions of women for a number of years.

For these reasons, FDA determined that equipment standards implementing the MQSA should be directed to the installed base to ensure that all women, not just those that utilize facilities with new equipment, receive an adequate and equal baseline of care. Based on facility inspection experience with the interim regulations, FDA does not expect a large reduction in providers and anticipates no access problems solely as a result of the equipment regulations. In addition, FDA has provided mechanisms for alternate standards in § 900.18 to allow for innovation and flexibility under the final rule. The agency has no reason to believe that the regulations will cause stagnation in the market for new and useful equipment.

(Comment 296). One comment asked if it was necessary to attempt to codify and regulate equipment standards that, in the respondent's opinion, will evolve anyway through competition in the market.

Again, the agency responds that the introduction of new products into the market place can be a slow process and waiting for manufacturers to manufacture and market and for users to purchase would not produce the change in minimum national standards that FDA perceives is needed. Additionally, in FDA's experience, certain segments of any market are often driven by price concerns rather than features or performance. FDA believes that regulations are the only mechanism that will provide the impetus to achieve the desired baseline of care in a reasonable time.

(Comment 297). One comment supported phasing in the equipment standards over the next 1 to 10 years, as discussed in the preamble to the proposal (61 FR 14909). Two comments stated that 5 years is not a sufficient amount of time to require the purchasing of new equipment and maintained that it would be more appropriate to allow a longer phase-in period, for example, 10 years.

Five comments offered a contrary point of view, suggesting that the majority of the mammography equipment presently in use meets most of the proposed standards in § 900.12(b) and that many of the timeframes proposed in § 900.12(b) are excessively long. One of these comments expressed concern that there are some facilities where the machine limits the ability to do adequate imaging and the facility will not get newer equipment if not forced by law to do so.

FDA appreciates these comments and recognizes that some facilities will not upgrade their equipment until the last possible moment, thereby using equipment that has become inadequate by current standards. The agency must balance these concerns with cost concerns that facilities, patients, and FDA all share. The decision to require certain equipment standards to be phased in relatively quickly and postpone others represents the agency's efforts to balance these competing concerns.

(Comment 298). One comment suggested that there should be regulations for needle biopsy systems in § 900.12, including provisions that address misalignment of the biopsy cross-hair. The comment stated that the cross-hair assembly, if not accurately aligned, may lead to inaccurate localization of lesions during needle localization, increasing the possibility of morbidity. FDA recognizes the need for regulation in this area and has raised the issue with NMQAAC in the past. As a result of discussions with NMQAAC and opinions offered by the ACR, the decision was made to delay regulations for this aspect of breast radiography until community consensus can be reached on all aspects of the process. As discussed earlier, FDA is currently working internally on possible regulations for interventional mammography, while awaiting the results of collaborative efforts between the ACR and the American College of Surgeons to reach consensus on recommendations for standards in this area.

(Comment 299). One comment recommended that the equipment specifications proposed under § 900.12(b) should not be included in the final regulations and that the entire section should be issued as guidance rather than a binding regulation.

FDA has considered this approach, but has determined that, because the guidelines would not have the force of law, they would not achieve the widespread results necessary to meet the goals of the MQSA.

(Comment 300). Nine comments expressed concern that the proposed regulations under § 900.12(b) were not specific as to whether all equipment in a facility must comply and one of these comments questioned if existing mammography units must be redesigned and/or upgraded to all the standards by the effective dates.

FDA intends that all facilities performing mammography shall meet each of the final regulations by the effective date of each requirement. In the case of equipment, all equipment used for covered mammography procedures must meet the requirements in effect at any given time. If equipment must be repaired, replaced, or upgraded to achieve this result, then such actions must be completed by the effective date or the facility must discontinue offering mammography services with the nonconforming equipment until compliance is achieved.

(Comment 301). One comment stated that the equipment standards sometimes

give very specific descriptions of testing equipment and procedures. For example, in proposed § 900.12(b)(4)(iv), FDA specifically described a 12 cm diameter acrylic disc 1.5 cm thick. The respondent was unsure why 12 cm was specified instead of 10, and why 1.5 cm was specified instead of 1 or 2.

FDA notes that in each case where test procedures and/or test objects are specified in these final regulations, the objects or procedures are usually based on established test protocols. In some cases where the test object itself could be variable, the specifications are identical to an object used in another required test in order to reduce the number of items required for the entire survey or inspection. In cases where the test or the test object is new, the details of its design are beyond the scope of this document. FDA intends, whenever possible, to issue guidance documents that will address the use of such new procedures and equipment. The particular example cited in the comment has been deleted from the final regulations.

(Comment 302). One comment stated that the proposed rules are not entirely consistent with the guidance document developed by ACR and CDC. The comment recommended that every effort should be made to ensure consistency with the ACR guidance document.

FDA is, of course, aware of the ACR/CDC document and, in fact, adopted many of its requirements for these final regulations. However, the ACR/CDC document was written as a guideline for new equipment and not as a regulation for installed equipment. As a guideline, its wording would not readily transfer to regulation and, as a specification for new equipment, its scope was not sufficiently broad to address the range of the installed base or the cost concerns associated with upgrade and replacement of equipment. The agency also notes that the recommendations in the ACR/CDC guidance represent an attempt to describe an optimal system. NMQAAC and members of the public have stated that some of the features, while desirable, would generate costs not justified by the expected benefit, especially when applied to the installed base. In those cases where the agency believes the benefit does not warrant the cost, FDA has not made particular features regulatory requirements. Within these limitations, FDA has generally made efforts to remain consistent with the ACR/CDC guidance where doing so is appropriate.

(Comment 303). One comment suggested that a section in § 900.12(b) or (e) should address the issue of screen placement in the cassette. The comment noted that, because the screen is sometimes not positioned with its edge in contact with the inside wall of the cassette at the chest wall, the film edge is underexposed or unexposed. The comment suggested that ''such cassettes should be rejected and the screens remounted.''

FDA agrees that such conditions should not exist, but believes the annual survey and normal QC procedures will identify and correct such problems and is not considering regulations to address this concern at this time.

(Comment 304). One comment recommended that the proposed equipment regulations in § 900.12(b) be rewritten to correspond more closely with existing international standards.

In certain aspects of equipment related requirements, FDA has attempted to conform to both national and international precedent. However, in some cases, those guidelines are inappropriate or do not address the specific concern being considered under the MQSA.

(Comment 305). One comment suggested that the proposed requirements of § 900.12(b)(17) through (21), which do not relate to X-ray equipment or film processors, should be included as part of the annual physics survey and need not be specified by regulation. FDA believes that this respondent misunderstood these provisions because the core of the annual physics survey is, in fact, set forth in these regulations. Some of these regulations have been modified and/or transferred to the quality assurance section of the final regulations, while others have been deleted. The remaining requirements may be checked as survey or inspection items, verified by documentation provided by the manufacturers, or established through normal QC procedures performed by the facility. Although the agency has not expressly prescribed how these requirements should be met in all cases, FDA has determined that the facility is responsible for establishing compliance with these standards rather than trusting that they would be included in all medical physicists routine surveys.

b. *Prohibited equipment (§ 900.12(b)(1))*

This paragraph prohibited the use for mammography of general purpose equipment or equipment designed for special nonmammography procedures.

(Comment 306). Seven respondents recommended that the use of xeromammographic equipment should be prohibited or phased out.

FDA considered taking this action but believes that the unique characteristics of the xeroradiographic process may provide a valuable tool in the diagnosis of some cases. Records obtained during the first year of facility inspections under the interim regulations indicate that there are an extremely small number of these units in service and it is believed that the number will continue to decrease as their use falls out of favor with the community. FDA has concluded, therefore, not to ban their use.

c. *General (§ 900.12(b)(2))*

This paragraph, as proposed, required that all equipment be designed for mammography and certified under § 1020.30.

(Comment 307). One respondent suggested that a definition of ''specifically designed for mammography'' be included because some units may be used for imaging of extremities.

FDA does not believe that this is necessary because the manufacturer's labeling, along with the FDA device approval process, ensures that the design is appropriate for mammography. FDA recognizes the fact that the characteristics of mammography radiographic equipment make it useful for other radiological examinations and does not intend to restrict such applications if the product has also been approved for that use.

d. *Motion of the tube-image receptor assembly (§ 900.12(b)(3))*

This paragraph proposed that the gantry be capable of specific rotation, that the angle of the gantry be indicated, and that the tube-image receptor assembly remain rigidly fixed in any position where it was designed to operate.

(Comment 308). Two comments noted a citation error in the proposed regulations. One comment recommended the deletion of the entire section, with the possible exception of requiring the system to remain fixed when placed in an operating position. Three other comments supported the proposed requirements, although one suggested that only one unit at each facility need meet the requirements. NMQAAC supported the proposed requirements, with the recommendation that they be applicable only to equipment acquired 5 or more years after the publication of the final regulations.

FDA has determined that NMQAAC's recommendation to require compliance only on equipment acquired 5 or more years after publication of the final regulations presents major problems with respect to enforcement. Such an approach would produce a situation where two distinct levels of quality would be in place for different facilities

and often within the same facility, based on when equipment was acquired. After reviewing the public comments and assessing the possible cost impact of the requirements, FDA decided to remove the provisions detailing the range of gantry motion and angle indication. If this area is considered for future regulation, all comments submitted on these sections will be reconsidered in the process. FDA has reworded the provision that requires the tube-image receptor assembly to remain fixed in its designed operating positions and this requirement remains under § 900.12(b)(3) in the final regulations. The citation error has been corrected.

e. *Image receptor sizes (§ 900.12(b)(4))*

This paragraph requires that all mammography systems have, at a minimum, both a 18 X 24 cm and 24 X 30 cm screen-film receptor and matching grids, and that the grids should be removable. This section also proposed that grid motion should not be impeded when a breast is subjected to compression in the system.

(Comment 309). Seven comments supported the proposal regarding the image receptor sizes and matching grid requirements proposed in § 900.12(b)(4)(i). Two comments opposed the specification requiring both a large and a small image receptor system in the regulations. One of these misread the proposal as being applicable to xeromammographic equipment and suggested that the regulation might prohibit the use of such equipment because such systems may not provide multiple image receptor sizes. The other comment supported the concept of requiring a large and small image receptor combination, but opposed a provision specifying the actual dimensions of these receptors. A related comment, while not actually opposing the proposal, expressed concern that requiring multiple image receptor sizes for screen-film systems might establish difficult precedents for future technology.

FDA believes that, for the present and foreseeable future, the dominant film sizes used in screen-film mammography will remain 18 X 24 and 24 X 30 cm and has not been persuaded to revise the provision that requires systems to have both sizes with corresponding grids. The agency believes that the last comment is concerned with digital systems currently under development and the concern that large or multiple sized image receptors would be prohibitively expensive with such systems. FDA has not formulated an opinion in this area and will wait to see what final technology and configurations evolve for digital systems before addressing this issue in regulation.

(Comment 310). One comment, while neither agreeing nor disagreeing with the requirement for multiple size image receptors, stated that the use of smaller image receptors, even on large breasts, results in clearer, sharper images and noted that larger areas compressed all at once do not provide the sharpness and detail needed to pick up very small cancers. The comment stated that, even though more films are taken when a smaller film size is used to image a large breast, the benefits of finding a life-threatening cancer far outweigh the minimal increase in radiation exposure to the patient.

FDA recognizes this practice as essentially the ''spot compression'' of the entire breast in multiple exposures. Although ''spot compression'' can yield improved images, it is not a recognized or accepted procedure in screening mammography. Interpreting physicians who deem such studies necessary will order them to be performed, but it is not standard practice for routine screening. The agency also notes that the regulation merely requires that the two-image receptor sizes be available; their use in any particular case is left to the judgment of the mammography personnel involved.

(Comment 311). One comment proposed that the requirement for multiple image receptor sizes be restated to require at least one unit at the facility to provide the multiple sizes, rather than requiring each unit to have both receptors. Experts on NMQAAC recommended that the requirements of § 900.12(b)(4)(i) not be weakened by permitting a facility to satisfy this equipment standard by having only one system with the multiple cassette sizes. The rest of the committee agreed. FDA has accepted this advice and retained this requirement under § 900.12(b)(4)(i).

Section 900.12(b)(4)(ii) requires facilities to have systems with moving grids matched to all image receptor sizes provided.

(Comment 312). One comment commended FDA for requiring both an 18 x 24 and a 24 x 30 bucky for each unit. Another recommended that the regulation read: ''Systems using screen-film image receptors shall be equipped with separate moving grids matched to all image receptor sizes provided.'' FDA does not believe that the suggestion was a significant improvement and did not make the change.

(Comment 313). One comment recommended the inclusion of a requirement in § 900.12(b) that specifies the image receptor support device shall match the cassette size.

The agency does not believe this additional requirement is necessary. By requiring the system to have both a large and small image receptor and corresponding sized grid assemblies, FDA is confident that most technologists will select the appropriate receptor and cassette size for each patient.

Section 900.12(b)(4)(iii) requires the grid to be removable for systems used for magnification.

(Comment 314). Three comments requested clarification regarding applicability and intent of this provision.

FDA notes that the final regulation was drafted to clarify the interim rule. Section 900.12(b)(4)(iii) simply states that the system must be operable with the grid removed from between the source and the image receptor when the technologist is performing magnification procedures. This could be accomplished in various ways, including actually removing the grid mechanism, substituting a nongrid film holder for the grid film holder assembly, or any other mechanism that ensures that the grid does not interfere with the image or the automatic exposure control, if one is used.

Under § 900.12(b)(4)(iv), FDA proposed that the grid motion not be impeded when the breast is compressed and also proposed detailed requirements for verifying compliance.

(Comment 315). Seven comments supported the proposed requirements for assessment of grid related artifacts, while 14 comments supported the concept of evaluating grid related artifacts, but opposed both listing the requirement in regulation and the test procedure outlined in the proposal on the basis that the test method was unproven and objective standards for evaluation of the seriousness of the problem were lacking. In April 1996, and again in January 1997, NMQAAC recommended removing § 900.12(b)(4)(iv) regarding the grid related artifacts.

FDA has accepted NMQAAC's recommendation and removed this paragraph.

(Comment 316). Twelve comments requested justification, clarification, or suggested modifications for the test procedure proposed under § 900.12(b)(iv). If the issue is revisited for future regulation, the comments to this section will be reconsidered at that time.

f. *Beam limitation and light fields (§ 900.12(b)(5))*

This paragraph covers devices for limitation of the X-ray field and specifies light localizer characteristics.

Under § 900.12(b)(5)(i), FDA proposed that all systems ensure that the X-ray field can extend to or beyond the chest wall edge of the image receptor.

(Comment 317). Two comments interpreted this as a requirement that the collimator must provide separate adjustability on the chest wall edge and suggested that such adjustability is unnecessary.

FDA accepted these comments and reworded § 900.12(b)(5)(i) to clarify that the intent is not that the collimator be adjustable, but that the collimator allow complete coverage of the image receptor at the chest wall edge unless it is the intent of the operator to not do so. This requirement has been moved to the quality assurance section and appears in § 900.12(e)(5)(vii).

Section 900.12(b)(5)(ii) proposed that any system with a light field that appears to approximate the X-ray field must approximate the X-ray field to a specified tolerance and that the light must produce a minimum specified brightness. Four comments supported the alignment recommendations with the observation that, in the respondents' opinions, the alignment was more important on the chest wall edge.

(Comment 318). Two comments expressed disagreement with this requirement. In § 900.12(b)(5)(ii), FDA also proposed a definition for the mammographic source to image receptor distance (SID) that was changed slightly from the definition used for more general purpose radiographic systems in order to be more consistent with the actual usage in mammography. Two comments supported this change, two opposed it, and one respondent expressed concern that the definition of SID in this section might be confusing.

After reviewing the comments, FDA has determined that the requirements for the alignment of the light field and X-ray field and the definition of SID are adequately addressed by existing regulations in § 1020.31, and has deleted the proposed requirements from this standard. A QC test to verify alignment now appears in the quality assurance section at § 900.12(e)(5)(vii).

With respect to the proposal that the light provide a minimum illuminance, two comments supported the requirement and four comments opposed it.

FDA notes that this proposed requirement is the same as that currently required for general purpose systems covered by § 1020.31. Thus, it already applies to such collimators using such light localizers on mammography systems. FDA has chosen to restate the specification here to eliminate any confusion and to clarify that the general requirement also applies to mammography equipment. The restatement now appears under § 900.12(b)(5)(ii) in the final regulations.

Under § 900.12(b)(5)(iii), (iv), and (v), FDA proposed a phase-in of additional requirements. The first stage required all mammography systems to incorporate such a light localizer 5 years after publication. The second stage required that 10 years after publication, all mammography systems were to prevent X-ray production unless the correct combinations of field size and image receptor were selected and to prevent any exposure with an X-ray field exceeding the size of the image receptor support device.

(Comment 319). Three comments supported the requirement for the light field as proposed, with one of these urging that it be instituted at the earliest date the regulations become effective. One comment agreed that a light field, as proposed, may be a desirable feature but thought properly trained personnel are able to position the breast correctly without a light and suggested that the requirement should be deleted because, in the respondent's opinion, the cost would be too high to justify. NMQAAC supported the requirement for a light field, as proposed. Four comments supported the proposed requirements in § 900.12(b)(5)(iv) and (v) but one of these suggested that a means to override the interlocks should be provided. One comment opposed both proposals.

FDA has reevaluated these proposals and concluded that they raise safety concerns related to X-ray systems in general rather than image quality concerns. For this reason, and the cost concerns discussed previously, the agency has decided to delete both § 900.12(b)(5)(iv) and (v) from these regulations and to develop such requirements under the authority provided in the act for regulatory products subject to the Radiation Control for Health and Safety Act of 1968. Accordingly, FDA is discussing relevant changes to part 1020 with its Technical Electronic Product Radiation Safety Standards Committee.

After the revisions to the proposal were completed, there remained only two paragraphs in this provision: § 900.12(b)(5)(i), requiring beam limiting devices that allow the useful beam to extend to or beyond the chest wall edge of the image receptor; and § 900.12(b)(5)(ii), which establishes the illuminance requirement.

g. *Source-image receptor distance (SID) (proposed § 900.12(b)(6))*

FDA proposed requirements for a minimum SID for mammography systems and specified that the SID must be displayed. The agency also proposed an accuracy specification for that display. In § 900.12(b)(6)(i), FDA proposed that all mammography systems have a minimum SID of at least 55 cm.

(Comment 320). One comment recommended that FDA include a definition of ''contact mammography'' as used in § 900.12(b)(6)(i) to eliminate confusion about its meaning. Another comment supported the minimum SID as proposed, and six comments supported the concept but recommended that the minimum SID be reduced to 50 cm; NMQAAC supported the proposal as published.

In considering these comments and other more general comments relating to avoidance of unnecessary specifications that may limit future technology, FDA has decided that other requirements in the final regulations (dose, resolution/focal spot condition, and system output) make issuing this requirement unnecessary. Therefore, the limitation on the SID has been removed from the final regulations. In the future, if the agency determines that regulations covering this area are required, all relevant comments will be reconsidered at that time.

In § 900.12(b)(6)(ii), FDA proposed that each system should provide a visual indication of the SID, accurate to within 2 percent.

(Comment 321). One comment stated that the actual SID needs definition or that there should be specification of an acceptable method of verifying the SID or location of the focal spot. Other comments were concerned with uncertainties in determining the end points of the SID. One comment noted that the indication of the SID proposed in § 900.12(b)(6)(ii) might differ between systems because of differences in interpretation of the location of the image receptor. Conversely, another comment suggested that the concept of an indication of the SID, as proposed in § 900.12(b)(6)(ii), is ambiguous for those systems having multiple focal spots and anode tracks because all focal spots are not at the same location on the anode. The comment further suggested that the ''source'' be defined as the average location of all focal spots.

Another comment noted that the standards in IEC 601–1–3(point 29.203.2) specify a tolerance of 5 percent for the SID indicator and requested that FDA consider adopting that specification rather than the 2 percent proposed. One comment suggested that FDA might wish to

consider recasting the proposal of § 900.12(b)(6) as an outcomes specification. Another comment recommended that the proposed requirement in § 900.12(b)(6)(ii) for indication of SID be restated to require the indication only for variable SID units. NMQAAC recommended that the section be deleted because they believed that it would add to the equipment costs with little benefit to the quality of mammography.

FDA has accepted the NMQAAC recommendation and deleted § 900.12(b)(6)(ii). If this issue is revisited, all comments will be reconsidered at that time.

h. *Magnification (§ 900.12(b)(6) (proposed § 900.12(b)(7)))*

As proposed, this paragraph required that systems used for procedures beyond basic screening mammography have magnification capability available to the user.

(Comment 322). One comment suggested that the proposal was unclear as to the intent of ''available to the user.'' One comment incorrectly assumed that, because there was no implementation date for the requirement, all diagnostic equipment installed presently have magnification capability and will meet the requirement. One comment expressed concern that this requirement made his facility's equipment obsolete and stated that most diagnostic mammography does not require magnification.

The radiologists on NMQAAC stated that magnification is needed for noninterventional problem solving mammography. The committee debated whether to recommend to delete or change these provisions and decided not to recommend such actions.

FDA has retained the provision, but reworded parts of the proposal to clarify the intent. The changes include replacing the term ''diagnostic mammography'' with ''noninterventional problem solving mammography.'' This change was necessary because there is no general consensus as to the definition of ''diagnostic mammography.'' ''Problem solving mammography'' refers to mammography requiring techniques beyond those utilized in standard mammography of asymptomatic patients and ''noninterventional'' indicates that the procedures are noninvasive in nature. The term ''available to the user'' simply means that any attachments or accessories necessary to allow the X-ray system to perform magnification procedures must be present with the system and available to the technologist to encourage and facilitate the use of the feature.

(Comment 323). Four comments recommended that the specification be reworded to require the facility to have the capability to provide magnification instead of requiring that each system provide the feature. However, the experts on NMQAAC stressed the importance of requiring the feature in each system used for such procedures and FDA has retained the requirement.

In § 900.12(b)(7)(ii) of the proposal, FDA specified that at least one magnification setting should be in the range of 1.4 to 2.0. One comment suggested that the use of magnification greater than 1.5 is questionable and that limits for the image quality and average glandular dose should be set for these conditions.

FDA agrees, in principle, with this comment. Generally, magnification for these procedures is accepted within the range specified by the requirement and most sources seem to agree that magnification at approximately 1.5 is optimal. FDA believes that by requiring the equipment to provide magnification in the optimum range the facility will then be able to adequately perform the procedure. Some systems currently used for magnification will not meet this standard. This will not, in itself, however, force the replacement of the equipment because the unit may still be used for the general population ''screening'' of asymptomatic patients so long as it meets the other requirements.

(Comment 324). One comment noted that ''magnification setting'' as used in the proposal was not defined. Another comment stated that the method of determining the magnification, along with acceptable limits, should be specified or referenced. FDA has removed the word ''settings'' from the requirement because it might be confusing but has not added a definition of ''magnification'' to § 900.2; FDA believes that the term is generally understood to be the ratio of the source-to-image receptor distance to the source-to-object distance.

Because the proposed SID requirements were moved, proposed § 900.12(b)(7) *Magnification* has been codified as § 900.12(b)(6).

i. *System resolution (proposed § 900.12(b)(8))*

This paragraph proposed requirements for the system resolution for both contact mode and magnification mode mammography.

(Comment 325). Nine comments requested that a test procedure be specified for the contact mode requirement proposed in § 900.12(b)(8)(i). One comment suggested that a specification of the appropriate resolution target should be included along with a specification of its position in the test plane, and a requirement for an absorber in the beam to lengthen the exposure times, because very short exposures may introduce interference from gridlines.

FDA agrees with these comments and has included a description of the test conditions in the final regulations.

(Comment 326). One comment correctly noted that the requirements in proposed § 900.12(b)(8)(i) and (ii) attribute failure to meet resolution requirement to problems with the focal spot when, in fact, the cause of observed low resolution values may be some other component in the imaging chain.

FDA agrees with this comment and has rephrased the requirement.

Based on recommendations from NMQAAC, FDA has removed this requirement from the equipment standard and established a QC requirement for system resolution that is codified under § 900.12(e)(5)(iii).

In § 900.12(b)(8)(ii), FDA proposed regulating the system resolution in the magnification mode. Based on guidance received from NMQAAC, FDA has moved this requirement to the quality assurance provisions in § 900.12(e)(5)(iii), and has designated it for phase-in after 5 years. If, in that time, other values are determined to be more appropriate, the regulations will be modified accordingly.

Thus, proposed § 900.12(b)(8) *System resolution*, no longer appears among the equipment requirements.

j. *Focal spot selection (§ 900.12(b)(7) (proposed § 900.12(b)(9)))*

As proposed, this provision included several requirements for indication of the focal spot selected for use in examinations, interlocking of the focal spot with selected kVp, and alignment of the focal spot with the image receptor. FDA also proposed that the system indicate which focal spot and, where applicable, which focal spot material is selected prior to exposure. The proposal also recognized that some systems may automatically select the focal spot during the exposure and required a post exposure indication of the focal spot used during such exposures.

(Comment 327). Three comments, including that of NMQAAC, recommended that the requirements proposed in § 900.12(b)(9)(ii) and (iii), concerning indication of the target material, be linked with an ''or.''

FDA did not accept this recommendation because it would essentially eliminate the requirement for post-exposure indication of the machine selected focal spot. The agency believes that the change would modify the

requirement in a way the agency does not intend or desire because it would permit the equipment to display only the initial preselected focal spot and never indicate the actual focal spot used.

(Comment 328). Two comments supported the proposal in § 900.12(b)(9)(iv) that the system be interlocked to prevent exposure with improper or incompatible combinations of kVp and target material. One comment opposed this requirement, two requested clarification, and one requested a test procedure. NMQAAC recommended that the initial clause in the proposal be deleted.

After further consideration of this requirement, FDA concluded that the requirement was already adequately covered by requirements relating to diagnostic X-ray systems in § 1020.30(m) and has deleted proposed § 900.12(b)(9)(iv).

k. *Focal spot location (proposed § 900.12(b)(10))*

This paragraph proposed a requirement that the focal spot be located in a specific geometric relationship to the image receptor.

(Comment 329). One comment supported the requirement, five (including NMQAAC) opposed it, believing that it was unnecessary, three requested clarification on its testing, and one, recognizing its relationship to the compression paddle alignment, recommended that the provision be moved to the section on compression paddle alignment.

FDA accepted the NMQAAC recommendation and deleted this requirement from the final rule.

l. *Filtration (proposed § 900.12(b)(11))*

This proposed paragraph contained a statement requiring mammography systems to comply with the beam quality standards for half-value-layer (HVL) codified at § 1020.30(m)(1).

NMQAAC recommended that the section specifying the HVL requirements should be moved to the QC section. FDA accepted this recommendation and codified the requirements for filtration under § 900.12(e)(5)(iv).

(Comment 330). One comment suggested that the proposed rule in § 900.12(b)(11)(i) was too vague and subject to arbitrary interpretations. Another comment recommended that more precise rules be used to determine the required HVL and suggested that existing dose tables could be used to determine the desired limits. The respondent based this position on the fact that § 1020.30(m)(1) requires the interpolation or extrapolation of HVL values in the mammographic range. One comment noted that filtration is not the same as HVL; the HVL measure indicates the filtration that is in the X-ray system, but it is not an actual measurement of filtration. Two comments noted that the proposed regulations refer to § 1020.30(m)(1) for the minimum filtration requirement and incorrectly interpreted this as a lack of specification for kVp's not listed. They asked what FDA is planning to do concerning the perceived lack of regulation of filtration for kVp's below 30 kV since the table of HVL specifications does not list any values below 30 kV. One comment stated that some realistic values for expected HVL at ranges of 25 to 30 kVp should be given. One comment stated that § 900.12(b)(11)(i) seems less specific than current requirements for filtration and another comment suggested that the requirement in § 900.12(b)(11)(i) should be referenced to the most recent ACR physics manual instead of § 1020.30(m)(1).

FDA believes that the comments indicate that relationship between filtration and half-value-layer (HVL) in the mammographic energy range and the concept of mathematical extrapolation and interpolation may not be fully understood by some members of the mammography community. It is generally understood that the first HVL is an indirect measurement of the filtration in the X-ray beam. In the kVp range up to 50 kVp, the values specified in § 1020.30(m)(1) represent a beam with an inherent filtration equivalent to 0.5 mm of type 1100 aluminum. FDA notes that, although the standard relates the HVL in terms of type 1100 aluminum, it does not specify that the same alloy be used to measure the HVL. Therefore, the measurement of the first HVL and the comparison of the result to the specification indicate whether the system has sufficient filtration in the beam; if the first HVL is less than the number specified in the table, there is insufficient filtration because the HVL is a function of the filtration and the energy of the X-ray beam (kVp).

In response to the comments, FDA has provided a table of the extrapolated values of HVL in the mammography kVp range under the quality assurance provisions in § 900.12(e)(5)(iv). Values not shown may be derived by interpolation. FDA believes that providing these values, which are derived from the Federal performance standard at 21 CFR 1020.30(m)(1) and are serendipitiously identical to the ACR recommended values when the paddle is not in the beam, makes it unnecessary to reference the ACR manuals or any other external source of HVL values.

(Comment 331). Five comments supported a specification of a maximum filtration requirement in § 900.12(b)(11)(i) and another comment recommended that a maximum HVL, specified as a function of kVp, be added for each known combination of anode and filter materials. One comment noted and agreed with the deletion of the upper limits for HVL that had been proposed in previous drafts of the proposed regulations.

FDA deleted those upper limits because it had concluded that other aspects of performance and image acceptability will serve to limit the maximum filtration. Comments to the proposal have not persuaded the agency to reverse that position.

(Comment 332). One comment noted that § 900.12(b)(11)(i) references § 1020.30 and questioned the need to repeat the requirement. The comment also found the proposal ''redundant with § 900.12(b)(2),'' which requires equipment to be specifically designed for mammography. FDA does not agree that the references are redundant and has concluded that the restatement in this regulation serves to clarify and reinforce the § 1020.30 specification.

One comment suggested that the regulation be recast in terms of desired outcomes and offered this example: ''The type and quantity of filtration interposed between the source and the breast entrance surface shall be such as to provide the maximum subject and image contrast consistent with limitations on dose (§ 900.12(c) of the interim regulations) and minimum half-value layer (§ 1020.30(m)(1)).''

FDA believes this suggestion would introduce an unacceptable level of subjectivity into the evaluation process without eliminating the need to reference the specification in § 1020.30(m)(1).

FDA also reconsidered the requirements in § 900.12(b)(11)(ii) for variable filtration systems, which proposed interlocking the filtration with the target material. Upon further review, the agency concludes that requiring equipment to meet standards that ensure that the minimum filtration required in § 1020.30(m)(1) is in the beam during each exposure is sufficient to ensure proper filtration and has deleted § 900.12(b)(11)(ii) from the final regulation.

m. *Compression (§ 900.12(b)(8) (proposed § 900.12(b)(12)))*

This paragraph proposed a number of requirements concerning the application of compression. The basic proposal was

that each mammography unit should have a compression device.

(Comment 333). Five comments and several members of NMQAAC supported the proposed requirement. One comment suggested that FDA should go further and require the use of the compression device.

If the compression device is present, most technologists will use it responsibly and also recognizes that the use of an item is difficult to enforce. FDA, therefore, has rejected this suggestion.

Under § 900.12(b)(12)(i) FDA proposed that, 5 years after publication, each system would be required to be equipped with an initial, foot controlled, power driven compression and also be required to allow the user to control additional ''fine adjustment'' of the compression. The proposal required that both controls be operable from each side of the patient.

(Comment 334). Two comments stated that power-driven compression by foot control is unreasonable or unnecessary. One comment stated that FDA should delete the requirement for fine adjustment controls and the specifications on how the compression controls should operate because they will increase the cost of new equipment while providing little benefit. Another comment stated that no requirement beyond one that the system ''be capable of maintaining a force of 25 pounds for 15 seconds and have a maximum force no greater than 40 pounds when used in automatic or power driven mode'' is necessary.

In contrast, twenty-eight comments agreed that ''automatic'' power driven compression should be required of all facilities but stated that it should be put in effect immediately, not 5 years from now, as proposed. Several of these comments expressed the opinion that the technologist needs to have both hands free to optimize the breast position. Five comments stated that manual and power compression controls, as called for, are essential for quality mammography. The comments further noted that manual controls are needed for finer adjustment and that the two controls complement each other, although one comment expressed the respondent's belief that the fine adjustment should be a manual control because that type of control was reassuring to some patients. One comment recommended that the reference to ''foot controls'' be deleted since the goal of ''hands-free'' application of compression may be achievable by some mechanism other than a foot operated control.

FDA has accepted the last comment and modified the requirement accordingly. However, FDA believes that this ''hands free'' application of power compression and the fine adjustment control are basic to the delivery of quality mammography care and is retaining the requirements in the final regulations. FDA appreciates that this will have a cost impact on the installed base; however, the agency believes that the benefit to public health outweighs this cost and also notes that most of the current equipment can be brought into compliance with modifications that are far less costly than total replacement.

(Comment 335). One comment suggested that FDA might wish to recast the proposal in terms of the desired outcomes, for example:

> Means of applying compression to the breast shall be provided that; (i) allow the technologist to use both hands to position the breast while applying compression, (ii) facilitate positioning from both sides of the patient without removing hands from the patient, (and) (iii) allow a slow, final adjustment of compression.

While FDA appreciates this suggestion, the agency believes that such terms as ''allow'' and ''facilitate'' require too much subjective evaluation in the interpretation of compliance. Under some design and use conditions, certain technologists may be able to demonstrate that the equipment meets these requirements, while others may not. FDA believes that establishing reasonable standards for the equipment allows the majority of technologist the greatest opportunity to achieve optimal positioning for even the most challenging patients.

(Comment 336). One comment stated that a number of different types of mammography systems in use either do not offer automatic compression or have only automatic compression with no manual compression knob. The comment suggested it would be worthwhile to retain maximum flexibility in the final regulation to allow evaluation of this type of retrofit system, so long as the intent and specifications of the final regulations were met. A second comment stated that the ''fine adjustment compression,'' as proposed, would place a costly burden on some facilities that do not have manual compression. Another comment indicated that when requiring all units to have a power driven compression paddle activated by foot controls, as proposed, it is also necessary to have a manual compression mode as well. One comment suggested that final compression should always be done using a hand control knob, which the technologist can easily control with direct tactile feedback. One comment agreed that it is necessary to have power driven compression, as proposed, but noted that it was not necessary that the fine adjustment control be power driven. One comment noted that the proposed requirements do not preclude the equipment from having a manual compression provision.

Many of these comments resulted from misreading the proposed regulations. The proposal does not require the fine adjustment compression be a manual operation. The fine adjustment is usually a ''manual'' adjustment in that it is applied by a hand operated (''manually operated'') control. This does not imply or require the provision of a direct linked drive dependent only on the input force provided by the operator. Many of the ''manual'' knobs are actually servo-driven power compression devices that are under a more closely controlled incremental advance than that provided by the foot control and, in these cases, the ''tactile'' feed-back sensed by the technologist is not necessarily related to the force applied to the patient. As the regulations are written, the design of the equipment can provide a truly ''manual'' control for the fine adjustment, or can provide a slower power driven application that may be adjusted by a hand control or other suitable means. FDA believes that most equipment with power-driven compression already provides a fine adjustment control and that the cost impact on those facilities not presently meeting this requirement will be outweighed by the advantages to positioning and improved image quality.

(Comment 337). Five comments suggested that a requirement for maintaining compression for a specified period of time should be added and one suggested that this specification should be established for both automatic and fine adjustment compression.

FDA proposed the criteria for application of compression without stating a specified time for maintaining the compression. This means that FDA expects the compression to meet the criteria in the regulations until the compression is terminated, either by an automatic release at the end of the exposure or by operator intervention during or after the exposure. Therefore, it is not necessary to expressly establish a time limit for maintenance of compression.

NMQAAC discussed these provisions at some length and several committee members spoke about the importance of compression to the overall quality of

mammography. The committee recommended that the requirements for power driven and fine adjustment compression become effective immediately but that the requirements for the maximum force in the initial power drive remain a 5-year phase-in requirement. The agency considered the recommendation to move forward the effective date for the power driven and fine adjustment controls, but has determined that the cost considerations associated with accelerating the implementation of these requirements cannot be justified based on the expected improvements. Therefore, FDA has reworded these requirements to address some of the above comments, and has retained the effective date that was proposed.

Section 900.12(b)(12(i)(C) proposed limits on the compression force required for the automatic power compression mode.

(Comment 338). Two comments stated that the proposed requirement for 25 to 40 pounds under power driven compression was excessive and may result in patient injury.

Based on input from NMQAAC, ACR, and the general comments provided by manufacturers, FDA believes that 25 to 45 pounds is an appropriate range and presents little risk of injury to patients when applied by trained technologists.

(Comment 339). One comment observed that the proposal only limits the compression under power driven control and recommended that an upper limit be set for the maximum compression under manual control.

Although FDA had considered such an upper limit, the idea was opposed by NMQAAC because they felt that it was unnecessary. FDA is not proposing such a limit at this time.

(Comment 340). One respondent was concerned that there may be units designed to achieve the proposed compression forces but that have user adjustable controls that allow adjustment to values below the minimum proposed specification.

FDA agrees that such equipment may exist or be introduced into the market place. The agency notes that under the regulations, as codified, the requirement is for values attainable by the user. If the user has direct control over any such system adjustment, then this adjustment must be used in testing the system. If such adjustment is only available through service or installation configuration, then the unit should be tested only to the limits adjustable by the operator. Under these circumstances, the respondent's concerns are adequately addressed because any user adjustable controls must be utilized in determining the compliance of the system with the standards. FDA has moved the requirement for the range of acceptable power driven compression to the quality assurance section under § 900.12(e)(4)(iii).

Under § 900.12(b)(12(ii)(B), FDA proposed that each system have a means for manual compression release in the event of failure of other decompression mechanisms.

(Comment 341). One comment questioned if the wording meant that compression must be maintained in the event of power failure and, if so, must the required display of override status also be maintained after power failure.

FDA intends that the compression be maintained after a power interruption. However, the display of override need not continue in such circumstance because the fact that the patient is still under compression would serve as adequate indication that manual release is required.

(Comment 342). One comment noted that there were many designs currently on the market that allowed for the manual release of the compression without the presence of a specific device as called for in § 900.12(b)(12)(ii)(B). The comment requested that the proposal be reworded to emphasize the desired outcomes rather than a specific means of obtaining those outcomes.

FDA believes that the wording in the proposal does address outcomes and does not intend the provision to require any specific release design. Any mechanism that allows the manual release of compression would meet the requirement. The requirements for the compression forces and decompression have been moved, as recommended by NMQAAC, to the quality assurance section of the regulations and are addressed in § 900.12(e)(4)(iii) and (e)(5)(xi).

In § 900.12(b)(12)(iii)(A), FDA proposed that systems be equipped with different sized compression paddles matching the sizes of all full-sized image receptors provided and that compression paddles for special purposes, including those smaller than the full size of the image receptor (for 'spot compression') could be provided. FDA did not require that these special paddles be provided but included the reference to clarify that these paddles could be included in the system and are exempt from certain parts of the requirements applicable to the full size paddles.

(Comment 343). Three comments supported the requirement in § 900.12(b)(12)(iii)(A) as written. One comment recommended that the proposed requirement be expanded to require that facilities have the ''spot compression paddles'' available. NMQAAC supported the proposal as published.

FDA has done some minor rewording in this paragraph and renumbered it in the final regulations under § 900.12(b)(8)(ii)(A).

In § 900.12(b)(12)(iii)(B), FDA proposed that the compression paddle be flat and parallel to the patient support and not deflect from parallel by more than 1.0 cm at any point when under compression.

(Comment 344). Nine comments opposed the proposed requirement. Three of these suggested that this is not the best way to compress the breast because it ignores the anterior tissues and the often thicker tail of the breast. One comment stated that nonparallel paddles are useful for compression of very large breasts in the MLO view. Another comment noted that one manufacturer's equipment does not meet the proposed requirement, suggested that the subject does not need regulation, and recommended that the section be deleted. This comment maintained that the exemptions available for alternate devices would be ''much too difficult to use to allow possible improvements.'' One comment responded to FDA's request for comments on the nonparallel ''alternate design'' compression paddle by supporting the concept of allowing such a configuration under the proposed regulations. The comment further noted that some manufacturers are investigating the use of compression paddles that apply compression in nonparallel geometry and that these paddles would have difficulty complying with the regulation as proposed. One comment suggested that the proposed requirement was too restrictive, stating that several manufacturers have measured the paddle deflection on their units and found that the requirement may be difficult to meet on the 24 x 30 cm paddles. One comment suggested that the proposed specification could be improved if the tolerance were loosened, if the measured compression force were reduced, or if the allowable flex were expressed as a function of the applied force.

Two comments asserted that the proposed regulation in § 900.12(b)(12)(iii)(B) places too great an emphasis on the position of the compression paddle, but does not address the position of the film in the patient support. These comments recommended that the regulations

address the film location with respect to the edge of the patient support and relax the requirements for the compression plate. Three comments suggested that the description of the test method as proposed in § 900.12(b)(12(iii)(B) should be deleted and that testing procedures should be left to the medical physicist to determine, or be included in a companion manual prepared by FDA. Fifteen comments neither supported nor objected to the proposed requirement, but were concerned with the test procedure as proposed and suggested modifications or requested clarification of the procedure.

NMQAAC discussed this section at some length. Some members and consultants were concerned that the specifications in the proposal would limit the introduction of new equipment and, even though the regulations provide procedures for obtaining approval for alternate standards, wanted to modify the requirement. Experts on the committee stressed that the purpose of this regulation was to eliminate those worn and faulty compression devices that were intended to be flat and parallel by design but which, through use, now flex unacceptably. After consideration, the committee recommended that the requirement remain but that a new provision be added that addressed those paddles that by design were not intended to remain straight and parallel under compression. They also recommended that the test procedure described in this section be deleted as a requirement because it could be determined by the physicist during the survey.

In response to the public comments and NMQAAC recommendations, FDA has made changes as outlined below. FDA is deleting the provision that established a test procedure for this section. The requirements have been modified and renumbered as § 900.12(b)(8)(ii)(B) and a new § 900.12(b)(8)(ii)(C) requires that all paddles intended by the manufacturer's design not to be flat and parallel under compression must meet the manufacturer's design specification and maintenance requirements. The agency will revisit and modify its proposal for the test procedure for this section in the future and all comments regarding the procedure will be considered again in that process.

Under § 900.12(b)(12)(iii)(C) and (D), FDA proposed that the chest wall edge of the compression paddle should be straight and parallel to the edge of the image receptor and that the chest wall edge of the compression paddle should not interfere with the chest wall edge of the image.

(Comment 345). Two comments requested clarification on how straight and how parallel the requirement intended the chest wall edge of the paddle to be. One comment agreed with the intent of the proposed regulation, but expressed concern that varying interpretations of the written regulation will lead to confusion in enforcement. This comment recommended that, if such specifications are included in the final regulations, there should be some tolerance specified that is both affordable and effective in the improvement of mammography.

FDA notes that the intent of this section is to eliminate the older style compression paddle that had a curved chest wall edge. The agency believes that the words straight and parallel are well understood but will address concerns raised by the comments through issuance of a guidance on this paragraph that contains a test procedure facilities may utilize. The description of this procedure should also clarify any confusion regarding FDA's interpretation of the regulation.

In § 900.12(b)(12)(iii)(D), FDA had proposed that the chest wall edge of the compression paddle should be bent upward.

(Comment 346). One comment recommended that the proposed regulation include a requirement that the chest wall edge of the paddle be perpendicular to the surface of the compression plate. Another comment stated that the use of ''should'' in § 900.12(b)(12(iii)(D) has little meaning and is unenforceable.

NMQAAC discussed both paragraphs and did not recommend any changes. FDA notes that this provision was not intended to establish a mandatory requirement but to clarify that such a design, intended to enhance patient comfort, was permissible. This requirement has been codified under § 900.12(b)(8)(ii)(E) in the final regulations. The word ''should'' has been replaced with ''may'' in the final rule. FDA does not agree that it is advisable to require the chest wall edge to be perpendicular to the surface of the compression paddle since this could lead to sharp edges that might cause patient discomfort.

Under § 900.12(b)(12)(iv)(A), FDA proposed that, 5 years after the publication date of the final regulations, the edge of the compression paddle shall align with the chest wall edge of the image receptor to within 1 percent. Proposed § 900.12(b)(12)(iv)(B) further restricted the alignment to within 2 millimeters 10 years after publication and § 900.12(b)(12)(iv)(C) proposed a test procedure for the requirement.

NMQAAC recommended that the § 900.12(e)(12)(iv)(A) be moved to the QC section of the final regulations and that the requirements should go into effect at the earliest opportunity. NMQAAC also recommended that the requirement under § 900.12(b)(12)(iv)(B) and (C) be deleted because the committee believed the proposed 2-millimeter requirement was too stringent. The proposed 2-millimeter requirement and the test procedure have been deleted and the final regulation regarding compression paddle-image receptor alignment was moved to the quality assurance section and is codified under § 900.12(e)(5)(vii)(C) where it will become effective at the earliest effective date.

(Comment 347). One comment recommended caution in specifying these alignment requirements because they might limit design in some areas of new technology. The comment recognized that these proposed specifications are only applicable to film-screen systems, but expressed concern that the concepts might carry over into new technology areas.

FDA assumes that this comment was directed toward the issue of image receptor size for digital systems, but does not anticipate any conflict.

(Comment 348). Eleven comments agreed with tightening the tolerance for alignment as proposed in § 900.12(b)(12)(iv) but suggested that only a positive misalignment should be allowed.

FDA agrees and accepts these comments.

(Comment 349). Eight comments noted a typographical error in § 900.12(b)(12)(iv)(A). FDA has corrected this.

(Comment 350). Three comments recommended that the ''October 1, 2000'' effective date be deleted and that the requirement go into effect in the earliest phase because, in the respondents' opinions, the vast majority of systems already meet this requirement.

FDA agrees with these comments and has accepted this recommendation to move the effective date forward.

(Comment 351). Six comments expressed concern regarding the test for this paragraph.

These comments will be reconsidered when FDA publishes its guidelines for the QC test.

Under § 900.12(b)(12)(iv)(D), FDA proposed that the alignment criteria for the contact mode should also be applicable to the magnification mode 10 years after the publication of the final regulations and proposed a test procedure.

(Comment 352). Five comments suggested that the requirement was unnecessarily restrictive and should be dropped. Four comments supported the proposed requirement, believing it serves to ensure the accuracy of the alignment of the edge of the compression paddle with the edge of the image receptor. One comment recommended a rewording for the requirement. Two respondents expressed concern regarding the test procedure. NMQAAC suggested that the requirement in the magnification mode was unnecessary and should be deleted.

After reviewing the comments, FDA has accepted the NMQAAC recommendation and deleted the requirement for paddle alignment in the magnification mode.

Under § 900.12(b)(12)(v), FDA proposed that, 5 years after publication of the final regulations, all systems should display the compressed breast thickness. The proposal also established a test procedure for the requirement.

(Comment 353). One comment pointed out that current indicators of compressed breast thickness are grossly inaccurate for a number of reasons, including paddle and compression arm flex, lack of uniformity across the breast, and differences in the location at which various manufacturers determine the breast thickness (since there is no agreement where the breast thickness is to be measured). Two comments recommended that the word ''correct'' be inserted between ''the'' and ''compressed'' in § 900.12(b)(12)(v). One manufacturer requested an exception for its product because the measured breast thickness read out could be off by 0.6 to 1.0 cm for their paddle. One comment expressed concern that there was no clear specification to the accuracy of the indicated value proposed in § 900.12(b)(12)(v)(A). NMQAAC discussed this provision at its April 1996 meeting and recommended that the requirement for a display remain but that no accuracy specification be associated with the display. NMQAAC revisited the issue at its January 1997 meeting but did not change its recommendation. Another comment suggested that the proposed requirement should apply only to equipment that uses the compressed breast thickness in an algorithm to determine technique factors. One comment supported the proposed requirement in § 900.12(b)(12)(v)(A) because it is especially important for implant patients, but recommended that it go into effect 5 years after the effective date of the regulations rather than 10 years after, as proposed.

FDA has reviewed the comments and reassessed the need for this requirement. The practical application of the information provided by the display to the mammography process appears to be questionable and the concept of having a display that has no associated accuracy is of debatable value. FDA has decided to remove § 900.12(b)(12)(v) from the final regulations in accordance with the agency's desire to minimize costs, as discussed previously. All comments requesting clarification or suggesting modification to the test procedure will be considered again if FDA revisits this requirement.

The portions of proposed § 900.12(b)(12) that have been retained in the equipment provisions were codified under § 900.12(b)(8).

n. *Technique factor selection and display (§ 900.12(b)(9) (proposed § 900.12(b)(13)))*

In this paragraph, FDA proposed requirements for the selection and display of technique factors.

FDA proposed in § 900.12(b)(13)(i) that every system shall have the capability for manual selection of mA's or, at least, of mA or time. No public comments addressed this issue. NMQAAC discussed the proposal at both the April 1996 and the January 1997 meeting and supported the proposal. FDA reworded the requirement slightly before codification to clarify its intent. Because of the deletion of paragraphs listed earlier in the proposal, paragraph § 900.12(b)(13) has been codified as § 900.12(b)(9), and this paragraph became § 900.12(b)(9)(i) in the final rule.

Under § 900.12(b)(13)(ii), FDA proposed that all technique factors be clearly displayed at the control panel prior to exposure. At § 900.12(b)(13)(iii), the agency proposed that such factors be preindicated in the AEC mode.

(Comment 354). One comment recommended FDA clarify that the specification in § 900.12(b)(13)(ii) applies only to the manual mode of operation. A comment on § 900.12(b)(13)(iii) requested clarification of which technique factors were intended to be covered by this requirement. At its April 1996 meeting, NMQAAC also expressed some confusion regarding the same issue. Another comment recommended that the requirements of § 900.12(b)(13)(iii) and (iv) be combined.

FDA believes that requirements for preindication and postindication of the technique factors should be presented under separate paragraphs and has not accepted this last comment. FDA did clarify § 900.12(b)(13)(ii) and (iii) and combined them into a single provision at § 900.12(b)(9)(ii).

Under § 900.12(b)(13)(iv), FDA proposed that, after AEC exposure, the system should indicate the actual kV and mA's used during the exposure.

(Comment 355). Two comments recommended that this requirement be deleted or its implementation date be delayed because the replacement or retrofit of many older units might be costly. Another comment stated that a mA's readout, as proposed in § 900.12(b)(13)(iv), has not been proven necessary. NMQAAC discussed this issue and the cost concerns related to retrofits to provide the postexposure mA's indication. The committee supported the requirement but requested some wording changes to clarify the meaning of mA's indication.

FDA has retained this provision because it concluded that the costs associated with the possible retrofits are not significant enough to outweigh the benefits and has included it in the final regulations under § 900.12(b)(9)(iii).

Under § 900.12(b)(13)(v), FDA had proposed that each unit provide an indication of kVp that was accurate to within + 5.0 percent of the actual kVp.

(Comment 356). Five comments agreed with the proposed five percent accuracy specification, but another comment suggested that the requirement for kVp accuracy of + 5.0 percent was not justified because there was no definition of what kVp really means and no calibration available for kVp meters. Another comment stated that ''5 percent of the actual kVp as proposed in (b)(13)(v), is a very large discrepancy,'' noting that 5 percent of 30 kVp allows 31.5 kVp, which, in the respondent's opinion, presently is considered to be unacceptable. The comment further suggested that § 900.12(b)(13)(v) be changed to read: ''All indications of kVp shall be within 1 kV of the actual kVp.''

In § 1020.30 FDA defines kVp to mean the maximum value of the potential difference across the X-ray tube during an exposure. FDA agrees with the comment that the + 5.0 percent accuracy is a large discrepancy and notes that it is the same specification currently established by the most recent revision of the ACR manuals. The agency intends to provide additional information regarding compliance with this requirement.

(Comment 357). Three comments, including one from NMQAAC, noted that there was a conflict between the kVp accuracy specification at § 900.12(b)(13)(v) and at § 900.12(e)(5)(ii)(A). NMQAAC also recommended that the requirement be moved to the quality assurance section

and that the + 5.0 percent accuracy specification be retained. FDA has accepted these recommendation and the requirement now appears in the final regulations under § 900.12(e)(5)(ii) and includes the + 5 percent accuracy specification.

In § 900.12(b)(13)(vi), FDA proposed that, 10 years after the publication of the final regulations, each X-ray unit used for mammography would be required to have a specific range of kVp and mA's selection and that adjacent selections of the kV selection and adjacent selections of the mA's should not vary by more than a prescribed amount. The public comments regarding this section were overwhelmingly against including these proposals in the final regulations. NMQAAC supported the proposals but only marginally so, with many opposing opinions. FDA has reconsidered the advisability of including these specifications in the final regulations, based in part on the public comments and in part on the difficulty in predicting the necessity for these limitations 10 years in the future and has deleted all requirements proposed under § 900.12(b)(13)(vi) from the final regulations.

o. *Radiation output (proposed § 900.12(b)(14))*

This paragraph proposed setting a minimum value for radiation output per second of mammography X-ray equipment, with an increase in that minimum value to occur 5 years after publication. This section has been codified in the quality assurance section of the final regulations.

(Comment 358). Two comments agreed with the requirement proposed in § 900.12(b)(14)(i), with one urging that the requirement be fully implemented at the earliest possible date rather than being phased-in. One comment suggested that the proposed requirements in § 900.12(b)(14)(i) and (ii) might actually be in conflict with each other. FDA reviewed these provisions and does not see a conflict because clause (i) specified an exposure rate and (ii) specified a time over which that rate must be met. However, in response to other concerns, as outlined in the preamble to the quality assurance section, FDA has modified the requirement to clarify that the specification is to be an average over three seconds and not an instantaneous rate measurement.

(Comment 359). One comment suggested that the proposed requirement in paragraph (b)(14)(i) be replaced by the equivalent air kerma expressed in milligray (mGy). The guidelines followed by FDA in the writing of regulations specify that all numerical limits, where applicable, be expressed in terms of the International System (SI) of Units, the internationally accepted standard, followed by the more common equivalent in parentheses.

In the proposed regulations, FDA had represented radiation limits in terms of exposure expressed in the SI unit of coulomb per kilogram (C/kg). Although C/kg is the correct SI unit for exposure, it is an awkward unit for the actual operating ranges of exposure (10–4 C/kg) of mammography systems. FDA believes now that it would be more advantageous to specify radiation limits in terms of the alternate quantity air kerma expressed in the SI base unit of gray (Gy). Air kerma, which is defined at § 900.2(d), is the sum (per unit mass of air) of the initial kinetic energies of all the charged ionizing particles liberated by the X-rays. At the X-ray energies typically used in diagnostic radiology and mammography, values for air kerma are practically indistinguishable from values of absorbed dose in air. Air kerma is increasingly accepted in the international community as the quantity preferred in the specification of radiation delivered, and it is being proposed to replace exposure in amendments in 21 CFR part 1020. Because amendments to those standards are not final, the units were not used in the proposal. However, FDA is replacing the quantity exposure with the quantity air kerma in these final MQSA regulations because it anticipates that parallel changes will be made in the international standards and part 1020.

(Comment 360). One comment suggested that FDA recast proposed § 900.12(b)(14)(i) as a performance objective, such as: ''The radiation output, in terms of exposure rate, at clinically useful kVp's shall be sufficiently high to avoid exposure times of such duration that loss of resolution due to motion or excessive dose due to film reciprocity failure is expected to occur.''

FDA appreciates the benefits of adopting performance standards when appropriate but believes that in this case the suggested wording introduces an unacceptable level of subjectivity into determining compliance.

(Comment 361). One comment recommended that the test procedure proposed to measure radiation output in § 900.12(b)(14)(iii) specify the position of the compression paddle during the measurement.

FDA assumes this comment is expressing concern regarding the scatter contribution to the reading and its variability depending on the distance the paddle is located from the detector. FDA recognizes the possible effects of scatter on this measurement but does not believe the contribution is of sufficient concern to warrant the prescription of paddle position relative to the detector. In clinical use, the paddle is obviously in contact with the breast. If a facility wishes to test with the paddle in a similar position, FDA has no objection. Similarly, if the paddle is moved nearer to the focal spot, FDA would find this acceptable. FDA does, however, require the compression paddle to be in the X-ray beam between the source and the detector as was specified in § 900.12(b)(14)(iii).

(Comment 362). One comment suggested that FDA require that compliance with § 900.12(b)(14) be determined ''with the phantom in the beam and that the exposure be completed within 2.5 seconds.''

FDA believes that placing any phantom in the beam during this test would not improve this test and that the three second exposure proposed is both reasonable and appropriate for this requirement.

(Comment 363). Two comments suggested that compliance with § 900.12(b)(14)(i) should be determined at a routine clinical kVp instead of the proposed 28 kVp. FDA notes that 28 kVp is used clinically for mammography, although not as frequently as other kVp values. It was selected first by the American Association of Physicists in Medicine and then by the ACR/CDC Imaging System Focus Group as the standard kVp to be used in association with their radiation output specifications. These specifications were utilized by FDA in establishing this radiation output requirement. If a different kVp were selected, the radiation output would likely have to be modified; however, professional consensus on what modifications would be appropriate is presently lacking. The agency, therefore, does not accept these comments.

(Comment 364). One comment recommended that the proposed requirements under § 900.12(b)(14) should be made part of § 1020.31 so that uniform requirements would be ensured nationwide. FDA reiterates its previous position that this would not achieve the desired impact on the installed base of mammography equipment. FDA believes that most modern mammography systems can meet this requirement. However, the agency is considering parallel requirements under § 1020.31 to ensure that future production is compliant.

(Comment 365). One comment supported the test procedure specified in § 900.12(b)(14)(iii) as being an

improvement over the current specification. Another comment suggested that the requirement in § 900.12(b)(14)(i), as written, should only apply to a molybdenum/molybdenum Mo/Mo anode/filter combination because other target-filter combinations may not need to meet the requirement to deliver adequate imaging.

NMQAAC supported the proposed requirements, but suggested that the specifications should be limited to Mo/Mo target-filter units only. They also recommended that all of § 900.12(b)(14) be moved to the quality assurance section.

FDA has accepted NMQAAC recommendations to limit the requirements to Mo/Mo target-filter units and to codify the requirement with the QC requirements.

(Comment 366). One comment noted that xeromammography equipment might not meet these proposed requirements.

FDA believes that xeromammography units should be able to meet the requirement, as proposed, but with the acceptance of the Mo/Mo limitation discussed above, the requirement would no longer be applicable to xerox systems, which incorporate tungsten targets.

(Comment 367). One comment suggested that the proposed requirements of § 900.12(b)(14)(i) and (iii) need to be linked in order to explain where the output is to be measured.

FDA does not agree with this comment although it has reworded the proposed § 900.12(b)(14) for clarification. The provision has been codified as § 900.12(e)(5)(x).

p. *Automatic exposure control (§ 900.12(b)(10) (proposed § 900.12(b)(15)))*

As proposed, this paragraph required that each mammography system have an automatic exposure control (AEC) for mA's, established a specification for the AEC reproducibility, and set requirements for the indication of the AEC detector positions and selected location.

(Comment 368). One comment suggested that the requirements proposed in § 900.12(b)(15) should be prefaced with a statement that they are intended to apply only to film-screen modalities. A related comment reported that xeromammography systems do not have AEC controls as required in § 900.12(b)(15) and that this would bar their use.

FDA agrees with these comments and has rewritten this requirement to limit it to screen-film mammography systems.

Under § 900.12(b)(15)(i), the proposal required all AEC devices to be operable in each equipment configuration provided and gave examples of common configurations.

(Comment 369). Several comments sought to limit the applicability of this requirement in different ways. One comment supported the proposed requirements in § 900.12(b)(15)(iv)(A) and (B) as a means to ensure appropriate detector location and thereby avoid repeat exposures and reduce patient dose. One respondent did not believe that the automatic exposure control photo-timing proposed in § 900.12(b)(15)(i) is significant in obtaining satisfactory diagnostic mammograms. Three comments recommended modifying § 900.12(b)(15)(i) by replacing ''of equipment configuration provided'' with ''where applicable.'' The comments further suggested that the examples of equipment configurations in § 900.12(b)(15)(i) be deleted. One comment agreed with the April 1996 NMQAAC recommendation that the requirements proposed in § 900.12(b)(15)(i) should be limited to clinically used configurations.

FDA remains convinced that the use of AEC devices on mammography equipment is an aid to quality mammography and believes that requiring it for ''all combinations of equipment configuration provided'' is appropriate and necessary. The agency notes that the requirement applies to the configuration of the individual unit. For example, if the unit is not provided with magnification capability, then it would not be required to have a functioning AEC in a nonexistent magnification mode. The agency also notes that NMQAAC reversed its April 1996 position during its January 1997 meeting and concurred with the requirement as proposed.

Under § 900.12(b)(15)(ii), FDA proposed that the AEC be capable of providing automatic mA's selection.

(Comment 370). One comment recommended deleting this requirement, stating ''that it is the purpose of AEC to provide automatic mA's selection'' and, therefore, the requirement was redundant. One comment requested clarification of the phrase ''automatic mA's selection.'' Another comment asked whether § 900.12(b)(15)(ii) required automatic termination of exposure or automatic display of mA's and questioned why the AEC should be able to automatically select mA's.

FDA defines an automatic exposure control as a device that automatically controls one or more technique factors in order to obtain a desired quantity of radiation at a preselected location. Such a device would automatically terminate the exposure when the selected quantity of radiation had been delivered. This definition does not restrict the technique factor(s) that may be selected; the control of target material, focal spot, filtration, time, mA, and/or kVp are all viable options for such a device. Because the mA's is the product of time (in seconds) and mA, the control of time and/or mA represents control of the mA's; therefore, AEC's generally function by controlling mA's and/or kVp. FDA was initially concerned that an AEC that controlled kVp alone, without capability to control mA's, could not adequately ensure the small incremental changes in radiation that are often necessary in mammography. FDA has reconsidered this position because it has concluded that any such device that reaches the marketplace would provide the necessary ranges of adjustment in order to have been approved under the FDCA's requirements for safety and efficacy of new devices. Therefore, FDA is removing the requirement proposed in § 900.12(b)(15)(ii) that all AEC devices provide automatic mA's selection.

Under § 900.12(b)(15)(iii), FDA proposed a limit on the reproducibility of the AEC.

(Comment 371). One comment suggested the wording be changed to include ''for each target/filter combination.''

FDA believes the change is not needed; because no target-filter combinations were specified in the regulation, all combinations are subject to the requirement.

NMQAAC recommended that this requirement be moved to the quality assurance section. FDA has accepted this recommendation and the specification for the evaluation of the AEC reproducibility is codified in § 900.12(e)(5)(i).

Under § 900.12(b)(15)(iv), FDA proposed requirements regarding the positioning flexibility of the AEC detector, visual location of the available detector positions, and indication of which AEC detector location was selected.

(Comment 372). Two comments recommended that the proposal be expanded to require increased flexibility in placement of the AEC detector. One comment commended the proposed requirement for AEC positions to be indicated at the input surface of the breast compression paddle. The comment believed that this requirement would improve the quality of imaging and prevent repeat images. Two

comments suggested that FDA add a requirement specifying the necessary accuracy of the indication of both the size and available position of the AEC detectors. The respondents' suggested the indication might depend on magnification of the indication resulting from various breast thicknesses.

FDA interprets these comments to mean that a projected indication on the input surface of the breast might vary in size and location depending on the magnification induced by the displacement of the input surface caused by various breast thicknesses. FDA agrees that this might occur and notes that such a system would be a design that might not be able to meet the requirements.

FDA intends the indications of the size and location represented on the compression paddle to be representative of the actual size and location of the detectors as they would appear if marked on the breast support device. The agency anticipates no confusion will be caused by varying displacement of the paddle from the patient support since the indication of size and position will remain constant.

(Comment 373). One comment suggested that the indicators should not ''give rise to artifacts in the image.''

FDA believes that any such artifacts will be detected and corrected during the normal QC process and, therefore, modification of this requirement is unnecessary.

(Comment 374). One comment stated that this requirement leaves too much room for interpretation and would be very difficult to inspect against. The comment suggested one could argue that merely knowing the position via the handle that moves the detector would be adequate for proper detector positioning. The comment further stated that all current units do provide clear indication of detector position, which is visible from both sides of the patient, and that the requirement should be removed.

FDA does not agree that the requirement is subject to conflicting interpretation or would be difficult to inspect, but does agree that the location of the position selector would be an adequate indication of which detector position had been selected (although it would not indicate the detector position itself). FDA also does not agree that the installed base of systems all provide such flexibility or indications and remains persuaded that the requirement will provide useful tools for the technologist.

NMQAAC recommended that FDA delete the proposal that the selected detector position be visible from both sides of the patient because they did not consider it of sufficient importance to require in the regulations. FDA has adopted this recommendation and the requirement has been amended accordingly.

Under § 900.12(b)(15)(v), FDA proposed that the operator be able to vary the optical density from the normal density setting. No specific comments were received on this proposal and FDA codified this requirement without change.

Under § 900.12(b)(15)(vi), FDA proposed that, 10 years after the publication of the final regulations, each unit would be required to provide four steps above and four steps below the normal optical density setting and proposed limits for the acceptable variability between adjacent settings on this control.

(Comment 375). FDA received a large number of comments on this section. The overwhelming majority were opposed to the requirement because of concerns regarding the wording of the provision, the perceived cost to facilities, the range of control to be provided, the incremental difference between adjacent settings, and the necessity for the requirement. In response to these comments and because of agency concerns regarding costs, FDA concluded that the proposal should be deleted from the final regulations and that further study should be undertaken to determine if future requirements in this area are warranted. If regulations or guidelines are proposed later, the individual comments will be reconsidered at that time.

Under § 900.12(b)(15)(vii), FDA proposed requirements for the optical density variation permitted with a screen-film mammography system under AEC.

(Comment 376). Three comments supported the proposed requirement in paragraph (b)(15)(vii) because it evaluates the equipment performance when used on breasts of various size and density. Two comments indicated that § 900.12(b)(15)(vii) was not stringent enough and one of these recommended that an initial value of 0.15 OD should be specified.

FDA disagrees with this comment because it believes that the initial value should remain the same as that used in the interim regulations. NMQAAC recommended that these requirements be moved to the quality assurance section and FDA agreed. The requirements have been codified under § 900.12(e)(5)(i).

In the proposal, FDA had specified that the system meet the requirements for AEC reproducibility at each available detector position.

(Comment 377). Three comments suggested that the test under § 900.12(b)(15)(vii) is necessary for only one detector position because the detector and associated electronics do not change.

FDA disagrees with these comments because some AEC detectors utilize individual detectors that are permanently fixed in position. The switching of position is actually a change in contact points or system logic to read the selected position. In such cases, the testing of one position provides no indication of the function at other locations.

(Comment 378). One comment suggested that the testing of photo-timer tracking with dosimeter positioning is usually not necessary unless multiple detectors are used.

The agency believes that when the process is accomplished by the relocation of the same detector to different positions, the functioning of the detector at each detector location is not guaranteed by testing at only one position. This could be influenced by broken wires, poor connections, or dirty contacts in the system.

(Comment 379). One comment stated that testing of the AEC at all detector positions will be dependent on the dimensions of the phantom. The respondent stated that the commonly used 10 cm x 10 cm phantom may not be large enough for all positions and that this will drastically increase the time required to perform this test.

FDA does not agree with this comment. The phantom could be placed near the focal spot and thereby cover all available detector positions without being repositioned.

(Comment 380). One comment suggested that with multiple detectors it is not necessary to test the tracking over the entire range of phantom thicknesses.

FDA interprets this comment to mean that, once the detector reproducibility at each position has been established, the testing of reproducibility for additional thickness need be performed at only one position. FDA does not agree with this comment; it does agree, however, that when one detector is used and moved from position to position, once it is established that the detector is reproducible over the entire range of thicknesses at one position, it is only necessary to establish the correct functioning for one thickness at each other position. In response to these comments and in recognition of the costs associated with testing reproducibility at multiple positions, FDA has deleted the specification for

testing at each detector position. Because the agency remains convinced that the best way to ensure that the detector(s) functions properly at each position is to test it/them at each position. FDA encourages facilities and the medical physicists to include such testing as a routine part of the annual survey. The remaining provisions of proposed § 900.12(b)(15) are codified as § 900.12(b)(10).

q. *Disabled examinees (proposed § 900.12(b)(16))*

In this paragraph, FDA proposed that each facility choosing to schedule disabled patients have equipment and protocols in place to ensure that the facility could adequately accommodate such disabled patients. This proposal did not require each facility to accept disabled patients, but did require those doing so to be capable of performing the service.

(Comment 381–382). Many comments expressed the mistaken belief that FDA was seeking enforcement powers under the American with Disabilities Act (ADA) or to duplicate the ADA.

Other comments on this section ranged from calling the requirement too lenient to calling it unnecessarily intrusive. The majority of the comments, although not opposed to accommodating disabled patients, were concerned that the screening of patients prior to their examination would be difficult or impossible because many appointments are not made by the patient. Comments also expressed concern that accepting disabled patients under this requirement would obligate facilities to be able to accommodate all disabled patients. Some comments also questioned whether there was equipment available that could offer this range of use.

Another area of concern was related to mobile units and facilities which, because of their size and stand-alone nature, would be difficult to adapt to accommodate the range of disabilities the facilities might encounter. NMQAAC consumer representatives supported this section and urged FDA to require facilities to either serve disabled patients or refer them to a facility that can. Other comments questioned the value of referrals, citing lack of knowledge regarding other facilities' equipment, staff, and ability to deliver the services necessary.

Because of the lack of consensus on the need for this requirement and the concerns raised in the comments, FDA has decided to delete the proposed requirement and revisit it at a future date if a problem is perceived. FDA strongly urges facilities to voluntarily institute procedures that will direct patients with disabilities to facilities that are capable of serving this population. The agency believes that local consumer groups and all accreditation bodies can pool information and educate the public and the mammography community about the availability and locations of such services.

r. *X-ray film (§ 900.12(b)(11) (proposed § 900.12(b)(17)))*

In this paragraph, FDA proposed a requirement that X-ray film used for mammography must be designated for such use by the film manufacturer.

(Comment 383). One comment supported the proposed requirement. Three comments suggested that it was too vague, one comment questioned how one would know if a manufacturer's designated mammography film is adequate for doing quality mammography under the requirements, and another suggested the adoption of the storage recommendations from ACR's *Recommended Specifications for New Mammography Equipment*. NMQAAC supported this requirement as proposed.

FDA has not proposed regulations governing film storage because it believes that each facility should follow the manufacturer's instructions for the particular film being used. The goal of this requirement is to ensure that the film used by the facility is considered, at least by the manufacturer, as being suitable for mammographic use. The regulation is not intended to establish standards for film; the only requirement placed on the facility is to check that the film it uses has been designated by the manufacturer for mammography. The requirement is not vague once its limited scope is understood. FDA codified this requirement, without change, in § 900.12(b)(11).

s. *Intensifying screens (§ 900.12(b)(12) (proposed § 900.12(b)(18)))*

FDA proposed in this paragraph that only intensifying screens that have been specified by the manufacturer as appropriate for mammography may be used for mammography.

(Comment 384). One comment supported the proposed requirement. Again, one comment questioned how a facility would know if a manufacturer's designated mammography screens are adequate for doing quality mammography under the proposal. Another comment stated that xeromammography systems do not use intensifying screens and that § 900.12(b)(18) would serve to ban their use.

FDA does not intend a specification about screen requirements to apply to any modality that does not use screens in the production of its images. Therefore, the agency sees no impact of this requirement on xeromammography. Although NMQAAC supported the requirement, one member expressed concern that the wording of the proposal implied that the facility was responsible for matching the spectral sensitivity of the film and the screen. As explained in connection with the mammography film specification above, the intent of the requirement is not to address the quality of the product, but rather to ensure that it is one intended by the manufacturer to apply to mammography. In general, the facility is responsible for matching the spectral sensitivities of the screen with the film. However, the facility is expected to use the information provided by the manufacturers and not to derive the information independently. FDA has reworded the requirement to clarify this point and codified it as § 900.12(b)(12).

t. *Film processing solutions (§ 900.12(b)(13) (proposed § 900.12(b)(19)))*

In this paragraph, FDA proposed that facilities use film processing solutions capable of developing films in a manner equivalent to the film manufacturer's minimum specifications.

(Comment 385). Three comments supported this proposed requirement and requested that guidance documents be established for this area. Six comments suggested that the word ''minimum'' be deleted because, in the respondents' opinions, most facilities generally comply with the regulatory requirement and the regulation should encourage them to meet more than the minimum. FDA appreciates these comments and notes that facilities are free to exceed this minimum; the requirement, however, is intended only to establish that facilities comply with the manufacturers' minimum standards.

(Comment 386). Three comments questioned how a facility could demonstrate equivalence under § 900.12(b)(19) because some manufacturers of film processing chemicals refuse to acknowledge that other vendors' chemicals produce ''equivalent'' results. The comments requested that the wording be changed to clarify compliance.

FDA believes these comments are similar to the ones regarding quality of the film and screens used in mammography. It is not the intent of the requirement that the facility experimentally determine the compatibility of various solutions with the film, but only that the facility obtain documentation from the suppliers showing that their products are intended to be used for processing the

particular film used by the facility and that they provide results consistent with the film manufacturer's specifications. The facility would only be required to establish the equivalence independently if no documentation, in the form of labeling or specifications, were available from the chemical or film supplier.

(Comment 387). One comment questioned how the requirement can be met when the film manufacturer does not manufacture chemicals for film processing.

FDA notes that, in such cases, it would likely be easier to establish equivalence because the film manufacturer would specify the requirements for the processing as opposed to a manufacturer that supplies both film and chemicals and is likely to specify solutions only by name rather than characteristics.

(Comment 388). One comment recommended that FDA allow accreditation bodies to review and monitor the use of chemicals for film processing and eliminate the requirement from the regulations.

Although the agency is continually working with the accreditation bodies to divide responsibilities when such division is useful and possible, FDA did not adopt the recommendation. The MQSA requirements, even when administered by the accreditation bodies, are implemented through Federal standards. FDA may consider requiring accreditation bodies to collect and monitor information about chemicals used for film processing in the future. NMQAAC agreed with the requirement as proposed. FDA has codified the requirement in the final regulations under § 900.12(b)(13).

u. *Lighting (§ 900.12(b)(14) (proposed § 900.12(b)(20)))*

In this paragraph, FDA proposed a requirement that facilities provide special lights for use during interpretation with variable luminance capable of producing light levels greater than that provided by the viewbox.

(Comment 389). Four comments supported the proposal. One stated that ''it might reduce the number of retakes, and provide better detail to the interpreting physician.'' Two comments noted that the light should be required wherever the interpreting physician is reading films, but that it may not be necessary at all locations where images are taken. One comment noted that the proposed requirement in § 900.12(b)(20) was for a ''bright light'' or ''hot lamp'' for viewing dense areas of films. The comment suggested that the purpose of the lamp should be included and that it should only be required for facilities that use the screen-film modality.

FDA agrees that the light is only required where mammograms are interpreted but recommends that it may be useful to the technologist in evaluating the quality of the films. FDA also agrees that facilities not interpreting screen-film mammograms, or not reviewing previous screen-film mammograms for reference, do not need these special lights.

(Comment 390). Two comments stated that a fixed output lamp may give the same information as the variable output ''hot lamp'' proposed. NMQAAC supported the requirement, but recommended that the word ''variable'' be removed because it is the increased intensity and masking provided by the light rather than any variability in output that actually enhance the reading of the image.

FDA has accepted these suggestion and has reworded the final requirement accordingly.

(Comment 391). One comment expressed difficulty imagining the benefits of this requirement to the patient.

FDA believes the usefulness of this device is well established, especially in view of the trend toward denser films in mammography; by optimizing interpreting conditions for physicians, the regulation increases the likelihood that the patient's mammogram will be accurately interpreted.

(Comment 392). One comment recommended that FDA allow accreditation bodies to review and govern the proposed requirement in § 900.12(b)(20), and eliminate it from the regulations. As indicated above in response to a similar comment by the same individual.

FDA has not adopted the recommendation, although it may consider requiring such action by the accreditation bodies in the future.

(Comment 393). Four comments suggested that the proposed requirement was too vague. One comment suggested that the requirement be reworded to specify that a ''spot lighting'' device be provided.

FDA agrees with these comments and amended the final requirement to clarify this point.

(Comment 394). A number of comments chose this section to offer suggestions regarding requirements for the viewbox or the viewing conditions. FDA has discussed those comments in the general equipment section above.

Because of the deletion or movement of other paragraphs in the equipment portion of the proposed regulations, the reworded § 900.12(b)(20) was codified as § 900.12(b)(14).

v. *Film masking devices (§ 900.12(b)(15) (proposed § 900.12(b)(21)))*

In this paragraph, FDA proposed that all facilities ensure the presence of film masking devices that are capable of limiting the illuminated area of the viewbox to the exposed or smaller area of the film, that facilities using nonrectangular collimation ensure suitable masking, and that such devices be available to the interpreting physicians.

(Comment 395). Six comments supported the requirement. Two of these comments further suggested that the requirement be modified to clarify that any effective means of masking, including ''black film or manual or automatic masking devices,'' would be acceptable. One comment questioned how effective the film masking devices must be because the respondent believed that many presently in use do a poor job of blocking the unnecessary light. FDA has not attempted to specify particular mechanisms for masking, only that provisions for masking be available. Any device that blocks viewbox light not required for viewing and interpreting the image would meet the intent of this requirement. The level of ''blocking'' was not addressed, but with the light levels under consideration, the agency believes that the elimination of any noticeable transmission through the masking is easily achievable. The device need not be an expensive or elaborate system, but it must be capable of eliminating extraneous viewbox light.

(Comment 396). Two comments supported the proposed requirement to provide appropriate masking for nonrectangular images as a means to further promote the correct masking of all shape images, but another comment stated that the nonrectangular collimation referenced should be eliminated because ''there is no need for it and it causes significant problems in the masking of the films for proper viewing conditions.'' NMQAAC suggested that the requirement regarding nonrectangular masking was redundant and recommended that it be removed from the final regulation.

FDA does not intend to express a preference for rectangular or nonrectangular collimation. This section was included in the proposal to reinforce the point that, in all cases, the masking should be appropriate to the image. FDA is accepting the NMQAAC recommendation and deleting the provision relating to nonrectangular collimation from the final regulations; FDA agrees with NMQAAC that the

general masking specification covers all sizes and shapes of images.

(Comment 397). One comment questioned how much limitation of the exposed image the proposal intended the masking to provide and one comment proposed that the masking requirement be expanded to require limitation of ''the illuminated area to a region or regions substantially smaller than the exposed portion of the film.''

FDA has not accepted this recommendation because it may not be desirable, in all cases, to limit the view to an area ''substantially smaller than the exposed portion of the film.'' The intent of the section is that masking be as close to the full darkened film area as possible. The masking can certainly be variable, so that the darkened area can be reduced to a specific area of interest. This is not required, however. Discussions with interpreting physicians have led FDA to conclude that it is often desirable to visualize the entire image to establish a ''gestalt'' impression before further interpretation of the film. A masking system that prevented such a practice, therefore, may be undesirable and is not being required.

(Comment 398). One comment questioned to what extent the film masking devices were required to be available. The comment asked if all mammograms were required to be read on viewboxes equipped with masking devices or if the facility need only require adequate masking for one viewbox, even if multiple reviewers were reading film at the same time on different viewboxes.

In response to this comment, FDA has modified the final regulation to indicate that such devices should be available in sufficient numbers to allow each physician requiring one to have access to one. NMQAAC recommended that the requirement that the devices be available to physicians should be deleted, stating that any physician who desired to use masking could provide their own at little or no expense and that the facility need not provide such devices for them. FDA partially agrees with this assessment but has not accepted this recommendation because it has concerns about facilities that require significant numbers of films to be read daily and where the interpreting physician simply does not have time to individually mask images. Placing responsibility with the facility will ensure that masking devices are provided in such cases.

(Comment 399). Two comments recommended that the regulation mandate the use of film masking devices by the physician, and one of these suggested that masking should be used by the technologists in their film critique area. While FDA certainly agrees that both interpreting physicians and technologists should utilize masking, the agency believes that, if the devices are available, most individuals will use them and that requiring their use would be difficult to enforce.

(Comment 400). One comment stated that film masking devices may be expensive to obtain and cumbersome to use. This comment maintained that, although film interpretation may be improved by using these devices, requiring that facilities provide such devices appears to be excessive regulation and this requirement should be deleted.

FDA notes that the goal of the MQSA is to provide a consistent baseline of quality mammography services to all patients. If an item that is consistent with that goal is identified as having a positive impact on the diagnostic process, FDA believes it is important to assure women that facilities at least have these devices available for use on their behalf. FDA also notes that masking devices do not ordinarily entail significant expense. FDA has codified the requirement for availability of masking in the final regulations under § 900.12(b)(15).

w. *Film processors (§ 900.12(b)(22) (proposed § 900.12(b)(22)))*

In this paragraph, FDA proposed a number of requirements for the film processors used to develop mammograms. As proposed, § 900.12(b)(22)(i), covering processor setup and maintenance, would go into effect 1 year after final publication; § 900.12(b)(22)(ii) and (iii), requiring display of the time cycle and maintenance of the developer temperature, would be phased-in after 5 years; and § 900.12(b)(22)(iv) and (v), requiring the display of the developer temperature and for variable cycle processors to be interlocked to prevent new film being accepted by the processor until cycle parameters are stabilized, would be phased-in after 10 years.

Section 900.12(b)(22)(i) proposed that all such processors be set up and maintained at the technical development specifications for the film used for mammography at the facility.

(Comment 401). One comment requested a definition of technical development specifications, as used in the proposed regulations. Another comment stated that, if it is going to be mandatory to meet film manufacturers technical requirements, then manufacturers should be required to make written guidelines available as to what factors are needed to achieve the maximum result from the film.

FDA coined the phrase ''technical development specifications'' to represent a listing of the technical aspects of correct processing as provided by the film manufacturer. This would be expected to include such items as correct solutions, proper temperatures, applicable immersion times, replenishment rates, and any other instructions the manufacturer deemed appropriate and critical to the processing of its film. FDA believes that many manufacturers do provide such information and that the market advantage these manufacturers will enjoy will encourage all manufacturers to do so. The NMQAAC recommended that this section be moved to the quality assurance provisions and FDA has followed that advice.

The agency has reconsidered the proposed requirements in § 900.12(b)(22)(ii), (iii), (iv), and (v). FDA received a number of comments both supporting and opposing these proposals. However, based on the anticipated costs associated with these proposals compared with the marginal benefits they would provide, FDA has decided to delete them from the final regulations. If the agency proposes future regulations for these areas, all related comments will be reconsidered.

3. Medical Records and Mammography Reports (§ 900.12(c))

This section establishes quality standards for medical records and mammography reports as required by the MQSA under 42 U.S.C. 263b(f)(1)(G). The regulation provides, in general, that facilities prepare written reports of mammography examinations, that results be communicated to the patient or provider, and that films be maintained for a reasonable period of time or transferred to the patient.

(Comment 402). Public comments were received on § 900.12(c). The most controversial areas were specific provisions in the proposal for use of standardized assessment categories in the mammography report, written notification of all mammography results, and for original mammograms to be transferred to other facilities or entities upon patient request. Each of these areas will be discussed below in connection with those specific provisions.

a. *General comments*

As an initial matter, FDA disagrees with four comments that asked FDA to delete the entire regulation on medical records and reports because it was an intrusion of FDA into the practice of medicine and abridged the rights of

radiologists. The agency's authority and responsibility to regulate these medical records, mammography reports, and communication of results was established by Congress through specific provisions of the MQSA. The agency could not eliminate the entire regulation, even if it believed such action was appropriate. Discussions with NMQAAC clearly indicated the committee's support for regulations in this area as well.

b. *Contents and terminology (§ 900.12(c)(1))*

The proposal established standardized assessment categories for interpreting physicians to use to evaluate mammograms, ranging from ''negative'' to ''highly suggestive of malignancy.'' In addition, the regulation requires the interpreting physician to address clinical questions, if possible, and include recommendations, if any, in the report.

(Comment 403). Comments in support of the proposed standardized assessment categories stated that such categories: would ensure that a definitive result for each mammogram is reached; would establish consistency across facilities; are a valuable tool to assist consumers and clinicians in understanding results; should also be used in the written notification to patients; and permit efficient and uniform analysis of outcomes in medical audits. One comment in support of this section suggested that the title be changed to ''Contents, terminology and timeframes.''

Fourteen comments stated that it is inappropriate for the Federal government to establish medical terms for classification of mammography results through regulation. Other comments opposing the establishment of standard assessment categories stated that: Such categories would prevent any particular facility from continuing to use its customary terminology and, thereby, cause confusion to its referring physicians; the message, rather than the exact words, are important and resources would be wasted in monitoring the correct use of particular phrases; and that establishing standard classifications would reduce flexibility for the reporting physicians.

Some comments objected to the details of a particular classification category, rather than to the idea of standard classifications. One comment stated that a ''negative'' report may mislead a referring physician about the existence of breast cancer because mammography cannot detect all breast cancers, while another comment concluded that the term ''suspicious'' inherently suggests that the lesion is malignant, and proposed ''indeterminate'' as a substitute category.

After considering all these comments, FDA has decided to keep the proposed categories in order to promote consistency and clarity in mammography interpretations. In discussions with NMQAAC, the use of final assessment categories was supported because they promote consistency in communication of results among medical care providers and standard categories are necessary in the medical audit of mammography interpretation. These particular categories are based on similar categories developed by ACR. The ACR Breast Imaging Reporting and Data System categories are: Assessment Is Incomplete-Need Additional Imaging Evaluation; 1-Negative; 2-Benign Finding; 3-Probably Benign Finding—Short Interval FollowUp Suggested; 4-Suspicious Abnormality—Biopsy Should Be Considered; and 5-Highly Suggestive of Malignancy—Appropriate Action Should be Taken.

FDA believes that the medical community is familiar with these categories and the assessment classifications established under the final regulations (''negative,'' ''benign,'' ''probably benign,'' ''suspicious,'' ''highly suggestive of malignancy'') are equivalent to the ACR system. The medical community has already affirmed their usefulness and value through widespread use of the ACR system. Accordingly, the agency concludes that requiring these classification terms in mammography reports will not be burdensome, given their current level of use and acceptance.

FDA has made minor changes in particular assessment categories in response to comments. Two comments requested FDA to delete the word ''imaging'' from the proposed assessment category of ''needs additional imaging evaluation'' and substitute the ACR category of ''needs additional evaluation'' because physical examination may be part of further evaluation. In fact, the ACR category is ''Need Additional Imaging Evaluation,'' with ''incomplete'' as its descriptor. Accordingly, FDA is adding the word ''incomplete'' to the description of this category, which will now read: ''Incomplete: needs additional imaging evaluation.'' The mammographic result should be categorized into this or one of the other assessment categories. The agency notes that, if the result is ''negative'' or ''probably benign'' based on the mammogram, but physical examination is recommended, the recommendation for clinical followup, surgical consultation, biopsy, or other action should be stated in the recommendations section of the report. The agency also is aware that there are screening mammography practices that do not issue a final assessment until followup diagnostic mammography has been scheduled and performed. These facilities, and others, can continue their policy of not issuing an assessment, and can use this category of ''Incomplete: needs additional imaging evaluation.''

FDA's proposed language for the ''negative'' category stated that if the interpreting physician is aware of clinical findings or symptoms, these should be explained. One comment asked if this explanation must be written into the report or could be attached as a symptom in-take form. The agency believes that the recommendations section of the report is the most effective way to direct referring health care providers to further work-up based on physical findings or symptoms, despite negative mammographic results.

(Comment 404). One comment stated that it would be hard to determine compliance with the proposed requirement that clinical questions raised by the referring health care provider be addressed in the recommendation section of the report.

FDA responds that it can determine compliance with a regulation in a variety of ways, including review during an inspection of a facility's standard operating procedures. FDA inspectors can be trained to verify that each facility has in place a system that requires its interpreting physicians to address the concerns of referring health care providers in the recommendations section of the mammography report. FDA agrees with comments that suggested that the recommendation section of the report remain separate and unstructured; the agency has not proposed specific categories or language for this portion of the report in order to provide maximum flexibility for clinical management recommendations.

(Comment 405). One comment stated that there should be a unique patient identifier to distinguish between two patients with the same first and last name. NMQAAC also agreed, stating that the medical report and the mammography films should have a patient identifier in addition to the name. FDA agrees that an additional patient identifier in addition to the name will improve the accuracy and clarity of the results and subsequent followup and the proposal has been amended to require reports to have this additional identifier. However, the

choice of the additional identifier, such as the date of birth or hospital number, is left up to the facility because each individual practice has a better understanding of its particular needs in this matter.

(Comment 406). Two comments asked if a radiologist who did not read the film or dictate the report can sign a report if the radiologist who did perform the interpretation is unavailable and concurs with this practice. Another comment stated that FDA should allow signatures that are authenticated through computers, which are normally accepted in a court of law. A third comment stated that signatures should be evident on the report filed in the patient's permanent file.

FDA interprets the MQSA's requirement that each mammography report be ''signed'' by the interpreting physician to mean that each report must identify who interpreted the mammogram and rendered the reading on the written report. The final regulations state that the name of the interpreting physician must be on the mammography medical report. This name may be handwritten, typed, stamped, written electronically, or recorded in any other manner. However, with respect to ''signatures'' that are used to proof-read reports or to ''sign'' them out for purposes of authenticating such reports or releasing them to other parties or institutions, FDA believes that each facility is in the best position to devise its own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations in this area.

(Comment 407). One comment recommended that there be a requirement for facilities to maintain records that include the signature of the qualified radiologic technologist who performed or supervised the examination and the signature of any individual who conducted all or part of the examination under supervision of a qualified radiologic technologist.

FDA disagrees with this comment. The MQSA does not have a signature requirement for the technologist. The final regulations require ''technologist identification'' on each film image (§ 900.4(c)(viii)(E)) and the agency believes each facility can adopt its own system to identify technologists without having the agency mandate such procedures.

(Comment 408). One comment suggested that the term ''health care provider'' should be replaced with ''referring physician.'' FDA disagrees because patients are referred for mammograms by nonphysicians, such as physician's assistants, nurse practitioners, and other health care workers.

c. *Communication of mammography results to patients (§ 900.12(c)(2))*

This provision requires that: (1) Each facility establish a system to ensure that results are communicated to patients; (2) patients without health care providers receive medical reports and lay summaries of their mammography results; (3) each facility establish a referral system for patients without health care providers, if necessary; and (4) results that are ''suspicious'' or ''highly suggestive of malignancy'' be communicated as soon as possible.

(Comment 409). FDA received hundreds of comments on the proposal that all patients receive written results of their mammography examination. Comments that objected to this proposal generally focused on disruption of doctor-patient relationships, confusion for patients, and additional expense to facilities without commensurate patient benefit. Ninety comments stated that the referring health care provider is responsible for communicating results to patients and is best able to convey such results and answer patient questions. Other comments that raised concerns about disrupting the referring doctor-patient relationship stated that written notification from the facility would allow patients to bypass a referring physician and never get a physical breast examination. Many comments stated that written notification to every patient would cause confusion for the patients. Twenty-three comments said confusion would arise if patients were notified about results before such results were reviewed by their referring physicians; twenty-one comments stated that many patients would misinterpret their reports; ten comments stated that the difference between the information provided in a lay notification and the information contained in a copy of the actual written report would confuse patients who received both.

Seventy-two comments stated that the additional cost associated with written communication to every patient would cause financial hardship for mammography facilities. In general, these comments and others argued that the cost of providing or ensuring written notification in every case outweighs any patient benefit that might result. Ten comments stated that radiologists would have to police referring physicians who agreed to provide patient notifications and followup. Other comments stated that: (1) Small or rural facilities would be burdened by patient notification requirements, especially those without a computerized system; (2) producing patient notification reports is time-consuming and hinders the accomplishment of daily operations, and would not directly improve patient care; (3) developing a notification document that could explain every possible scenario involving diagnostic findings is virtually impossible; and (4) radiologists and providers of mammography would become more frequent targets of litigation because of this reporting requirement. Thirty-seven comments stated that it is unrealistic to expect radiologists, who may never see patients, to determine the literacy level, ethnic, cultural, and social sensibilities of those patients in order to tailor an appropriate written notification. Fifteen comments stated that the requirement would create excessive waste paper for the environment. Some comments found the proposal for written notification unnecessary in light of other reporting and followup requirements, the individual patient's responsibility to communicate with her physician, and the belief that patients are always informed of results by their physicians. Two comments asserted that written notification for all patients was not authorized by the MQSA.

FDA also received 66 comments that supported the proposal for all patients to receive written notification of mammography results including comments offering strong support from national breast cancer patient groups. These comments generally focused on the fact that women otherwise were not assured of timely and accurate information about their mammography examinations and that such written notification could save lives by encouraging initiation of necessary followup.

It was also noted that the experience of facilities that instituted such notification was positive. Comments in support of written patient notification stated that such notification was appropriate because patients are entitled to know the results of their exams, it is the facility's responsibility to inform patients of results, and there is a public health need for written notification because not all referring physicians discuss results with their patients.

(Comment 410). Comments described written notification as an important addition to quality mammography practice, a crucial component to ensuring reliable mammography and consistency across the country, and a major step toward fostering better communication between doctors and their patients. One comment supported the proposed system to ensure that patients and referring physicians receive reports, and that all patients receive a

report in lay terms, but also stated that the referring physician should continue to be responsible for patient followup. Another comment stated that FDA should not allow any party, other than the facility, to distribute these written notifications.

Many comments asserted that written notification for each patient may ultimately reduce health care costs and extend lives because of earlier treatment. Five comments stated that written notification empowers the medical consumer and minimizes the possibility of tragic error when abnormal results slip through the cracks of the referring physician systems. Comments asserted that referring physicians do not always communicate results to patients, even when the results are abnormal. Several breast cancer survivors commented positively on this proposed requirement and one author stated that such written notification saved her life. Seven comments stated written notification has reduced medical liability of facilities, but that costs should be offset with increased reimbursement.

Comments from State health officials and some facilities having experience with written patient notification reported that the experience had been positive. Facilities that have instituted written notification stated that the practice is appreciated by patients and does not cause the facility any particular hardship. Massachusetts has required such written notification since 1994. The comment from a State official stated that, although initially resisted, the procedure is now accepted by physicians throughout the State; facilities in Massachusetts receive positive feedback from patients and no facility has closed in that State because of this additional requirement.

Some comments recommended that the notification include additional information. Twelve comments asked that the written notification also include information about the location of the films, directions about how a woman could obtain them, and the facility contact person for questions concerning the result. Another comment said the notification should include information about the importance of clinical breast examinations by a qualified physician, monthly self-breast examinations, and mammograms at appropriate times, especially for patients without physicians. Some comments wanted facilities to be required to provide written notification to referring physicians and patients.

Many comments suggested alternatives that were variations to the proposed requirement for written patient notification. Ten comments supported the current interim regulations, which require written notification from the facility only to those patients who do not have a health care provider or referring physician. Thirteen comments stated that, for referred patients, the required notification should simply state that the mammogram report has been mailed to the physician and the examinee should contact that physician. Twelve comments stated that only those patients who request a written report should be sent one.

Other comments agreed that patient notification of results by the facility was appropriate, but preferred to leave the method of communication up to the facility, which could tailor notification procedures to its practices and the circumstances of particular patients. Comments observed that in some screening cases, where the radiologist never speaks to the patient, written notification of results makes sense; however, where there is extensive interaction and verbal communication with the examinee onsite, written notification can be redundant, expensive, and wasteful of paper. Five comments stated that patients should be verbally told at the time of the examination to contact her physician's office and not to assume that ''no news is good news.'' Other alternatives suggested by comments included several that were in direct contradiction to each other: (1) Require written notification only to those patients who have not received the final report verbally at the facility or, if findings are negative, by telephone; (2) encourage notification of patients with abnormal studies; (3) require patient notification in lay terms only if the results are negative and notify referring physicians, including followup notes, when there are abnormal results; (4) send referring physicians lists of patients who had mammography at a facility with positive studies highlighted; (5) require notification of patients who request results after a specified time period has passed in order to allow communication between the patient and the referring physician and to prevent duplication and failure to inform; and (6) require that every patient receive a copy of her mammography report, if desired, or by default if her preference is not stated.

After reviewing and considering the hundreds of comments FDA received concerning patient notification, the agency concluded that these many comments all share the common goal of providing an effective mechanism for communicating mammography results to patients, but that the comments clearly advocate different approaches to achieving this goal. FDA agrees with consumer groups that written notification of mammographic results represents ''best practices'' in ensuring that each and every woman is clearly and effectively notified of the results of her mammogram. These ''best practices'' are outlined clearly in a series of recommendations published by AHCPR in Chapter 4 of the 1994 guidelines entitled, ''Quality Determinants of Mammography'' (Ref. 2). In these guidelines AHCPR strongly recommends that mammography facility personnel provide each patient with written notification of the results of her mammography examination either onsite or by mail. Studies cited by AHCPR have shown that direct communication with patients, which is in addition to written communication to health care providers, dramatically increases compliance with followup recommendations. However, FDA also recognizes that many in the health care community have strong reservations, for the many reasons cited above, about making written notification to all patients a Federal requirement. Finally, FDA notes that although the MQSA requires mammography facilities to notify patients' referring physicians, in writing, of the examination results, the statute requires those facilities to notify patients directly in writing, only in those instances where the patient has no referring physician. FDA believes that the best way to reconcile the many different points of view on this subject—and achieve the goal of effective patient notification consistent with the statute—is to issue a general rule requiring patient notification, together with a recommendation that facilities follow the AHCPR guidelines regarding written notifications to patients. The relevant portions of the AHCPR guidelines have been printed as an appendix to the preamble of this document for ease of reference.

Accordingly, the agency has revised the final rule to eliminate the requirement for written notification to every patient and has substituted a performance-based regulation that requires each facility to ensure that the results of each mammographic examination are communicated to the patient. Under the final rule, each facility will be responsible for establishing a system of notification, through its own efforts or in cooperation with third parties, that guarantees that patients are informed of the results of their examinations in a timely manner. The system must also ensure that women who do not have health care

providers receive written notification, along with the mammography medical report, no later than 30 days following an examination and that each facility communicate abnormal results as soon as possible.

As noted above, FDA continues to believe that written notification of mammographic results is the most reliable way to guarantee that each patient is notified of results and that any necessary followup will occur. Comments from consumer groups and breast cancer survivors about the importance of early and accurate communication to patients supports the public health need for systems that ensure patient notification. Written notification to a patient of results can permit that patient to make informed medical decisions at critical times. One cancer survivor informed the agency that having the actual results of an abnormal study in hand allowed her to pursue treatment options that saved her life. Furthermore, the agency disagrees with comments that assume all patients are notified of their mammographic results; many referring health care providers do not communicate results of mammograms to patients and the adage ''no news is good news'' still rings true for many patients. During the MQSA inspections, FDA has uncovered a handful of facilities that do not even issue written mammography reports to referring physicians. Accordingly, the agency is continuing to require each facility to establish systems that will ensure that patients are notified of the results of their mammograms.

FDA believes that high quality mammography extends from the production of high quality mammographic images to the communication of results to the patient. Ensuring that patients get their results is the responsibility of all participants in the mammography imaging chain: The patient, the facility, and the referring health care provider. The final regulations fully charge facilities to meet their responsibility.

At its January 1997 meeting, NMQAAC recommended that all facilities should not be required to provide written notification. While some concern was voiced about difficulties in directly notifying all patients who underwent diagnostic mammography, many members advised FDA to require some type of direct notification of all patients and that this notification be documented. Although the agency continues to support written notification to all patients as the optimum practice under most circumstances, the final regulation does not prescribe any particular form of notification. Comments from facilities and physicians indicate that facilities have devised a variety of systems of communication to notify patients of mammography results. These include verbal conversations at the time of the examination, telephone communication after the examination, cooperative arrangements with referring physicians who convey the results verbally to their own patients, and written communications that are either directly issued from the facility and convey results or instruct the referring physicians to issue these reports. The AHCPR guidelines recommending direct written communication to all patients also provided examples and suggestions about the other types of communication.

Under the final regulation, in the case where a facility decides to rely on a third party to communicate results (either written or verbally), there should be a documented agreement between the facility and the third party that establishes this cooperative responsibility. This documentation may be in the form of attestation by the third party or letters of agreement signed by the third party. In addition, the agency reserves the right during inspections to confirm not only the presence of such documentation, but also to ask for further documentation from the facility to verify that patients were indeed notified. Further documentation can include copies of referring physician medical records documenting that results were discussed or sent to the patient. These descriptions of systems and documentation are intended to be examples; others may also be acceptable. However, if third parties do not provide the mammography facility with further documentation when requested during inspections, the mammography facility is subject to regulatory enforcement action under the MQSA for failing to document that results were provided to patients. Thus, for facilities that choose to rely on third parties for communicating results, whether they be referring physicians or communication consultants or other parties, the facility still has ultimate responsibility to meet the patient notification requirements of the final regulations.

The agency also believes that the approach taken in the final regulation will address the concerns about communication and cost that were raised by so many of the comments. The flexibility that has been built into the final regulation will permit facilities to tailor notification systems to the particular needs of the general patient population and individual patients they serve. At the same time, requiring each facility to establish and document the existence and operation of such systems achieves the primary goal of ensuring that patients receive the results of their mammograms.

In addition, the agency notes that the requirement for reasonable attempts at immediate communication when results of an examination are ''suspicious'' or ''highly suggestive of malignancy'' has been retained in the final regulation. Potential delays in diagnosing and treating breast cancer are reduced with this requirement that facilities directly notify patients who have no health care provider of abnormal results as soon as possible. (The same requirement for immediate communication in the case of ''suspicious'' or ''highly suggestive of malignancy'' findings applies to the facility's communication with the referring physicians of those women who have identified health care providers). The agency concludes, therefore, that the most significant public health risk that may result from failure to communicate results is addressed in the final regulation.

The final regulation continues to require written notification by facilities to patients who do not have referring physicians, as specified in the MQSA. The statute also sets forth, and the regulation incorporates, the requirement that such self-referred patients receive a copy of the actual mammography report that would be prepared and sent to the referring physician, if there were one. In response to comments that questioned the agency's authority to require patient notification, FDA notes that the language of the MQSA is very explicit with respect to patient notification of test results and the form that notification must take in these particular circumstances (see 42 U.S.C. 263b(f)(1)(G)).

(Comment 411). Many comments urged FDA to require referring physicians to be responsible for the communication and followup of results of mammography examinations. FDA agrees that a physician with knowledge of a particular patient's entire medical history is often the best source of communication and followup of results. However, FDA's primary jurisdiction under the MQSA is related to mammography facilities and not individual practices of referring health care providers.

One comment suggested an arrangement whereby facilities and each provider of care enter into a written agreement that the referring physician assumes responsibility and liability for informing his or her patients of mammography results, and the mammography facility would be

allowed to breach this contract at any time when a patient requests the results in writing. FDA agrees that this arrangement would meet the requirements of the final regulations. However, if referring physicians fail to communicate results to patients despite their agreement to do so, the mammography facility is responsible under the MQSA for failing to ensure communication of results and is subject to regulatory action by FDA.

FDA intends to look for documentation during inspections to establish that patient notification systems are in place and operational. For example, if a verbal communication system is used to tell patients of results, this communication should be documented in the patient's medical record and should be capable of verification by the MQSA inspectors. If a facility sends letters to patients, records of that correspondence, or standard operating procedures describing this correspondence, must be available for inspection. In circumstances where a facility relies on referring physicians or other third parties to communicate results to patients, the facility must provide documentation of these arrangement and their implementation, as described above. In those cases where the mammography facility is the primary breast care provider for the patient, there must be documentation of results being conveyed to the patients. By allowing a variety of notification systems, the agency has attempted to ensure that communication of results will be accomplished effectively, but without undue burden on mammography practices or unnecessary increases in the cost of mammography services. Finally, the agency notes that the regulations being issued to require facilities to establish and maintain systems that ensure patient notification of results does not preclude any patient from requesting additional reports or records from the facility. Nothing in the record and report section of the MQSA should be construed to limit a patient's access to the patient's medical records (42 U.S.C. 263b(f)(1)).

(Comment 412). One comment stated that FDA's intention to inspect and monitor systems established by facilities to verify that patients receive notification of results in lay language is unrealistic and that facilities should not be required to establish such systems.

FDA disagrees. FDA has issued interim regulations, as required by the MQSA, that required notices in lay language to be issued, along with the actual report when patients do not have a referring health care provider (42 U.S.C. 263b(f)(1)(G)(ii)(IV)). This is a current requirement for all facilities and is already subject to inspection and verification.

(Comment 413). One comment stated that complex situations, such as when a mammogram is assessed as negative, but the patient has clinical findings, need careful explanation to patients so that the importance of the situation and recommendation for followup will be understood. This comment recommended that the mammography facility be responsible for patient care if it is accepting women who have no physicians.

FDA believes this practice standard is largely being adopted by the mammography community and supports this. Under the final regulations, each facility is required to maintain a system for referring patients to health care providers when clinical followup is recommended and the patient has no physician.

(Comment 414). One comment stated that followup reminder letters are critical and should be mandated.

FDA disagrees that these should be mandated. Rather, each practice should be allowed to determine if such letters or other forms of reminders are needed.

(Comment 415). One comment reflected confusion about the immediate followup call to patients required under § 900.12(c)(2), which is in addition to the notification requirements. Although notification is required for all patients under the system established by the facility to ensure such communication, FDA believes that special efforts at communication are required when there are abnormal results and the patient does not have a referring physician. In these cases, the facility is expected to contact the patient who has no health care provider as soon as possible and the 30-day timeframe for sending reports and long summaries is superseded. Under the final regulations, this immediate communication is required only in situations where the probability of cancer is high (mammograms assessed as ''suspicious'' or ''highly suggestive of malignancy''). In cases where such immediate notification is required, the facility remains obligated to also provide the necessary written notifications within 30 days as followup.

(Comment 416). One comment supported the requirement that, when an examination shows suspicious findings, a facility should directly communicate with a nonreferred patient. This provides patents the assurance that they will receive the care they need.

FDA agrees and the final regulations contain this requirement.

(Comment 417). One comment stated that, in cases where assessments are ''suspicious'' or ''highly suggestive of malignancy'' and results must be ''immediately'' communicated to the examinee or physician, FDA should define what ''immediately'' means. Another comment suggested ''immediately'' be defined as 24 hours.

FDA believes that the variety of circumstances that may arise when followup is required make a rigid definition of ''immediate'' unreasonable. Because there are circumstances when immediate communication is not possible, FDA has revised the requirement to communicate abnormal results from ''immediately'' to ''as soon as possible.'' Health care professionals understand the importance of accomplishing such notification when there are suspicious or highly suggestive findings. Although it is impossible to establish a precise timeframe, FDA expects such communication ordinarily can be accomplished within 48 to 72 hours and not later than a week following the examination.

(Comment 418). One comment stated that 30 days is an unreasonably long window in which to notify patients of results. Three other comments agreed with FDA that 30 days was reasonable. Another comment stated that reports and notification should not be sent out for at least 5 days in order to wait for outside comparison films; otherwise, addenda lay notification and reports would confuse patients and physicians. Another comment recommended that notification to patients should wait until all mammography imaging work up has been completed.

FDA believes that issuing medical reports to health care providers (or to patients with no health care providers along with lay summaries) within 30 days is a reasonable standard. This does not mean facilities must wait 30 days, as the first comment suggests, but rather that 30 days is the outside limit. FDA disagrees that notification of results should be delayed until the total imaging work-up is completed because situations arise when imaging work-ups can extend over more than 1 month. Therefore, FDA is requiring a report of the medical finding for each mammogram to be generated within 30 days. Under the final regulations, facilities must also ensure that patients have their results communicated to them within that time. Many facilities may notify patients or have other parties notify patients after written medical reports are provided to physicians; other facilities may choose to communicate

results to patients prior to the issuance of the medical report to the referring provider by means such as providing verbal results at the time of the mammography examination. As discussed above, a variety of systems will be acceptable as long as they ensure that results are communicated to patients and that communication is timely.

(Comment 419). Eight comments stated that patients without health care providers should not get the actual medical report along with the lay notification. These comments claimed that the terminology in the medical reports would confuse patients and either generate more inquiries or keep them from understanding that further studies are needed. They recommended instead, that patients can request the report be sent to a physician if further medical advice is desired. One comment also stated that, while it is critical to include the patient in the information loop for the results of her mammogram, it is poor medicine to send the patient who is self-referred the copy of the mammogram report that is intended for the physician.

FDA disagrees. The MQSA expressly requires facilities to provide patients without referring physicians both the medical report and the lay summary (42 U.S.C. 263b(f)(1)(G)(ii)). This requirement allows the patient to provide her mammography report immediately to a subsequent health care provider, if needed.

(Comment 420). Two comments asked what is meant by ''reasonable attempts'' to communicate results of suspicious studies to patients without referring physicians as soon as possible. The comments asked whether a certain number of phone calls or a registered letter would be acceptable.

FDA does not intend to mandate procedures for communication with patients in these circumstances because different methods are likely to be more or less effective with different facilities and patient populations. Telephone calls and registered mail are examples of attempts at communication that may work. Verification that contact has been made is the goal. Each facility can consult with its risk management director to establish procedures to convey results and document attempts at communication that are ''reasonable.'' FDA recommends that mammography facilities utilize the AHCPR's guidelines in ''Quality Determinants of Mammography'' that address the effective communication of mammography results to patients and follow those guidelines with respect to written notification to patients. That document includes excellent sample lay notices that facilities could adopt. As noted previously, information from Chapter 4 of these guidelines has been reprinted as an appendix to the preamble of this document for ease of reference.

d. *Communication of mammography results to health care providers (§ 900.12(c)(3))*

The final regulation requires each facility to provide the mammography report to a referring or named health provider within 30 days of the date of the examination. The regulation also requires a facility to make reasonable attempts to communicate with the health care provider or the provider's designee as soon as possible when an examination reveals suspicious results. These requirements paralleled those for communication of suspicious results to patients without identified health care providers.

(Comment 421). Five comments requested guidance in defining who is a responsible designee of the health care provider.

In response, the agency notes that when referring health care providers are not available, they ordinarily have responsible designees, such as medical coverage services or partners, to assume medical responsibilities for the unavailable provider's patients. These requirements parallel and complement those related to patient notification.

(Comment 422). Twenty-nine comments stated that 30 days is a reasonable time period for getting reports out (unless there are delays in obtaining comparison studies). Three comments asked FDA to define the timeframe required for ''immediately'' communicating the results of suspicious or highly suggestive mammograms to health care providers. One comment expressed concern that the requirement to attempt to communicate ''suspicious'' or ''highly suspicious of malignancy'' findings to health care providers immediately will impose an unmanageable burden on understaffed facilities.

FDA disagrees with this last comment but, as with the provision relating to communication with patients, the agency has changed the language from ''immediate'' to ''as soon as possible'' because immediate communication may not be possible given the variety of circumstances that may be associated with communication of suspicious results to a particular provider. FDA believes health professionals understand the urgency of the situation when a patient has a suspicious or highly suggestive mammogram and they are mandated to communicate this result to the referring health care provider in an attempt to expedite diagnosis or treatment. Again, although it is not realistic to mandate a rigid schedule, the agency expects that such communication ordinarily can occur within 48–72 hours, and not later than a week following the evaluation of the examination. NMQAAC discussed this section and supported the regulations as revised.

(Comment 423). One comment questioned the ability of physicians who read only twice a week to comply with the requirement to communicate with health care providers within the mandated timeframes. FDA believes timeframes and procedures are sufficiently flexible to balance the need to protect patient health with the realities of good mammography practices. Reading twice a week does not preclude a physician or the facility that employs that physician from complying with the requirements.

(Comment 424). Another comment recommended that radiological reports transmitted to the referring physician be acknowledged by electronic signature, which should be kept in the electronic file indefinitely. As stated previously, with respect to proof-reading reports and ''signing'' them out (for authentification or release), FDA assumes that facilities are able to devise their own procedures to ensure accuracy of reports and integrity of the system without the MQSA regulations at this time.

e. *Recordkeeping (§ 900.12(c)(4))*

FDA's final regulation implementing recordkeeping standards for facilities requires each facility to maintain films and reports at least 5 years or until the patient requests them or requests their transfer. If the film and report represent the only mammogram for that patient, the facility must retain them for 10 years or for any longer period of time that is required by State law or until the patient requests them or requests their transfer.

FDA received numerous comments supporting its proposal to require transfer of the original mammogram upon the request of the patient.

(Comment 425). Fourteen comments stated that original films should be transferred because copies are frequently poor quality and jeopardize successful followup. Four comments stated that the request for transfer should be in writing and that the regulation should state ''temporary or permanent transfer.''

FDA believes each facility should be free to establish its own procedures for transfer of films and may wish to consult its risk management director for

guidance. FDA agrees in part with the last comment and has modified the final regulation to clarify that a patient may request that the transfer of the original films be temporary or permanent. FDA will leave it to the facility to decide whether the request for transfer should be in writing or may take some other form. NMQAAC also supported the addition of this language to the final regulation.

The agency has also amended the language of the provision to clarify that a request for a transfer supersedes a facility's responsibility to maintain the films for a particular length of time and that the request may be made by an individual on behalf of the patient as, for example, might be necessary in cases where the patient is incapacitated or has a legal guardian.

(Comment 426). Two comments agreed that original mammograms should be sent for comparison to other facilities. However, these comments stated that FDA's suggestion in the preamble to the proposal that facilities make a copy is very difficult and expensive. Another comment stated that copying originals to retain in the record when transfer is requested should not be required because this would increase costs, would not be adequate for comparisons, and would delay sending films out in the timely manner.

In response to these comments, the agency notes that there are no requirements for facilities to make copies of films they are requested to transfer. If this suggestion to make and keep a copy of the mammograms is not practical or useful to a facility, it need not be followed.

(Comment 427). Three comments supported the transfer of original films, but would require their return within 30 days in cases of temporary transfer.

FDA does not intend to establish a time limit on transfer of films at the request of patients. Even in cases where the transfer is temporary, the originals may be used during clinical procedures that may not be completed in 30 days. However, FDA does support the return of films in a timely manner and expects facilities that transfer and receive films under such circumstances to cooperate in the interest of the patient's treatment.

(Comment 428). FDA also received many comments expressing concerns about original film transfers. Twenty-six comments stated that transferring original films is problematic because the films may be lost, their transfer may breach confidentiality, the originating institution will not be able to make comparisons, and patient may be denied access to films at a later date. One comment stated that FDA should clarify if the transfer of original films conflicts with State or locals laws and how facilities should proceed if that is the case. Four comments urged FDA to delete the proposal because the films themselves are historically the property of the physician or institution which generated them and their absence would disadvantage those physicians or institutions in defending against claims asserted against them. Fourteen comments asked if FDA will indemnify the radiologist for not having original films in the event of a malpractice action. One comment stated that there is no enforcement provision against those facilities who refuse to release original mammography studies on the grounds of ownership or the potential for legal action.

FDA understands that the transfer of original films has not been a universal practice among facilities and that physicians may have concerns about the consequences of loss or misplacement. Nevertheless, the agency has concluded that the overwhelming benefit to patients from access to original films by other facilities or physicians providing followup for patients justifies the need for this provision in the final rule.

All expert comments FDA received on this matter, including advice from NMQAAC, emphasized the value of having original films for comparison to subsequent studies or followup clinical procedures. There was general agreement that copies of mammograms could not adequately substitute for originals when difficult diagnoses or additional procedures were required, and that clinical decisions, such as whether to do surgery, require review of original films. The agency notes that even those practitioners who criticized the proposal agreed that the transfer of films was likely to enhance patient care. Those who objected did so on grounds that were unrelated to patient care, namely potential for liability and difficulty in defending malpractice actions.

FDA has not been persuaded that these concerns are insurmountable or that they are sufficient to override the public health benefits associated with the provision.

Many facilities do routinely transfer films upon the request of patients and have established procedures and systems to implement that process. Those procedures may include written requests from patients, release forms that establish transfer of responsibility for the films, and agreements with receiving institutions for subsequent return. In some cases, facilities that transfer films do make and retain copies for their own files; other facilities have determined that the expense of copying is not warranted. Loss of films will not be indemnified by FDA.

With respect to facility concerns about defense of malpractice claims, FDA notes that rules of evidence, including civil discovery, establish judicial procedures that are designed to protect each party's ability to develop its case. Judges have authority and discretion to craft remedies in situations where a patient has lost, withheld, or is resisting production or examination of a necessary original record.

FDA is not aware of any State laws that conflict with the requirement that original films be transferred upon the patient's request. State laws governing the management and retention of medical records appear to be silent about the transfer of original films. Rather, they are likely to state that patients are entitled to copies of their records or that doctors are required to maintain records. This was the case with the Florida and New York laws that were brought to the attention of the agency.

Were a State to enact a law that conflicts with this regulation or if, contrary to FDA's understanding, such laws currently do exist, those State laws would be preempted. The agency disagrees with comments that have inferred such laws would be permissible under the provision of the MQSA that allows States to establish more stringent requirements relating to mammography (42 U.S.C. 263b(m)). The public policy considerations underlying any State laws that would restrict a patient's access to original films and the quality data that may only be available from these original studies would not be related to the public health objectives of the MQSA. Accordingly, such State laws could not be characterized as more stringent than the MQSA or this regulation. The agency also notes that the records provision of the MQSA that is being implemented by this regulation explicitly states that nothing in that provision shall be construed to limit a patient's access to that patient's medical records (42 U.S.C. 263b(f)(1)(G)).

(Comment 429). One comment recommended that FDA add that, upon receipt of authorization to release mammography film, the mammography facility must forward the films to the requestor in a reasonable timeframe to minimize reporting delays. Another comment suggested that each facility be required to provide original films and copies of reports within 10 working days of receipt of a written request.

FDA does not believe it is necessary or useful to mandate the details of such transfers. The agency believes that each

facility will develop standard operating procedures to implement this standard and that those procedures will reflect the controls required by risk management and acceptable practice standards.

(Comment 430). Six comments suggested that the facility that took the most recent mammogram should maintain ownership of all the originals because this practice would make it easier to keep the films available for future comparisons. FDA's final regulations do not preclude this arrangement if the patient requests transfer of previous films to the current facility.

(Comment 431). Twenty-four comments asked who should bear the cost of copying films when the original is released. One comment stated that facilities should only be able to charge a nominal fee for transfer of films and reports. Another comment believed that the fees must be closely monitored; the comment noted that reports have been received in the past from facilities charging unreasonably high fees for sending reports and copies of mammography films. A third comment stated that FDA should develop fee guidelines for charges for copying film and postage to prevent some institutions from charging high fees.

FDA generally agrees with these comments and its final regulations limit charges to the documented cost of the transfer, so as to not deter patients from requesting transfers when necessary. The agency notes that nothing in the regulations requires facilities to charge fees for transfer of records. If copies are made as part of the facility's standard transfer process, then the cost of copies may be documented and included in the transfer fee charged by the facility.

(Comment 432). One comment asked if the fee can include a storage charge or is it for medical records transfer only.

The regulations clearly state that any fee is for services provided under § 900.12(c)(4)(ii), which is the transfer of films and reports.

(Comment 433). Twelve comments stated that the proposal that fees charged for transfer of films and records not exceed costs appears to be price controls, if not price fixing.

The agency does not agree that it has taken any action to establish prices. FDA is responding to complaints that fees charged for transfers of records have been unreasonable. This practice prevents consumers from making such transfers and obtaining medical care with the best quality medical data. The regulation does intend to control such charges in order to ensure access by patients to their films but the final rule does not require facilities to absorb additional expenses. Instead, each facility that decides to charge consumers for this service must limit its charges to documented costs.

(Comment 434). Nine comments stated that original mammograms should be provided by other facilities for comparison purposes free of charge as a courtesy among institutions.

FDA supports this process; the final regulations do not mandate a charge. However, if any fee is established, FDA's regulation requires that it not exceed costs of transfers of such records.

(Comment 435). Two comments suggested that FDA's regulations should consider future technology, which may include the electronic transfer of films.

FDA regulations are for screen-film and xeromammography. As other technology is approved for medical use, alternative standards under the MQSA will be issued.

(Comment 436). One comment asked if a facility must retain a series of mammography records for 10 years and discard them as each record is 10 years old, or discard them when the oldest record is 10 years old. FDA interprets the provision in the MQSA to mean that, if there is a series of mammograms for a patient, the oldest mammogram of the series can be 5 years old. If there is only one mammogram for a patient, it must be kept 10 years unless a transfer is requested. One comment stated that mammograms should be maintained for longer than 10 years if mandated by State or local law. In fact, the MQSA mandates this and FDA has written its regulations to conform to this provision.

(Comment 437). Two comments recommended that mammograms be kept indefinitely in order to spare a patient an unnecessary biopsy and another comment recommended that FDA establish a standard retention period of 5 to 7 years.

The final regulations do not preclude facilities from keeping mammograms longer than what is required by the statute as a minimum. However, the agency rejects the 5 to 7 year standard because the timeframes set forth in the regulation are prescribed by the statute.

(Comment 438). One comment recommended that FDA reinstate a HCFA requirement that previous mammograms be obtained for comparison with present films.

FDA believes that this is good medical practice, but it is not an appropriate focus for FDA regulations under the MQSA.

f. *Mammographic image identification (§ 900.12(c)(5))*

This provision describes the elements that must be included on any mammography film to identify the image. They are: patient identifier, date of examination, view, laterality, facility identification, technologist identification, cassette/screen identification, and unit identification, if the facility has more than one unit.

The NMQAAC advised FDA that these elements need to be present on all mammogram films to ensure proper patient care. FDA agrees. These are the same elements as those established by § 900.4(c)(2)(viii) to identify films submitted to accreditation bodies for clinical image review. Comments received from the public relating to these elements for film identification are addressed in that section of the preamble that discusses § 900.4(c)(2)(viii).

4. Quality Assurance—General (§ 900.12(d))

This paragraph was intended to identify the individuals responsible for the actions required by § 900.12(e) and (f), including those intended to ensure that safe radiation dose levels were used. With one or two exceptions, the requirements of this paragraph were included in the ACR quality assurance manuals that were made part of the interim regulations by reference. The ACR manuals are not referenced in the final regulations. However, certain significant aspects of those manuals, such as the requirements in this section, were incorporated into the proposal because there is broad agreement that these principles are basic to a good quality assurance program.

a. *General comments on quality assurance*

(Comment 439). Two comments stated that all facilities should follow the same set of universal guidelines to maintain the same quality of results.

FDA notes that the MQSA and the implementing regulations are designed to require that facilities meet universal minimum standards. Nothing in the statute or regulations is intended to prevent a facility from applying additional, more stringent standards or procedures that strengthen QC at that facility.

(Comment 440). One comment stated that FDA should eliminate this entire paragraph except for a single provision that would require each facility to have a quality assurance manual and to verify, through the signature of a responsible official, that the manual is followed.

FDA does not believe that the general requirement suggested by the comment would effectively establish minimum levels of quality assurance at all facilities.

b. *Responsible individuals (§ 900.12(d)(1))*

This paragraph identified the responsibilities of the individuals associated with the quality assurance program.

(Comment 441). Two comments recommended that FDA be more specific about what responsibilities should be listed and to whom they should be assigned.

FDA does not believe that additional detail will be useful in these provisions. Greater specificity would limit the facility's flexibility to design a quality assurance program that best meets its individual needs and to quickly change its program in response to changes in circumstances or technology.

(Comment 442). One comment expressed the author's disappointment that this section and the rest of the regulations failed to allot any responsibility to administrators and Chief Executive Officers (CEO's), who have the authority to make the decisions that control quality but seem to be more motivated by financial concerns.

FDA agrees that administrators, CEO's, owners, and operators of facilities share responsibility for the quality of mammography at their facilities. However, individuals working more directly in and with the mammography facility on a daily basis often are better able to determine when quality problems exist and how to correct them. The agency recognizes that it is sometimes difficult for the staff to obtain the administrator's support for necessary actions. Nevertheless, if necessary actions are not taken to correct quality assurance defects, the result could be sanctions against the facility by FDA. Because such sanctions can affect the reputation and profitability of any facility, FDA believes that administrators and CEO's will cooperate to support actions to improve or maintain mammography quality.

c. *Lead interpreting physician (§ 900.12(d)(1)(i))*

This provision requires facilities to identify a lead interpreting physician to have the general responsibility for ensuring that the quality assurance requirements of § 900.12(d) through (f) are met. This is a change from the interim regulations, which assigned this responsibility to a mammography medical physicist. This change drew a number of almost evenly divided comments.

(Comment 443). Eleven comments plus NMQAAC supported the change. Various comments pointed out that the medical physicist often does not have the authority to implement needed actions, especially if he or she is a contract physicist who is rarely at the facility, and the medical physicist usually does not have the expertise to deal with nonequipment issues. One comment noted that Massachusetts' regulations have a similar provision to the proposal and it had been found to improve the quality assurance programs.

Eleven other comments opposed the change. Some of these comments stated the belief that interpreting physicians did not have sufficient knowledge of or interest in quality assurance to properly handle this responsibility. Others said that, in modern medicine, the physicians also lack authority to implement necessary changes and pointed out that interpreting physicians may also be contract employees and not actually at the facility. A related comment warned that, if the interpreting physician is to be given responsibility for oversight, he or she must also have authority to institute necessary changes. One comment stated that while it is important to have an interpreting physician in this role, it is more important to assign this responsibility to someone at the facility, even if it means involving a nonphysician. Another comment questioned the basis for designating a lead interpreting physician if he or she can assign their responsibilities to other people. Two comments suggested that wording be changed to allow each individual facility to decide who would be most appropriate for this responsibility. Finally, one comment stated that the MQSA specifically said that the medical physicist was to have responsibility for the quality assurance program.

After considering all these comments, FDA has decided to leave this responsibility in the hands of an interpreting physician, as proposed. Because the interpreting physician is the final arbiter of the quality of a mammogram, it is logical that the responsibility for the quality assurance program rest with an interpreting physician. The agency recognizes that interpreting physicians in some facilities face the same limitations on their authority as medical physicists. However, FDA believes that an interpreting physician is more likely to have adequate authority, or the ability to influence those that do, than a medical physicist. The agency also recognizes that the interpreting physicians may not be located at the facility itself. Even in those circumstances, interpreting physicians have more regular interaction with the facility through their mammography interpretations than do contract medical physicists conducting annual surveys. Again, the agency realizes that interpreting physicians may not have the knowledge to carry out all aspects of the program themselves, but notes that this is likely to be true of any other individual in this position. For this reason, the final regulations do not require the lead interpreting physician to perform all of the duties personally, but rather to see that they are carried out in such a way as to meet the requirements. The basic responsibility remains with the interpreting physician, even if some or all individual duties are delegated to people with specific training to carry them out. Contrary to the opinion expressed in one comment, identifying a lead interpreting physician is valuable because it assigns this basic responsibility and establishes accountability even when tasks are delegated.

Many important duties will be delegated to the medical physicist. FDA is aware, as one comment noted, of the MQSA provision that requires the medical physicist to ''survey mammography equipment and oversee quality assurance practices at each facility'' (42 U.S.C. 263b(f)(1)(F)). As noted above, the interim regulations did assign to the medical physicist the overall responsibility for quality assurance. FDA's experience under the interim regulations, however, established that the interpreting physician, who ordinarily has more interaction with the facility and is more likely to be onsite, also has an important role in the oversight of quality assurance. As discussed, members of NMQAAC and public comments pointed out problems with the medical physicist having the primary responsibility for all quality assurance at the facility. After evaluating its experience and the comments, the agency proposed, and now intends, to shift overall responsibility for the quality assurance program to the lead interpreting physician. The medical physicist will continue to do the annual survey and oversee quality assurance practices, especially those related to the equipment, as required by the MQSA and the agency expects that the physicist's expertise will inform all final decisions that are made on quality assurance issues. The final regulation, however, requires additional oversight through the lead interpreting physician. FDA believes this change from the interim regulations is in accordance with its general authority to require the facility to establish an effective quality assurance program (42 U.S.C. 263b(f)(1)(A)).

Section 900.12(d)(1)(i) requires the lead interpreting physician to determine whether individuals assigned to quality assurance responsibilities are qualified to carry them out. FDA agrees with the comment that urged that the lead interpreting physician also be given authority to make needed changes because effective quality assurance will require facilities to respond appropriately to situations that need improvement or correction. Internal administrative and budgetary decisions, however, are beyond FDA's authority and the agency cannot control the business and management relationships that will affect any lead interpreting physician's ability to institute change.

d. *Interpreting physicians (§ 900.12(d)(1)(ii))*

This paragraph was intended to emphasize the role that all interpreting physicians should play in establishing and maintaining quality mammography at a facility. As previously mentioned, the interpreting physicians are the final arbiters of the quality of mammography images. It is important that they communicate their satisfaction or dissatisfaction with the quality of the images they are provided to interpret to the technologists who produced them. Such communication is the crucial first step in the identification of problems and the initiation of corrective actions. FDA is aware that this communication has not always occurred in the past, especially if the interpreting physicians are not located at the facility. Media investigations and many anecdotal accounts have illustrated this failure in communication.

None of the 17 comments on this provision disagreed with the basic premise that interpreting physicians should provide feedback to facility staff producing the mammograms. However, there were some misunderstandings as to just what was required.

(Comment 444). In particular, 13 comments mistakingly assumed that each interpreting physician was required to contact every technologist about the quality of each film taken. These comments requested that the requirement be limited to reporting technically inadequate mammograms to the QC technologist. Another comment pronounced the requirement as excellent, but asked whether a report was required on the technologist's performance for every film or if a summary of each technologist's performance was sufficient. Another comment suggested that feedback be given to the lead interpreting physician or, in his or her absence, to the QC technologist. One comment requested that this provision be more specific, and another recommended that all interpreting physicians be required to have training in the technical aspects of mammography, quality assurance, and QC.

FDA drafted the proposed regulation to be general in order to give each facility the flexibility to design a feedback system that best fits its own situation. The agency believes this flexibility should be retained in the final regulations. In response to the comments, however, FDA has clarified that followup activities by interpreting physicians are required only when the image is of poor quality. FDA recommends, however, that positive feedback also be given when warranted because such feedback is an effective incentive for maintaining quality performance.

e. *Medical physicists (§ 900.12(d)(1)(iii))*

This paragraph summarizes the role of the medical physicist in establishing and maintaining quality mammography.

(Comment 445). Eleven of the comments received on this provision suggested various wording changes. Seven of these supported changes that would state that the physicist is to evaluate the equipment and to survey it. An eighth comment wanted to amend the language to give the medical physicist authority to take necessary steps to ensure quality in his or her area of responsibility. Two comments suggested changes that would limit the physicist's responsibilities to overseeing the equipment-related quality assurance practices. These comments further suggested limiting the physicist's review of the QC technologist's work to verifying that it is performed and not to include providing advice on tests or suggestions for corrective measures. Another comment, however, clearly disagreed with this point of view and stated that the medical physicists should be required to oversee the facility's entire quality assurance program.

FDA agrees that the physicist should be involved in equipment evaluation and the annual survey and notes that changes made elsewhere, in the survey definition and in § 900.12(e), will achieve this goal. FDA cannot require that the medical physicist be given authority to initiate changes at the facility to improve quality for the same reasons that it did not issue regulations giving the lead interpreting physician similar administrative and budgeting authority. The agency does agrees that the physicist's oversight responsibility should be focused primarily on the equipment-related areas. The definition of the position of lead interpreting physician in § 900.12(d)(1)(i), as discussed previously, should clarify that general overall responsibility rests with that physician while responsibility for equipment-related matters resides with the physicist. FDA does not agree with the suggestion that would limit the medical physicist's role in the oversight of the QC program to merely verifying that the technologist's work was done. The agency believes that, as the equipment and imaging physics expert, the physicist's role must be more active and that ensuring an adequate QC program clearly should be part of the medical physicist's duties. The medical physicist should not stop with verifying that the QC tests were performed but should also ensure that they were performed properly, that the results were analyzed, and that any problems detected by the analysis were corrected.

(Comment 446). A final comment on this paragraph suggested that a new intermediate position be created at a level between the QC technologist and the physicist. The comment recommended that the person in this position could do tests that do not require a physicist but are beyond a technologist's training, and noted that such a position has been quite useful in the respondent's facility.

Provisions of § 900.12(e) require that surveys and mammography equipment evaluations be performed by medical physicists. Under the interim or final regulations, a facility is free to create an intermediate position for personnel to perform other testing during the time periods between the surveys and evaluations, including performance of the tests normally done during surveys. However, the agency does not have sufficient evidence to demonstrate that it would be beneficial to make this a general requirement and believes each facility is in the best position to decide whether such a position would be of value in its situation.

f. *QC technologist (§ 900.12(d)(1)(iv))*

This provision describes the QC technologist's responsibility to perform all quality assurance duties not assigned to the lead interpreting physician or the mammography medical physicist. The main issue raised by the comments on this provision was about the qualifications of the individual holding this position.

(Comment 447). Eighteen comments expressed the opinion that the person doing these tests should be a radiologic technologist who meets all of the requirements necessary to perform mammography examinations. Seven additional comments stated that the QC technologist should be a technologist but, to increase flexibility for the

facility, should not necessarily have to be qualified to do mammography examinations. One of these seven recommended that the QC technologist should have some training in mammography. Ten comments argued that the individual performing at least some of the tests did not even have to be a technologist, as long as that person had training in the test performance. Some of these pointed out that requiring a technologist to do the tests would increase facility costs without an equivalent increase in the quality of mammography.

After considering the comments, FDA has revised the proposal to permit nontechnologists to perform tasks for which they were trained, as long as their work is supervised by a QC technologist who meets the requirements to do mammography examinations. FDA believes this change strikes the proper balance between the need for expert oversight and the need to reduce unnecessary costs for facilities.

NMQAAC discussed this issue at several meetings and, at different times, expressed varying points of view. However, after its own review of the public comments, NMQAAC supported the approach FDA has taken in the final rule.

(Comment 448). Twelve comments suggested changes, primarily to allow or prohibit the facility from having more than one QC technologist.

FDA agrees that there are advantages to the consistency that can be achieved if there is only one QC technologist. The agency also recognizes that the facility may find it useful and necessary to have more than one QC technologist, e.g., to ensure coverage when one QC technologist is ill or on leave. The agency notes that facilities also have the option of having the lead interpreting physician or medical physicist fill in for the QC technologist, assuming they have the necessary qualifications, by temporarily ''reassigning'' the technologist's duties.

(Comment 449). Another comment suggested that the QC technologist should report directly to the lead interpreting physician rather than to the medical physicist.

FDA notes that the regulations permit the facility to decide for itself what lines of communication to the lead interpreting physician should be established. The agency believes that this flexibility should be retained.

(Comment 450). Another comment suggested that all mammographers should be trained in all QC tests and procedures.

From the context of the comment, it was clear that the author was using the term ''mammographer'' to refer to technologists doing mammography, and not, as is becoming increasingly common, to interpreting physicians interpreting mammography. Section 900.12(a)(2)(ii)(A) does require such training as part of initial training for technologists who will begin performing mammography after the final regulations become effective. Training in these areas could also be used to fulfill initial requirements under the interim regulations, so many technologists presently doing mammography will have had this training. Although FDA encourages all radiologic technologists currently practicing to include such training as part of their continuing education, the agency does not believe that the benefits of retroactively requiring all present technologists to receive this training would outweigh the costs.

(Comment 451). A final comment suggested that adequate time should be allotted for the quality assurance/QC duties.

FDA fully agrees with this comment but does not believe that this kind of commitment can be codified through a regulation. The agency also notes that the amount of time needed will vary significantly, in view of the different situations in different facilities and the differing abilities of the individual QC technologists. As discussed in connection with earlier sections, FDA believes that owners, operators, and managers will have new incentives to ensure that quality assurance programs are properly implemented and that these programs meet the Federal standards with which all facilities must comply.

g. *Quality assurance records (§ 900.12(d)(2))*

The provisions of this paragraph have been significantly changed from the proposal. The proposal required that the facility have a quality assurance manual covering the procedures to be used in meeting the requirements of § 900.12(e) and (f). The manual was to be readily available to all staff members and documentation that it was read and approved by the lead interpreting physician and the medical physicist was required. A list of individuals assigned quality assurance responsibilities and details of their assignments was also to be available to all staff members. Records were to be kept showing that these individuals were qualified for their assigned duties. Records were also to be kept showing the data obtained during monitoring of the facility performance, the analysis of the monitoring data, the problems detected and corrective actions carried out, and the effectiveness of the corrective actions in resolving the problems. The records were to be kept for each test for a minimum of 1 year or until the test had been performed two additional times at the required frequency, whichever was longer.

In response to comments received, as summarized below, and in keeping with the FDA's goal of less prescriptive and more flexible regulations, this paragraph has been greatly simplified. The final regulations do not require any description of the procedures to be followed in performing the QC tests or a list of the individuals with quality assurance responsibilities and their responsibilities. The proposal requiring records documenting the qualifications of these individuals to perform their duties is changed to simply require that records be kept concerning employee qualifications. No review, revision, or sign-off of the manual is required at any frequency but there is a general requirement that the lead interpreting physician, a QC technologist, and a medical physicist are to ensure that records are maintained and updated. The time that the records of testing and followup actions must be kept has been clarified but remains essentially the same.

The proposal divided the provisions of § 900.12(d)(2) into four paragraphs, (i) through (iv). As a result of these changes, paragraphs are no longer needed but the comments received on the proposed four paragraphs will be discussed, following the general comments.

h. *General comments on quality assurance records*

(Comment 452). One comment asserted that keeping quality assurance records was an unnecessary burden but did not suggest an alternative means by which a facility could demonstrate that it had carried out the quality assurance tests and all necessary followup activities. A second comment recommended that mammography facilities be required to retain written specifications in a standardized format from the processor manufacturer.

FDA cannot accept the first of these comments without an adequate alternative to keeping records. FDA agrees there would be value in processor manufacturers providing specifications in a standardized format but believes it would be premature to make this a requirement. The agency's previous attempts to encourage the provision of processor operating characteristics for different types of film showed that there are significant problems to be solved, among them the very large number of

possible combinations of film, chemistry, and processors.

i. *Records to be kept (proposed § 900.12(d)(2)(i), (ii), and (iii))*

(Comment 453). A few comments were received on the records to be kept. Three comments opposed the change from requiring the use of the ACR manual to allowing the use of whatever manual best fits the facility's needs.

FDA believes that the increased flexibility provided by allowing the use of manuals other than the ACR manuals is desirable because it permits facilities to more rapidly adjust their programs to incorporate improvements in quality assurance procedures or new techniques for new technology. When a manual is specified in regulations, the regulations may have to be amended to facilitate use of even a new edition of that manual, let alone an improved manual from another source. To increase flexibility even further, in the final rule FDA has dropped the use of the word ''manual'' altogether because it seemed to imply a certain format. Facilities will now be able to keep the required records in any suitable format.

(Comment 454). A number of comments recommended addition of items to the list of those required to be kept. Six comments suggested adding technique charts to the required records, while a seventh suggested adding documents related to the medical outcomes audit program. Another comment stated that documentation for darkroom cleaning, screens, and view boxes should not be eliminated.

NMQAAC members pointed out that there was already a requirement in the ACR manuals, which were incorporated into the interim regulations by reference, that a technique chart be available. Although there was some difference of opinion, NMQAAC seemed to support retaining a requirement for keeping a technique chart with the equipment but not necessarily in the manual. With respect to the quality assurance manual in general, the view of NMQAAC seemed to be that elements required in the final regulations were ''key'' or ''basic'' to the success of a quality assurance program. At least one NMQAAC member expressed reservations about the detail required and would have preferred to limit the regulation to a general requirement that there be a quality assurance manual. However, both this member and a second member recognized that enforcement by inspectors would be difficult without more detailed requirements.

FDA notes that documentation of facility cleanliness activities is required in § 900.12(e)(11). The list of other records that must be kept, although not necessarily in a ''manual,'' has been revised as discussed previously.

(Comment 455). Other issues that drew a number of comments were who should sign off on the manual and how often should review, revision, and sign-off take place. Nine comments supported having the QC technologist sign-off in addition to the lead interpreting physician and mammography medical physicist. A tenth comment would limit the physicist sign-off to only those items related to his or her responsibility. Three comments stated that the review, revision, and sign-off should occur at least annually. NMQAAC supported both adding the QC technologist to the sign-off list and the annual review, revision, and sign-off.

FDA has replaced the requirement for a formal sign-off with a general statement that the lead interpreting physician, QC technologist, and medical physician should ensure that the specified records are kept.

(Comment 456). Another comment stated that qualifications of the individuals assigned responsibilities in the QC program should be kept on record only if those individuals are not listed in the facility's application (presumably for accreditation).

FDA disagrees with this comment. The accreditation bodies do not check the qualifications of personnel to perform quality assurance tasks during the accreditation process.

Proposed § 900.12(d)(2)(ii), which required that a list be kept of the individuals with quality assurance assignments and their assignments, drew only one comment. The comment supported the list but urged that the requirement be clarified so it was not construed to mean that only the listed individuals could carry out the duties. As discussed above, FDA has eliminated this proposed requirement.

The only comment on the proposal for keeping records of qualifications of quality assurance personnel, § 900.12(d)(2)(iii), suggested that those records should be kept indefinitely. As discussed above, FDA has reworded the requirement slightly. Requirements for record retention are discussed below.

j. *Monitoring performance (proposed § 900.12(d)(2)(iv))*

As proposed, this provision would have required facilities to maintain records related to monitoring of their facility's performance for 1 year or until the tests has been performed two additional times at the required frequency, whichever was longer.

(Comment 457). One comment stated that the words ''for a minimum of 1 year'' should be replaced with ''from inspection-to-inspection'' because inspections may not occur precisely at annual intervals. FDA has changed the wording to ''until the next annual inspection has been completed and FDA has determined the facility is in compliance with the quality assurance requirements.'' This change addresses concerns raised by this comment and clarifies that an inspection includes the followup and the actual visit to the facility.

5. *Quality Assurance—Equipment (§ 900.12(e))*

The primary purpose of the equipment aspects of the quality assurance program is to prevent problems with equipment or detect and correct problems before they can have a significant effect on clinical image quality. In order to achieve this objective, the performance parameters of the equipment must be tested at appropriate frequencies, the test results must be analyzed promptly to determine if the performance of the equipment is satisfactory, and any identified problem must be corrected as soon as possible. Followup tests must also be conducted to determine whether the corrective actions were effective and adequate. Requirements for the types of equipment tests to be performed and for the necessary followup actions were proposed in § 900.12(e). These requirements have generally been retained in the final rule. However, on the basis of a number of valuable comments the agency received in response to its proposals, some revisions to the proposal have been made. Many of the revisions have been made after discussions with NMQAAC. In addition, tests for radiation output and decompression have been added to the annual QC tests as § 900.12(e)(5)(x) and (xi). The action limits for these tests were proposed as equipment specifications in § 900.12(b).

a. *General comments on equipment quality assurance*

In the preamble to the proposal (61 FR 14912), FDA specifically requested comments on the value of a simple daily total system test based upon the evaluation of the optical density and artifacts on an image of a uniform phantom. The agency believed that the total system test, when performed in conjunction with the processor performance test set forth in § 900.12(e)(1), would ensure the overall quality of X-ray machine and processor performance and of the films produced. This test would only takes a few minutes to perform and records of the test would enable a medical physicist to

quickly detect the source of a problem when it occurs.

(Comment 458). A large number of comments opposed the idea of such a test. Several of these comments, however, confused this test with the alternative phantom testing identified earlier as a possible basis for performance-based standards (See 61 FR 14860). Some members of NMQAAC also opposed this test. The agency also received a number of comments supporting this test. Several comments agreed that more frequent phantom testing in conjunction with daily processor testing is important.

In view of the mixed comments, FDA concluded that it should not require the test until it gathers additional data on its usefulness. However, FDA strongly encourages facilities to test their machines as frequently as possible, either by a phantom evaluation or by the total system test.

A number of comments requested that FDA provide a detailed description of all QC test procedures. Several comments wanted FDA to reference ACR QC manual, while some comments considered the proposed Quality Assurance-Equipment requirements to be appropriate.

FDA notes that § 900.12(e)(1) through (e)(5) lists the minimum performance tests to be conducted on screen-film systems and their required frequency. Action limits for the tests are also specified. The agency has refrained from providing extensive detailed requirements or prescriptive descriptions of test procedures, as some comments recommended, in order to provide facilities with the flexibility to use their own judgment as to what testing methods best enable them to meet the required criteria. FDA has also decided not to base its QC requirements on a single manual and, therefore, no such manual has been referenced. In addition, NMQAAC has advised FDA that the ACR manuals were intended to be used as guidelines, not in a prescriptive manner. A facility may consult any appropriate manual on agency guidance to meet the requirements in § 900.12(e)(1) through (e)(5).

(Comment 459). One comment stated that some of the tests should be more rigorous. The comment further questioned why a monthly visual checklist was not included.

While conducting regular visual checks of the equipment is a desirable practice, it is not an action that can be confirmed from test data. Therefore, the agency has decided to encourage this and similar desirable practices through educational means instead of making them regulatory requirements.

(Comment 460). Another comment stated that FDA should only issue more stringent requirements if their benefits clearly exceed their costs.

FDA agrees with this comment and believes that the tests it has required meet this criterion.

(Comment 461). One comment stated that numerous paragraphs refer to films, optical densities, and processors, without limiting the requirements to any specific modality.

FDA notes that the initial words in each paragraph from § 900.12(e)(1) to (e)(5) are ''Facilities with screen-films shall * * *,'' making it clear what modality is referred to.

(Comment 462). Another comment maintained that FDA should require proper QC tests for stereotactic units. One comment stated that the quality assurance standards should include a requirement to use a digital mammography evaluation phantom developed by the author's company that has been designed specifically for QC of digital machines for stereotactic biopsy.

Interventional mammography is presently exempt from the MQSA requirements for reasons discussed in response to the comments on the definition of mammography in § 900.2(y). The agency is in the process of developing quality standards for interventional mammography and these will include QC tests. QC tests for other mammographic modalities have been addressed in § 900.12(e)(6).

(Comment 463). Another comment stated that FDA should provide its inspectors with more latitude to accept variations from regular inspection procedures, if the physicist can adequately explain the rationale for the deviations and demonstrate how the standard is met. From the context, the agency assumes that the author of the comment is actually referring to survey procedures rather than inspection procedures.

FDA has instructed inspectors to discuss variations with QC personnel or medical physicists available in the facility during inspection. In some cases, the inspectors, after receiving satisfactory explanations for variances in test procedures, have refrained from giving citations or withdrawn citations initially given to the facility during inspection. However, because it is essential that the evaluations of facility conformance with the quality standards be consistent nationwide, the latitude provided to inspectors necessarily has to be limited. Moreover, those wishing to use alternatives to the requirements of the regulations who can demonstrate that their alternative provides assurance of quality mammography equal to the regulatory requirement, may do so in accordance with § 900.18.

(Comment 464). A few comments urged FDA to require testing with all cassettes wherever that is appropriate.

In the proposed regulations, the agency proposed that screen speed uniformity of all cassettes in the facility be tested. In the final regulations, FDA added that artifact evaluations should be performed with all cassettes in the facility. The agency also considered requiring performance of the phantom image quality test with all sizes of image receptors. However, when FDA staff members carried out phantom image evaluations using two different image receptor and cassette sizes with five different mammography machines, no difference was seen in the phantom image scores when results with larger image receptors were compared to those with smaller. NMQAAC strongly advided FDA not to require weekly phantom testing for all image receptor sizes because the members do not believe that phantom image quality is affected by receptor size. NMQAAC pointed out that the ACR manual did not recommend phantom image evaluation with large image receptor sizes. Based on all this information, the agency concluded that facilities should not be required to conduct phantom image quality tests with all available sizes of image receptors.

b. *Daily QC tests—screen-film system (§ 900.12(e)(1))*

The only daily tests required under the final regulations are those that ensure adequate processor performance by assessing base plus fog density, mid density, and density difference, using mammography films used clinically at the facility.

(Comment 465). Five comments stated that there should be a maximum limit between time of exposure and time of processing. NMQAAC discussed this issue in connection with requirements for mobile units, for which image degradation due to delayed processing is a particular concern. The committee concluded that, in general, this was not a significant enough problem to require a regulatory requirement and FDA accepted this position.

(Comment 466). Ten comments suggested the word ''examinations'' should be replaced with ''films'' and the word ''performed'' with ''processed.'' The agency agrees with these comments and has made such changes in the final regulations.

One comment suggested adding the words ''and evaluate'' after ''shall perform.''

FDA notes that § 900.12(e)(8) generally defines tests for which the evaluation of test results (and corrective actions) must be performed before further examinations are conducted. The processor tests are among them.

(Comment 467). Several comments suggested that the last few words in § 900.12(e)(8)(ii), ''of no less * * * 1.2 OD, [optical density]'' should be deleted. These comments stated that in some cases, the step averages may turn out to be lower, for example 1.05, and that should be acceptable if the next higher step shows a substantially higher OD, such as 1.4. Another comment offered a similar argument, noting that the proposed rules would not allow the use of modern high gradient mammography films where the change in optical density between adjacent steps in this density range can be as high as 0.7.

FDA agrees with these comments and has deleted ''of no less * * * 1.2 OD'' in § 900.12(e)(8)(ii).

(Comment 468). One comment stated that QC measures should be in place for densitometry and sensitometry equipment.

FDA requires all sensitometers and densitometers its inspectors use to be properly calibrated. If FDA inspectors detect problems in the processor performance, the facility will have to identify the cause. If the cause turns out to be related to inadequate performance of the facility's sensitometry or densitometry equipment, the effort required to determine the nature of the problem will give the facility sufficient incentive to take actions to avoid a recurrence without the need for a regulatory requirement.

(Comment 469). Three comments asserted that the ± 0.15 OD action limits for mid-density and density difference were too restrictive as proposed and requested changing this limit to allow a wider range.

Under the interim regulations, facilities have been required to comply with this limit and the inspection data reveal that most facilities are able to do so. The agency does not find that there is adequate reason for changing this limit in the final regulation.

(Comment 470). One comment stated that a guidance document should be published to provide a clear explanation of the scientific basis for establishing an H&D curve and the importance of parameters taken from this curve to monitor trends in processor QC.

FDA believes that this is a widely accepted practice and the most effective procedure that is currently available. Sufficient materials providing the type of guidance requested already exist.

c. *Weekly QC tests—screen-film system (§ 900.12(e)(2))*

In the proposal, the image quality test using a phantom approved by FDA, which was required monthly by the interim regulations, was made a weekly test.

(Comment 471). Twenty comments opposed changing the phantom testing from monthly to weekly, arguing that the additional cost of performing phantom image evaluation weekly would be burdensome to many facilities. However, a larger number of comments supported this change, many indicating that their facility already performs phantom tests weekly.

FDA is convinced by the experience of the facilities that have been performing phantom image evaluation at a higher frequency that the test should be performed weekly. The agency believes that the benefit outweighs a slight increase in costs. As noted in the preamble to the proposal, if the daily total system test had been required, returning the required frequency of the image quality test to monthly could have been justified. However, because FDA is not mandating the total system test at this time, it is essential that all facilities perform weekly phantom image evaluation as an overall assessment of all aspects of the imaging chain.

(Comment 472). Some comments suggested changing ''image contrast'' to ''density difference'' and ''assess density difference'' to ''assess image contrast'' in § 900.12(e)(2)(iv).

The agency agrees with these comments and has revised the wording.

(Comment 473). One comment stated that the density difference between the background and the test object needs to be defined. The comment further stated that there is presently confusion over the ACR recommendation for a density difference of 0.40 at 28 kVp.

FDA notes that, with the changes made as suggested by the previous comments, it is clear that the density difference is measured between the background and a test object added to the phantom to assess the image contrast. The agency has determined that the regulations should not specify a number for the operating level for this density difference, specify the test objects, or prescribe any technique factors to achieve the desired operating level, because all these variables may change with future changes in technology. However, FDA considers it important that facilities make sure that the measured density does not vary by more than ± 0.05 from the established operating level.

(Comment 474). Several comments considered the requirement of a minimum 1.20 optical density (OD) at the center of a phantom image to be high and believed that many facilities will not be able to meet that standard. One comment stated that higher OD is achieved at the expense of patient dose. Some comments considered 1.20 OD too low. One comment recommended that there be an upper limit of OD. Another comment stated that OD within ± 0.20 is reasonable if the film manufacturer's tolerance is better than 0.3 OD from batch to batch.

FDA believes that proper OD is vital to the early detection of micro calcifications and, with the advent of new mammography screen-film systems, an OD of 1.2 with a variation of no more than 15 percent can be achieved if the processors and the units perform properly. NMQAAC also advised FDA to require that the film OD at the center of the phantom image be no less than 1.2 for the purposes of this test. The agency, however, believes that a requirement for an upper limit on OD may hinder any future development of mammography screen-film systems. Therefore, the agency will retain § 900.12(e)(2)(i) and (ii) as proposed.

(Comment 475). One comment stated that the point of the image quality test is to determine constancy; therefore, it was unnecessary to mandate the measuring position of optical density as the center of the image, as long as the same location is measured each time.

The intention of this requirement is that the OD be measured at the same location of the phantom image each time, as the comment suggested. The agency believes that the center of the phantom image is a reasonable and easy place to locate such measurements. Further, it is not advisable to measure OD too far away from the center towards the anode side of the phantom image in order to avoid a decrease in density due to the heel effect. This could lead to a failure to meet the ≥ 1.2 OD requirement when it might have been met if measured at the center of the same phantom image.

(Comment 476). One comment recommended that § 900.12(e)(2)(iv), the phantom image contrast requirement, be deleted because daily film sensitometry already measures this parameter.

FDA disagrees. The daily sensitometry test only uses light that simulates the screen phosphor luminescence. However, emitted light due to X-ray induced fluorescence from the screen phosphors is different both in spectral dependance and in intensity from the light output from the currently available sensitometry equipment. It is

very important that contrast is evaluated when the film is exposed by the emitted light from the actual screen phosphors, induced by the X-ray beam. For this reason, the daily film sensitometry test cannot replace this test of image contrast.

(Comment 477). Several comments noted that the current phantoms are not tissue equivalent and recommended that FDA specify only one type of phantom and minimum acceptable performance criteria. A related comment urged FDA to provide guidance to establish the adequacy of image quality. Another comment requested specification of the test object and measurement conditions for phantom evaluation.

FDA has refrained from specifying phantom or test object type, performance criteria, or scoring methodology in order not to inhibit future advances in phantom technology. The agency continues to believe that accreditation bodies should establish phantom specifications and related performance criteria. However, as part of its responsibilities for accreditation body approval and oversight, FDA will examine each body's phantom specification and performance requirements, which will have to be substantially the same among the different accreditation bodies.

d. *Quarterly QC tests (§ 900.12(e)(3))*

Two QC tests were required to be performed quarterly in the proposal. These were a test of the fixer retention in film and the repeat analysis.

e. *Fixer retention in film (§ 900.12(e)(3)(i))*

This test determines the quantity of residual fixer in processed film, which is an indicator of insufficient washing. Insufficient washing may have a considerable adverse effect on image quality.

(Comment 478). One comment believed that the fixer retention test should be a semiannual test.

FDA notes that quarterly performance was recommended by the ACR manuals and required under the interim regulations. The agency believes that it is generally accepted that facilities should perform this test quarterly and has retained the frequency requirement of this test as proposed.

f. *Repeat analysis (§ 900.12(e)(3)(ii))*

Facilities must perform this test quarterly with repeated and rejected films. If the repeat or reject rate, calculated as a percentage of the total films included in the analysis, changes by more than 2 percentage points from the rate determined the previous quarter, the cause of the change must be identified. (For example, if the repeat rate the previous quarter was 4 percent and this quarter it is 7 percent, the cause of the change must be identified. If the repeat rate this quarter is 6 percent, no further action is needed.)

(Comment 479). A few comments suggested changing ''repeat'' to ''reject.'' One comment stated that it might be more appropriate to simply refer to repeat rate change, rather than repeat or reject rate change.

FDA believes that while the repeat rate is perhaps the better indicator of unnecessary radiation exposure in the facility, the reject rate gives a better picture of the image quality situation. Both rates give useful information and should be calculated.

(Comment 480). Some comments recommended that FDA define repeat and reject to ensure that all but nonclinical films are analyzed. Several comments requested FDA to clarify that films repeated to correct positioning should be included in the repeat analysis. FDA believes that it is current practice that all repeated films are included in the repeat analysis, regardless of the cause of such repeats, and so a regulation mandating this practice is not needed.

Other comments expressed opinions on the most desirable frequency of the repeat analysis. One comment suggested that all repeats be evaluated and corrective action be taken when possible. Several comments recommended monthly repeat analysis and stated that this test would be less useful if it were done quarterly. Another comment urged monthly repeat analysis with 400 films. Another stated that the current method of repeat analysis every 3 months was sufficient.

FDA believes that low volume facilities would not have sufficient numbers to conduct a meaningful analysis if the required frequency is increased. Similarly, if the minimum number of films is set too high, the time period required to collect them in a low volume facility will be so great that problems could go undetected for a significant period of time. FDA, therefore, has left the required frequency as quarterly and has not specified a minimum number of films to be included in the analysis. The agency notes that nothing in the regulations would preclude a high volume facility from performing the analysis at an increased frequency and with as many films as it wished.

(Comment 481). Several comments urged FDA to include an acceptable limit of repeat rate in the regulations, some suggesting that it be 2 to 5 percent. Two comments wanted FDA to require corrective action to lower the observed repeat rate.

FDA again notes that, while most of these comments referred to ''repeat'' analysis, an analysis of both the repeated and the rejected films is required. In response to these comments, FDA observes that it has long been recognized that the parameter with the greatest impact on the repeat or reject rate is the subjective opinion of the physicians doing the interpreting as to what is acceptable. As noted in the preamble to the proposal (see 61 FR 14860), the repeat or reject rate could be reduced by a facility through acceptance of lower quality films. Any range or maximum value for repeat or reject rate that was established as acceptable through a regulation thus could quickly be rendered meaningless as an indicator of acceptable facility performance by such action. Consequently, the agency believes that, while it is important to keep the repeat or reject rate low, it is more important and useful to assess the cause of any change (increase or decrease) in the repeat or reject rate from the previously determined value. Therefore, the agency has retained the proposed requirement that the cause of a variance of more than 2 percent from the value previously determined must be properly assessed and recorded.

In looking for the cause of the change, the agency strongly advises facilities to assess all the factors that can affect repeat or reject rate. These can include personnel ability and preferences, changes in personnel, or variance in machines, processors, films, or chemistry performance.

(Comment 482). Some comments asked why a decrease of 2 percent requires action.

FDA notes, that while it may appear that a decrease in repeat or reject rate is a desired goal and should not require further assessments of the results, this is not necessarily so. For example, if a facility added a mobile unit to its operations, the interpreting physician might feel a subtle pressure to interpret films taken with that unit that he or she might normally reject because of the greater difficulty in scheduling repeat examinations at mobile units. This practice could lead to a reduction in the repeat or reject rate that does not necessarily indicate an improvement in quality. Therefore, the agency believes that the cause of either an increase or a decrease of more than 2 percent from the value previously calculated must be determined and any corrective actions should be recorded and assessed.

(Comment 483). A few comments stated that repeat analysis for each technologist should be evaluated and followup studies should be standardized. One comment wanted

such analysis performed for each machine used in the facility.

The agency supports the idea that analysis of the repeat rate for each technologist, radiologist, and/or machine can be valuable. However, many facilities with a sufficient volume for a meaningful analysis of their total operation would not have a sufficient volume for meaningful analysis of each technologist, interpreting physician, or machine. For this reason, FDA does not believe that a separate analysis for each technologist, interpreting physician, and machine should be a regulatory requirement. However, the agency recommends that each facility consider whether such analysis would be useful in its particular situation.

(Comment 484). One comment urged FDA to provide more guidance, either in a guidance document or by reference to the ACR QC Manuals, as to criteria for repeat and reject rate evaluation and corrective action. Another comment stated that this section needs to be elaborated to specify the frequency at which this test needs to be performed both for large and small volume facilities, guidelines about whether the analysis should be site- or technologist-specific, and acceptable repeat or reject rates. FDA notes that it has provided guidance for establishing an effective repeat and reject analysis program in the past and may provide additional information in the future. However, the agency believes that, as repeat or retake analysis has been an established procedure in radiology for 20 years or more, abundant guidance is also available from other sources. As stated previously, the agency in the final regulation will not reference any manual in order to provide the QC technologists and the medical physicists with flexibility to design their own analysis, recording, and corrective action procedures.

g. *Semi-annual QC tests (§ 900.12(e)(4))*

The proposal included requirements for semiannual tests of darkroom fog, screen-film contact, and compression.

The test of darkroom fog in § 900.12(e)(4)(i) is intended to be performed to identify light sources in the darkroom that can cause significant mammographic film fogging.

(Comment 485). One comment supported § 900.12(e)(4)(i) as written. The comment further stated that retaining the paragraph as proposed would eliminate variables for inspectors when performing this test. Several comments urged that certain test conditions be required, such as: ''Carry out the test under clinical conditions, with or without the safelight;'' ''use previously sensitized film;'' or ''place the test film on the counter top or on the processor feed tray (if not covered), whichever is closer to a safe light that remains on when the film enters the processor.'' Several other comments recommended adding words such as ''emulsion side up'' or ''where the mammography film is usually handled'' at specified points in the requirement.

After discussions with NMQAAC, FDA concluded that the comments did not provide a basis for amending the provision. The agency has retained § 900.12(e)(4)(i) as proposed, except that the words ''emulsion side up'' have been added for clarification. The agency will provide information on test procedures, as some comments requested, separately. Each facility can design its own procedures to meet the generally accepted features of an adequate darkroom fog test.

(Comment 486). A number of comments suggested requiring the darkroom fog test after any change in the darkroom that could result in an increase in the amount of fog.

FDA agrees that many changes in the darkroom could produce darkroom fog but it also believes that it is difficult to specify which changes will lead to increased film fogging. The agency has left it to the judgment of the facility as to which changes may lead to increased film fogging and thus warrant an additional darkroom fog test.

(Comment 487). One comment recommended that the acceptable value of darkroom fog be raised to 0.10 OD and believed that 60 percent of facilities will not be able to pass the test as written.

FDA does not agree that the majority of facilities will not be able to meet the required acceptable level of dark room fogging within 0.05 OD. This requirement is currently in effect under the interim regulations and the agency's inspection data indicate that most facilities are in compliance with this requirement.

(Comment 488). One comment urged FDA to require a clearly written procedure that ensures that the darkroom tests are performed using mammography films.

The agency considers this a good practice and recommends that facilities adopt such procedures. However, FDA does not believe that this requires a regulation.

The screen-film contact test in § 900.12(e)(4)(ii) is intended to ensure that proper contact is maintained between the screen and film in each cassette used in the facility for mammography.

(Comment 489). Several comments noted that the material of the 40 mesh screen used for the test was not specified and suggested that it be copper or a material with an atomic number similar to copper.

FDA agrees with these comments and has specified the requirement of 40 mesh copper screen in the final regulation. It has also clarified that all cassettes used in the facility for mammography must be tested.

(Comment 490). Two comments asserted that a minimum background density needs to be specified for the screen-film contact test, with one of these stating that it should be 0.60 to 0.85 so that the films are not underexposed leading to false readings. One comment wanted acceptance levels to be prescribed in some detail, while another comment stated that additional information was needed as to what constitutes an adequate screen-film contact test result. Two comments suggested the following criterion: ''Areas greater than 1 cm are not acceptable, five or more areas less than 1 cm are acceptable.''

FDA considers this test very important. A 40 mesh copper screen provides adequate resolution and contrast with a mammography film when exposed to a proper density. However, evaluations of these test results can be subjective and cannot be verified against a quantified acceptance level. Therefore, the agency cannot prescribe a numerical value of acceptance level in the regulation, as some comments suggested, because it would not be readily enforceable. FDA notes, however, that it does not agree with the comment that stated that five or more areas of poor contact with a size smaller than 1 cm are acceptable. The agency intends to provide further information on this test. The agency also notes that advice is also available in most QC manuals.

Compression testing is required to ensure that a mammographic system provides adequate compression and, at the same time that the equipment does not allow dangerous levels of compression to be applied. In the proposal, FDA required the compression device to meet specifications described in § 900.12(b)(12)(i) and, in accordance with § 900.12(e)(4)(iii), to be tested semi-annually to see if the specifications continue to be met. After further consideration, the agency determined that in the final rule it would be more appropriate to treat the compression forces as performance outcomes rather than equipment specifications. As a result, the standards for the amount of the compression force

have been transferred from § 900.12(b) to § 900.12(e)(4)(iii). The comments received on this aspect of proposed § 900.12(b)(12)(i) are discussed at this point with the related comments received on § 900.12(e)(4)(iii).

(Comment 491). A number of comments stated that some of the characteristics of the compression system described in § 900.12(b)(12)(i) did not need semiannual QC testing.

FDA agrees with these comments and, in the final regulation under § 900.12(e)(4)(iii), has required that only the compression force be tested.

Under § 900.12(b)(12)(i)(c) FDA proposed that, 5 years after publication, the compression device shall provide a maximum compression from the power drive between 111 newtons (25 pounds) and 200 newtons (45 pounds).

(Comment 492). Several comments urged FDA to make the compression force requirement in the power drive mode effective immediately, not 5 years from publication as proposed. On the other hand, one comment disagreed with the April 1996, recommendation of NMQAAC that the proposed requirements be implemented 1 year after the publication of the final rules. One manufacturer stated that this requirement would affect approximately 2,000 of their units in the field and noted that it would be impossible to upgrade many of these units to the full 25 pounds. Additionally, the retrofit kit is likely to be very expensive and not welcomed by users who find a precompression force of 17 pounds adequate when accompanied with appropriate manual compression.

Although NMQAAC did recommend making the requirement effective 1 year after publication at its April 1996 meeting, they reversed that position in January 1997 after considering the possible cost of the action. The agency has thus retained in the final rule at § 900.12(e)(4)(iii), the requirement of compression force in power drive mode 5 years from the date of publication, as proposed in § 900.12(b)(12)(i)(c).

FDA, however, also considers it important that all mammography machines used currently provide adequate compression force. Under the interim regulations, facilities are required to use equipment that provides a minimum compression of 111 newtons. The agency is continuing to require this minimum compression force. In case of machines where such force is not available in power drive mode, the facilities may use the manual compression to attain this minimum compression requirement. However, 5 years after the publication of the final rule, all machines must provide a maximum compression force in power drive mode of between 111 newtons (25 pounds) and 200 newtons (45 pounds).

h. *Annual QC tests (§ 900.12(e)(5))*

Section 900.12(e)(5)(i) through (xi) lists a number of tests a facility must perform annually. Action limits for the test results are specified, except for the system artifacts (§ 900.12(e)(5)(ix)) and decompression (§ 900.12(e)(5)(xi)) tests; the nature of these do not allow the agency to provide any quantified acceptance level. The tests described in § 900.12(e)(5)(i) through (ix) were proposed as QC tests. The tests in § 900.12(e)(5)(i)(x) and (xi) have been moved from § 900.12(b) of the proposal after FDA concluded that they are more performance than specification oriented and, therefore, are more appropriately located in § 900.12(e) in the equipment quality assurance section of the final regulation.

(Comment 493). One comment stated that the regulation should require these tests to be done by a qualified medical physicist. FDA notes that this requirement already appears at § 900.12(e)(9), which requires that these tests be done as part of the facility survey and further requires that the survey be performed by a qualified medical physicist.

Two comments questioned why the proposed requirements under § 900.12(e)(5) established testing limits different from those used by the accreditation body. The comments claimed that these ''discrepancies'' will hinder compliance. FDA believes that the authors of these comments are mistaken. The agency assumes that by ''testing limits,'' the comments are referring to action limits. FDA notes that the action limits of § 900.12(e)(5) are the same as those in the ACR manuals, and thus, the same as those the facilities and the accreditation bodies are using under the interim regulations.

The automatic exposure control (AEC) test in § 900.12(e)(5)(i) measures several parameters of the AEC system.

The first action limit specified for the AEC is that it shall be capable of maintaining the film optical density within ± 0.30 of the mean optical density as the phantom thickness and kVp are varied in § 900.12(e)(5)(i)(A).

(Comment 494). Some comments wanted a definition of ''Mean Optical Density.''

FDA notes that such a definition was provided in § 900.2(w) of the proposal, now § 900.2(ee) in the final regulation.

(Comment 495). Other comments asked FDA to specify the type of phantom needed for this test or asked if the same phantom used for the image quality test is required. A related comment stated that the test blocks used by the physicists should be specified to be 15 x 15 mm homogeneous material, in order to ensure an even scatter pattern or distribution that would not be affected by the position of the AEC and inhomogeneous scatter. The comment suggested that phantoms made up of either acrylic or BR12 can be used. Another comment wanted the test details and acceptance levels to be prescribed.

The agency requires the thickness of the phantom to be varied from 2 to 6 cm. These thicknesses are currently required under the interim regulation and the facilities may use any homogeneous material of appropriate thicknesses that will provide a film OD of no less than 1.2 at the center of the image. The agency has previously discussed its rationale for not providing detailed test procedures.

(Comment 496). One comment requested FDA to clarify whether testing is required with all available thicknesses and kVp's. FDA has changed the wording in the final regulation to clarify that AEC tracking is required only for phantom thickness varied over a range of 2 to 6 cm and for kVp's varied appropriately for such thicknesses over the kVp range used clinically.

Proposed § 900.12(e)(5)(i)(C) established an alternative to proposed § 900.12(e)(5)(i)(A) by allowing the development of a technique chart of kVp and density control settings to ensure that the film optical density requirements of § 900.12(e)(5)(i)(A) would be met in cases where it could not be done directly by AEC.

(Comment 497). Two comments stated that a technique chart should be required for all machines under all situations. Two others stated that the proposal created a loophole for the AEC equipment specification requirements proposed in § 900.12(b)(15)(vii)(A). One comment asked if a technique chart would be acceptable in the year 2000 when all machines are expected to meet the ± 0.3 OD variance requirement. One comment suggested eliminating the option of using a technique chart.

The agency has combined the provision permitting the use of a technique chart with § 900.12(e)(5)(i)(A) in the final rule. After consideration of the comments, FDA has decided to permit the use of a technique chart to meet the ± 0.3 OD variance requirement only for 5 years after the publication of the final regulation. After 5 years, the AEC equipment must meet the ± 0.30 OD variance requirement directly.

FDA has moved a provision proposed as an equipment requirement in

§ 900.12(b)(15)(vii)(B) to the quality assurance paragraph as § 900.12(e)(5)(i)(B). As explained earlier, the move was made because this provision was more appropriately located with the QC performance tests than with the equipment specifications. This provision requires, effective 5 years from the publication of this regulation, that the film optical density be maintained within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. Use of the technique chart to compensate for inadequacies in the AEC will no longer be permitted after that date.

(Comment 498). In response to the original proposal in § 900.12(b)(15)(vii)(B), one comment requested that FDA clarify whether compensation steps using a technique chart will be allowed. The comment also stated that ± 0.15 OD criteria can not be met if the film manufacturers allow 0.3 OD variation from one film batch no another.

As noted in the previous paragraph, FDA will permit the use of a technique chart to compensate for inadequacies in the AEC for 5 years after the publication of the final rule; after that time the technique chart can no longer be used as an aid in maintaining the film optical density within ± 0.15 of the mean optical density at the appropriate kVp-thickness combination. The agency also advises facilities to use films from the same batch so that film variability, if any, is not introduced while testing AEC performance. Because film variability can be eliminated as a source of bias in the AEC performance test, there is no justification for increasing the AEC actions limit to ± 0.30 OD because that would simply mean that the facility would have to contend with variability of ± 0.30 from the film and another ± 0.30 from the AEC.

(Comment 499). Two comments stated that the proposed requirement was too lenient, while two others believed that it was too restrictive. Three comments supported the proposed requirement.

FDA believes, after discussion with NMQAAC, that it is reasonable to require that the ± 0.15 OD limit be met by all units 5 years after publication of the final rule. The agency believes that the cost to meet this requirement will be minimized by the fact that, by the end of this period, many of the units unable to meet the ± 0.15 OD requirement will have been replaced by facilities on their normal replacement schedules. The agency does not believe it has any basis to require a tighter limit than ± 0.15 OD.

Section 900.12(e)(5)(i)(C) (proposed § 900.12(e)(5)(i)(B)) proposed that the operating OD be no less than 1.20.

(Comment 500). Several comments suggested deleting the word ''operating.'' One comment requested the definition of ''Operating OD.''

FDA agrees that the word operating should be deleted. This requirement is now moved to § 900.12(e)(5)(i)(C) in the final rule.

One comment urged FDA to require a mean optical density of at least 1.3 OD. FDA notes that the regulation allows facilities to use a higher film OD if they believe that will make the test a better indicator of the ability to detect micro-calcifications and will aid in improving image quality. However, the agency does not consider it necessary at this time to require any higher OD. The agency also notes that NMQAAC advised FDA to retain the 1.2 OD requirement as proposed.

The annual test in § 900.12(e)(5)(ii) tracks the kilovoltage accuracy and reproducibility.

(Comment 501). A large number of comments stated that kVp accuracy should be within 5 percent instead of the proposed ± 10 percent.

The agency is persuaded by these comments and has made the change in the final regulation.

(Comment 502). One comment questioned the justification of a very tight coefficient of variation for the kVp reproducibility.

FDA believes that the coefficient of variation of a given set of kilovoltage measurements should be less than 0.02, as was proposed. This is the standard presently required under the interim regulations and most facilities are currently in compliance with it; there is no justification for relaxing the standard, either from the point of view of public health or a cost consideration.

(Comment 503). Several public comments and a member of NMQAAC expressed concern that one widely used kVp testing instrument does not read below 23 kV, while kilovoltage settings as low as 21 or 22 kVp are sometime used. A few comments suggested requiring kVp testing at two clinical setting values. One comment stated that § 900.12(e)(5)(ii)(B), as written, could be interpreted to mean kVp reproducibility should be measured from 25 to 30 kVp in 0.5 kVp increments. Another comment stated that it should be acceptable to test kVp reproducibility in just one setting within the clinical range.

In response to these comments, FDA has revised the final regulation to require that the lowest kVp at which accuracy be tested is the lowest clinical used kVp that can be measured by a kVp test device. The agency, however, disagrees with the comments that recommend testing kVp at one or two clinical settings only. FDA considers it important to test kVp accuracy at least at the highest and lowest measurable clinically used values, and at the facility's most commonly used clinical kVp. The agency, however, has modified the regulation to require that the coefficient of variation of reproducibility be determined at the most commonly used kVp only.

One comment claimed that the kVp accuracy requirement should be checked with all focal spots. The agency has no reason to believe this is necessary.

The focal spot condition (proposed as system resolution) test in § 900.12(e)(5)(iii) was proposed to evaluate the performance of the mammography unit by assessing the resolution capability of the system.

(Comment 504–505). A few comments stated that some mammography machines could not meet the proposed resolution requirement even though the focal spot size was adequate. One comment maintained that the line pair resolution requirement was too restrictive. A member of NMQAAC stated that, in magnification mammography, the resolution requirement would be difficult to meet. These comments suggested that the focal spot size measurement be added as an alternative requirement, as is the current practice under the interim regulation. Two other comments also urged FDA to continue to permit focal spot dimension measurements as part of acceptance tests for mammography equipment evaluation. One comment supported replacing focal spot measurement with performance related specifications of system resolution.

FDA considered the immediate economic impact on facilities of meeting the resolution requirement as proposed and decided to permit continued use of the focal spot size measurement as an alternative to the measurement of system resolution for a period of 5 years from the publication of the final regulation. During this period, facilities may evaluate the condition of the mammography unit by determining either the system resolution, proposed as § 900.12(e)(5)(iii) (new § 900.12(e)(iii)(5)(A)), or the focal spot dimensions as described in § 900.12(e)(5)(iii)(B). The agency believes that by the end of this period, when the regulation will require the evaluation of system resolution only, many of the units unable to pass the system resolution test will have been replaced by the facility on its normal replacement schedule.

The agency believes the benefits of assessing overall performance of the system through use of the system resolution test justify their transition. NMQAAC also advised FDA to require the system resolution test.

(Comment 506). One comment suggested that FDA should only require that the resolution shall be sufficient so that the system can detect micro-calcifications of 300 µm and greater sizes.

FDA notes that available scientific data indicate that 50 µm resolution is necessary in mammography imaging for early and proper detection of micro-calcifications. This is equivalent to about 10 cycles (lp)/mm resolution when the bar pattern is used. The agency believes that all new equipment meets this requirement as proposed. Under the interim regulation, this criterion is already being met by the facilities which chose to evaluate focal spots by assessing system resolution. Further, NMQAAC advised FDA to adopt such a requirement in the final regulation. For these reasons, the agency did not accept the comment.

(Comment 507). A member of NMQAAC advised FDA that the units should be specified in SI units and suggested using ''ycles/mm'' in place of ''ine pairs/mm.'' One comment stated that the height of the line-pair test pattern above the image receptor must be specified in association with the resolution limits and suggested that the height should be 4.5 cm. Other comments requested clarification of ''parallel'' and ''perpendicular'' to the axis in terms of the bars of a test pattern whose orientation was being described. Three comments urged that test specifications be included in the regulations.

In response to these comments, FDA has added a new § 900.12(e)(5)(iii)(A) to specify that the high contrast resolution bar patterns must be placed 4.5 cm above the breast support surface and be oriented parallel and perpendicular to the anode-cathode axis. FDA has also introduced cycles/mm as the primary unit.

(Comment 508). One comment asked at what magnification the system is required to resolve 11 and 13 lp/mm. Another comment suggested that the tests should be performed at all magnifications used. Two comments urged FDA to require focal spot assessment for all focal spot sizes. One comment suggested that the system resolution should be tested with the grid in use. One comment suggested that the grid should not be in the imaging chain during magnification.

FDA reiterates that 5 years from the date of publication of the final rule, all facilities must perform the system resolution test annually and must meet the requirements specified in § 900.12(e)(5)(iii)(A)(1), both in contact mode and in all magnification mammography modes used in the facility. The agency believes that if a machine can meet the requirements using the large focal spot size used in contact mode, it will meet the requirements using the small focal spot size also. The agency also believes that the resolution test must be conducted under the normal operating condition, that is, for contact mammography the resolution assessment must be performed with the grid in place whereas for magnification mammography, the grids should be removed. The agency intends to provide more discussion about these procedures in educational documents.

(Comment 509). Two comments stated that the line-pair minimum should be increased.

FDA believes that the present values are generally accepted as representing the best cost/benefit compromise.

(Comment 510). One comment recommended requiring a monthly phantom test with indicators of what should be expected in resolution capabilities at a given magnification to ensure adequate performance between physicist surveys. The comment also recommended that the system resolution in magnification mode be monitored to determine whether it diminishes with time.

Although it encourages facilities to carry out this type of performance-based study, FDA does not believe there is adequate evidence to show that these additional tests would produce benefits that outweigh the costs facilities would incur in performing them. Therefore, at this time, the agency is not including them in the regulation.

The beam quality and half-value layer (HVL) paragraph as proposed in § 900.12(e)(5)(iv), required the HVL to meet the specifications provided in § 900.12(b)(11). Two comments stated that the exact specifications should be included under § 900.12(e)(5)(iv), rather than merely by reference. Two comments suggested that the upper HVL limits described in the 1994 ACR QC Manual should also be included and that HVL limits should be specified for other target filter combinations.

In the final rule, FDA has specified HVL requirements only in § 900.12(e)(5)(iv). The specifications for kVp's in the mammographic range are provided in a tabulated form. Values not shown in the table may be determined by linear interpolation or extrapolation. NMQAAC members were unable to reach a consensus on the value of having an upper limit of HVL or on what the upper limit should be. FDA views this as an indication that there is a general lack of consensus on this topic in the mammography community and, therefore, the agency has decided not to include any upper limit in the regulation.

The breast entrance exposure and AEC reproducibility paragraph, as proposed in § 900.12(e)(5)(v), established the action limit for the coefficient of variation of these two variables at 0.05.

(Comment 511). Three comments suggested deleting the breast entrance exposure requirement, while another considered it to be an equipment standard. This last comment further stated that lack of AEC reproducibility will be identified by other QC tests and the phantom image. Another comment inquired whether it was the intent of the provision to require facilities to calculate exposure reproducibility for data points consisting of mR divided by mAs, or to separately measure the reproducibility of exposure and mAs.

FDA believes that this test must be performed at least annually and that the coefficient of variation must be calculated for both exposure and mAs. If a unit does not indicate a post-exposure mAs value, then mAs should be obtained by a secondary method. In accordance with the movement towards the use of SI units discussed in connection with the new definition of air kerma (§ 900.2(d)), the agency has also introduced air kerma as the primary quantity to be measured in this test. Breast entrance exposure remains as an alternative quantity.

The dosimetry test in § 900.12(e)(5)(vi) determines the mean glandular dose delivered during a single cranio-caudal view using an FDA approved phantom simulating a standard breast. When the mean glandular dose exceeds 3.0 mGy, corrective action is required.

(Comment 512). A number of comments were received on the specifications for the phantom to be used in performing this test. Some comments stated that most facilities are using phantoms simulating a 4.5 cm breast and it would not be cost effective to change to phantoms simulating a 4.2 cm breast. One comment suggested that FDA should recognize that most technique charts are set using whole number thicknesses, arguing that 4.0 cm is probably the most reasonable. One comment stated that ACR phantoms are not tissue equivalent phantoms.

Another comment stated that, to date, most dose data had been set using the RMI accreditation phantom. The comment questioned its actual tissue equivalence and further stated that dose standards should be set using a phantom that correlates as closely as possible to actual thickness.

In the preamble to the proposal (61 FR 14912), FDA solicited comments about actual thickness that the existing phantoms simulate. FDA did not receive enough evidence in response to this question to convince the agency that the existing phantoms simulate a 4.0 cm compressed breast more closely than they simulate a 4.2 cm compressed breast, which is the figure currently used. The agency, therefore, continues to require that the dose should be determined under the assumption that the phantom simulates a 4.2 cm compressed breast and that the technique factors should be chosen accordingly. FDA did not propose, nor has it required in the final rules, any change in the phantoms currently being used. As stated earlier, the agency believes that accreditation bodies should establish phantom specifications and related performance criteria. In the future, if better tissue equivalent phantoms are available to simulate a different compressed breast thickness that can change dose calculations significantly, the agency will revise the thickness requirement for average dose calculation. FDA also notes that a change from 4.2 cm to 4.0 in thickness does not result in a significant change in the calculated dose.

(Comment 513). One comment stated that calculation of the entrance dose to the phantom is not necessary if kVp, HVL, and mAs for the exposure are within limits. Another comment stated that, because the existing image quality phantom simulates a 4.2 cm compressed breast, not 4.5 cm, the dose limit could be lowered. One comment stated that the regulations should not allow any dose less than 0.8 mGy, while another comment stated that there is no reason for accepting 300 mrad as a maximum mean glandular dose because, even at 25 kVp, the typical mean glandular dose is 120–150 mrad (1.2–1.5 mGy). This comment recommended setting the dose limit at 250 mrad (2.5 mGy). Another comment recommended that FDA consider lowering the patient dose requirements to that of the State of California requirement.

FDA strongly believes that a proper dose calculation at least once a year for each unit is critical for public health and safety. FDA further believes that the present dose limit of 3.0 mGy provides adequate protection from unnecessary radiation and does not want to change the dose limit to 2.5 mGy or establish a lower limit of 0.8 mGy, in order to avoid the possibility of inhibiting future advances in imaging technology, as discussed in the preamble to the proposal (61 FR 14912).

(Comment 514). One comment suggested that the phantom kVp and mAs must be compared to the average of 20 or more 4.2 cm clinical breast mammograms to ensure that the measured glandular dose is consistent with patient radiation doses.

In response to this comment, the agency notes that the dose must be determined with technique factors and conditions used clinically for a standard breast. The agency understands that, for some facilities, commonly used technique factors may be slightly different from what would be technique factors for a standard size breast and therefore different from what would be used for the available phantom, which simulates a standard breast. However, the agency does not believe that dose will vary so significantly that it will exceed the required limit of 0.3 mGy in cases of patients with non standard breast size, as long as the mammography unit is capable of meeting the dose requirement using a phantom simulating a standard breast.

(Comment 515). Two comments urged FDA to require that the time of exposure be less than or equal to 2.5 seconds. FDA did not accept this comment because the agency believes that it does not have enough evidence to confirm that 2.5 seconds is the absolute maximum exposure time needed to cover all patient sizes. The agency recommends that facilities determine the proper exposure time for their needs through consultation with the medical physicists and the equipment manufacturers.

The requirements for X-ray field/light field/image receptor/compression paddle alignment in § 900.12(e)(5)(vii) are intended to ensure that: (1) All systems have beam limitation devices that prevent the patients from receiving unnecessary radiation dose, permit imaging of the critical breast tissue near the chest wall, and avoid white borders on the film; (2) if a light field is provided, the congruence of the light field with the X-ray field should be such that the sum of misalignments on opposite sides between X-ray field and light field is within 2 percent of the SID; and (3) the alignment of the edge of the compression paddle with the chest wall edge of the image receptor is sufficient to permit pulling the breast tissue away from the chest wall for imaging and to keep the shadow of the vertical edge of the paddle from being visible on the image. The test also ensures that the extension of the edge of the paddle is within 1 percent of the SID so that the patient's chest is not pushed away from the breast support surface.

(Comment 516). One comment stated that § 900.12(e)(5)(vii) should include exact specifications rather than just a reference to those specifications in § 900.12(b)(5). One comment argued that confinement of the X-ray field within the image receptor cuts off useful film area and misses some of the breast tissue. The comment further suggested that this requirement should be changed so that the X-ray field can extend slightly beyond the edges of the image receptor in order to make full use of the film area and not potentially miss any breast tissue that is overlying the image receptor, and to blacken what would be an otherwise clear border.

In the final regulation, FDA has moved the X-ray field/light field/image receptor/compression paddle alignment specifications to § 900.12(e)(5)(vii). FDA notes that § 1020.31(f)(3), which the agency referenced in the proposal, allows extension beyond the chest wall edge of the image receptor by as much as 2 percent of the SID so as to properly image breast tissue on the chest wall side. In the final rule, the agency allows extension of the X-ray field beyond all edges of the image receptor but limits this extension to within 2 percent of the SID.

(Comment 517). Two comments suggested that the term ''image receptor'' should be defined. In the agency's earlier discussion of the definitions, the agency has referenced § 1020.31 as providing a definition of image receptor.

(Comment 518). One comment stated that the requirement for a light field in this section imposes an unwarranted expense.

FDA notes that a light field is not required but if one is present, it must meet the light field-X-ray field alignment requirement.

(Comment 519). One comment urged FDA to consider relaxing the requirement for the alignment of the compression paddle and the breast support surface. One comment questioned whether limiting the extension of the compression paddle beyond the image receptor to within 1 percent of SID is achievable in all units. Another comment suggested that this requirement be written to more accurately reflect the need to extend past the edge of the image receptor, although by no more than 1 percent of the SID. Three comments stated that it appeared from the proposed regulation

that it was permissible for the compression paddle to be visualized on the mammography film.

FDA believes that the one percent extension limitation can be achieved and notes that the current requirement under the interim regulations is one percent. The agency has also clarified the final rule to emphasize that the shadow of the compression paddle shall not be visible on the image.

(Comment 520). One comment requested clarification on whether the reference was intended to be with respect to a vertical line or with respect to a line connecting the focal spot and edge of the image receptor when the requirement that the chest wall edge of the compression paddle not extend beyond the chest wall edge of the image receptor by more than one percent of SID is being met.

(Comment 521). One comment suggested that FDA specify whether this requirement is with respect to the interior surface of the paddle or the exterior surface. The comment, however, acknowledged that this is not an important issue with a 1 or 2 mm paddle thickness.

FDA disagrees with comments that suggest including all these details in the regulation. However, the agency wishes to clarify that the reference is the vertical line and the requirement refers to the interior surface of the paddle.

One comment stated that this requirement should be met with all image receptors. FDA notes that the regulation as written requires this test to be performed for all full-field aperture sizes used for beam limitation in the facility; this will ensure that all image receptors meet the requirement.

The screen speed uniformity test, as proposed in § 900.12(e)(5)(viii), requires that at least once a year, each facility must ensure the consistency of the screen speed among all cassettes used in the facility for mammography. The same test is required currently at the same frequency under the interim regulation.

(Comment 522). One comment stated that § 900.12(e)(5)(viii) did not allow for slow and fast screen variations due to large and small screens having different relative speeds. Another comment suggested that the maximum optical density difference should be reduced to 0.15.

FDA believes that the difference between the screen speeds of all cassettes, small or large, should be such that the OD variation is within 0.3 OD. The agency, however, does not believe that tightening the restriction on density difference to 0.15 is justified. Members of NMQAAC supported this view.

One comment requested FDA to describe the test procedure to be used. As discussed earlier, FDA made a general decision to refrain from describing specific test procedures for QC tests in the regulations. The agency will include a more detailed description of some tests in its guidance document.

System artifacts in § 900.12(e)(5)(ix) mean artifacts produced by any part of the mammographic system, including the X-ray machine, screen-film system, and/or processors. This subparagraph requires the facility to determine the level and possible adverse effects of artifacts produced by its systems. These artifacts should be distinguished from the patient related artifacts.

(Comment 523). One comment stated that the evaluation should be done for all full-field image receptor sizes.

FDA agrees and has added this requirement to the final regulation.

(Comment 524). One comment recommended elimination of this test because the physicists always watch for artifacts whenever a film is taken.

FDA strongly believes that a separate test solely meant for artifact evaluation is necessary. Further, this test should also evaluate the whole imaging chain for the source of any artifacts detected.

(Comment 525). One comment stated that the test can also be done with a smaller phantom positioned closer to the collimator. As advised by NMQAAC, FDA proposed that artifacts should be evaluated through the use of a test object of high grade defect-free material that is large enough to cover the mammography cassette.

FDA notes the intent in requiring an object of this size is to capture and identify artifacts that are caused anywhere in the cassette and its screen-film combination. In this way, the quality of the entire film can be better assured. FDA understands that there may be other ways of accomplishing this goal, such as the method suggested in the comment, but the agency lacks data to confirm that the suggested procedure will produce equivalent results. The agency notes that the alternative requirement mechanism of § 900.18 provides a way by which alternatives to the requirements can be evaluated, and possibly accepted, by FDA.

(Comment 526). One comment stated that more guidance should be provided on evaluating artifacts. One comment wanted the test details and acceptance levels prescribed.

Again, FDA has decided that test details are subjects more appropriately addressed separately from the regulations. The agency also notes that the acceptance level for artifacts is at present a subjective assessment and not amenable to the establishment of specific numerical standards.

(Comment 527). One respondent believed that testing X-ray systems for artifacts does not require the use of a test object. Another comment stated that use of a thick (4 cm) acrylic test object will harden the beam to the point that it will mask grid and/or carbon fiber cover artifacts and may even mask grid lines.

FDA disagrees. The agency believes that an exposure time sufficient to image appreciable artifacts may not be achieved if a test object is not used, while these artifacts would be visible during a normal patient exposure.

FDA has moved the radiation output requirement from § 900.12(b)(15) to § 900.12(e)(5)(x) because it concluded that it was more appropriate to treat this test as an annual QC test rather than an equipment specification. This test is intended to determine if the mammographic system is capable of producing a minimum required output. Five years from the publication of the final rule, the requirement will change to require a higher output from each system.

(Comment 528). Two members of NMQAAC opposed this requirement as an annual test. One member stated that a 3-second field test of the unit may cause damage to the tube. The same NMQAAC member further stated that averaging the results over a 3-second exposure time would not reveal whether the output rate dropped unacceptably low at any time during the exposure.

FDA does not have evidence indicating that any significant fluctuation in exposure takes place within an exposure time of the order of 3 seconds. However, the agency has revised this requirement in § 900.12(e)(5)(x)(B) from that originally proposed in § 900.12(b)(14) to clarify that no instantaneous radiation output requirement is intended; instead, the requirement is the output averaged over a 3-second period. Also, because the exposure times can be lengthy for some patients, the agency does not consider 3-second exposure time unreasonable. The agency also considers a yearly check of radiation output important and reasonable.

i. *QC tests—other modalities (§ 900.12(e)(6))*

This provision requires facilities using image receptor modalities other than screen-film to establish a quality assurance program that is substantially the same as that recommended by the image receptor manufacturer, except that the maximum allowable dose is not allowed to exceed that established in

§ 900.12(e)(5)(vi) for screen-film systems.

No public comments were received on this paragraph and it has been codified as proposed.

j. *Mobile units (§ 900.12(e)(7))*

This provision requires mammography units used at more than one location to meet all of the quality assurance requirements established in § 900.12(e)(1) through (e)(5). In addition, at each visit at each examination location, before any additional examinations are conducted, the facility is required to verify the performance of such units using an adequate test method.

(Comment 529). Three comments supported the additional testing of mobile units. One of these noted that the many environments in which the units operate made the testing necessary. Six comments opposed the additional testing. The most common reasons given for the opposition was concern about being able to process the test images before mammography is performed and that the additional testing was unnecessary because moving the unit did not create any problems.

When the need for additional testing of mobile units was discussed at the NMQAAC meeting of September 1994, it was noted that a recent ACR survey of facilities operating mobile units had found that about one in seven facilities reported quality problems with their mobile units at least weekly. Largely based on this information, NMQAAC recommended that postmove, preexamination testing of mobile units be included in the final regulations. NMQAAC continued to support this proposed requirement at its January 1997 meeting.

FDA agrees that no change should be made to the proposal. The agency further notes that several of the opposing comments based their concern upon the difficulty of processing phantom images at the mobile site. However, the final regulation does not require the use of any specific test, only that the test method be able to verify that adequate image quality is being produced by the unit. This gives the facility the option of using other tests that do not require processing of images before examinations are conducted, as long as the test can demonstrate that adequate image quality is likely to be achieved. One such test, based on the consistency of mAs readings, was described by a speaker at the September 1994 NMQAAC meeting.

(Comment 530). Five comments expressed concern about the fact that acceptable testing methods were not specified in the regulations. Three of these comments asked who a facility should consult to determine if its test method would be considered adequate by FDA. Related comments on this issue asked how inspectors would determine adequacy without guidance and noted that the State of Massachusetts left it to the medical physicist to determine what test method should be used. One comment urged that a test based on the mAs reading be considered acceptable, while another stated the performance test required by the State of Illinois should be recognized by FDA.

FDA plans to issue information describing test methods that it is likely to consider acceptable for verification of performance of mobile units after a move and before examinations are conducted. It is expected that at least one of these methods will not require the processing of images before the examinations begin. Because these methods will not be regulatory requirements, FDA may accept other test methods proposed by facilities, medical physicists, or other interested parties. Facilities are always free to discuss any particular method with FDA prior to establishing its use.

(Comment 531). One comment opposed allowing central film processing for mobile services out of concern for degradation of the latent image during the time between exposure and development.

This issue was discussed at some length at two NMQAAC meetings and the conclusion was that this degradation would not be significant during the typical times between exposure and development of mobile facility images. FDA, therefore, has not prohibited central processing.

(Comment 532). One comment stated that if diagnostic imaging is done at a mobile facility, a radiologist should be present. Practice of medicine issues have made it difficult to define the distinction between screening and diagnostic mammography. Because of this difficulty, FDA has issued the final regulations to apply to all mammography, rather than addressing specific requirements to one area or the other.

k. *Use of test results (§ 900.12(e)(8))*

The provisions of this proposed paragraph were intended to ensure that the facility did not stop with the performance of the quality assurance tests but analyzed the results of the tests to determine if problems existed and took necessary actions to correct those problems. Ongoing anecdotal evidence and the MQSA inspection data indicate that, even 20 years after the introduction of the concepts of quality assurance, some facilities are still neglecting to take the important final steps in the process.

Section 900.12(e)(8)(i), as proposed, requires facilities to compare the results of their quality assurance tests with action limits specified in § 900.12(e)(1) through (e)(6) and, if their results fall outside the action limits, to repeat the tests immediately to verify that the testing process was not responsible for the result.

(Comment 533). Thirteen comments opposed, at least in part, the requirement to repeat the tests immediately. Some of these comments urged that it be applied only to the processor QC, screen-film contact, and average glandular dose tests. Two comments supported exempting annual tests. Four of the comments stated that the decision about what tests should be repeated should be left to the medical physicist. NMQAAC recommended complete deletion of the proposed requirement that the tests be repeated immediately. One comment took the opposite view, stating that this requirement helps facilities identify trends.

FDA notes that this requirement was originally added to ensure that the facility confirmed whether the problem was due to the equipment rather than an improperly performed test before it went to the trouble and expense of taking corrective actions. However, the agency has been persuaded that a facility that goes to unnecessary expense to correct an equipment problem that was actually a testing problem is likely to take steps on its own to avoid repetition of such a situation. In view of that conclusion, and the public comments, the requirement to repeat the test has been deleted from the final regulations.

Section 900.12(e)(8)(ii), as proposed, stated that if the repeated tests continue to produce unacceptable results, the problem shall be identified and corrected before any further examinations are performed.

(Comment 534). Seven comments stated that this provision, as proposed, was too broad and that at least in some cases it would not be necessary to shut down the entire facility until the problem was solved. Other comments gave the views of their authors as to which tests, if failed, indicated problems serious enough to require the facility to stop doing mammography until the problem was solved. The most frequently mentioned tests in this category were the processor QC tests of § 900.12(e)(1) and the average glandular dose test of § 900.12(e)(5)(vi), each of which was listed by 13 comments.

(Comment 535). Seven comments included the image quality test of § 900.12(e)(2) and six each, the screen-film contact test of § 900.12(e)(4)(ii), the compression test of § 900.12(e)(4)(iii), the tests for modalities that did not use screen-film of § 900.12(e)(6), and the additional test for mobile units of § 900.12(7) on their lists of tests important enough that their failure required problem detection and correction before mammography continued. The system resolution test of § 900.12(e)(5)(iii) was listed in five comments. One comment each also would include the artifact test of § 900.12(e)(5)(ix) (if there were ''serious'' artifacts), the kVp test of § 900.12(e)(5)(ii), and tests of output and the phototimer (if the errors were ''large'') on the list.

NMQAAC as a group supported the requirement that the problem must be corrected before mammography continues only in the cases of the processor QC tests, the average glandular dose test, and the screen-film contact test. However, the medical physicists serving as committee members and consultants for NMQAAC, when discussing specific tests in their individual comments, presented somewhat different and conflicting views. They agreed that the processor QC and the average glandular dose tests were of sufficient importance that, if they were failed, the facility should cease doing mammography until the problem was corrected. They also supported adding the image quality test to that list. Opinions of these physicists were split on whether the screen-film contact test, the automatic exposure control tests of § 900.12(e)(5)(i), the breast entrance exposure and AEC reproducibility test of § 900.12(e)(5)(v), the tests for modalities other than screen-film, and the additional test for mobile units should be considered important enough that their failure would require problem correction before mammography continued.

After consideration of the comments, FDA agrees that not all test failures are serious enough to require the facility to cease doing mammography until the source of the problem is corrected. The agency also agrees with two additional comments that stated that, even if the test failure does indicate a problem that requires immediate correction, it may not be necessary to shut down the entire facility. For example, if the processor QC tests are failed, it may be possible to continue to perform mammography, but to delay processing the films until the processor problem is corrected, as long as the anticipated processing delay is not of such duration that image degradation becomes a concern. Similarly, if the facility has more than one mammography unit, the failure of one unit would not be a reason for stopping the use of another unit that did pass the tests.

In response to these considerations, FDA has revised § 900.12(e)(8)(ii) by dividing the tests into two groups. Those tests listed in § 900.12(e)(8)(ii)(A) are those whose failure requires immediate problem evaluation and correction. However, the wording has been changed to state that the corrective actions must be taken ''before any further examinations are performed or any films are processed using the component of the mammography system that failed the test'' (emphasis added). If the failure is related to a component for which there is no alternative, for example, a failure of the facility's only mammography unit, then the facility will still have to cease doing mammography until the problem is corrected. However, if there is another unit or processor that has passed the tests, the facility will be able to continue producing and processing mammograms with that equipment while the problem with the first unit is corrected.

Included in § 900.12(e)(8)(ii)(A) are the processor QC tests (§ 900.12(e)(1)) and the average glandular dose test (§ 900.12(e)(5)(vi), both of which everyone who commented on this paragraph agreed were important enough that their failure required evaluation and correction of the problem before the piece of equipment was used for further mammography. FDA has also included the image quality test (§ 900.12(e)(2)) in this group, even though it was mentioned in fewer comments. The importance of this test is underscored by the fact that the primary goal of the MQSA is to ensure adequate quality mammography for all women. The agency has also included the additional test for mobile units (§ 900.12(e)(7)) because it is a test that directly evaluates image quality.

FDA has also included the tests for nonscreen-film modalities (§ 900.12(e)(6)) on this list. This particular provision was intended to facilitate the introduction of new modalities because it ensures that facilities using the new modality will have an adequate quality assurance program, while at the same time not requiring amendment of the requirements of § 900.12(e) before the new modality can be used. Because it is not possible to predict in advance what new modalities may appear and what QC tests may be required for them, FDA believes they must be placed in § 900.12(e)(8)(ii)(A) to adequately protect the public. Should it prove to be the case that some or all of the tests that are applicable to the new modality might more appropriately be placed in § 900.12(e)(8)(ii)(B), regulatory relief can be provided through the alternative requirements mechanism of § 900.18 until § 900.12(e)(8)(ii) can be amended.

FDA has also agreed with comments urging that the screen-film contact test (§ 900.12(e)(4)(ii)) and the compression test (§ 900.12(e)(4)(iii)) be placed on the list of those tests whose failure should require taking a piece of equipment out of service until the problem is detected and corrected. The agency notes that the new wording referred to above means that failure of the first of these tests only requires taking the cassette in question out of service and, as one comment pointed out, the corrective action most likely will simply be replacement of the cassette. The compression test is included out of concerns raised by both anecdotal accounts and reports to FDA's Medical Device Reporting System of injuries resulting from excessive compression and the knowledge that inadequate compression can lead to poor quality images.

Finally, FDA retained the darkroom fog test (§ 900.12(e)(4)(i)) on this list, even though it was not mentioned by any of the comments. FDA has concluded from studies, such as the Nationwide Evaluation of X-ray Trends program of the Conference of Radiation Control Program Directors, that excessive darkroom fog is more pervasive and has a greater impact on image quality than is commonly realized. The agency also notes that the detection and correction of the problems contributing to darkroom fog is a relatively uncomplicated process and can be carried out relatively rapidly. Often the problem is associated with the safelight and simply discontinuing use of the safelight until it can be replaced or repaired may provide a temporary correction that would permit returning the darkroom to service.

FDA has placed all other tests under § 900.12(e)(8)(ii)(B). These are tests whose failure indicates that there are problems that must be corrected, but, for various reasons are not considered to present a health hazard serious enough to require taking a piece of equipment out of use until the problem is corrected. Retake analysis is included in this group (§ 900.12(e)(3)(ii)). In this case, mammography must be allowed to continue to determine if the corrective action has indeed had the desired effect on retake rate. Also in this group are tests such as kVp accuracy (§ 900.12(e)(5)(ii)) and alignment (§ 900.12(e)(5)(vii)), for which, as one of

the NMQAAC physicists argued, there are compensation methods that can be used as temporary corrective actions until the problem can be given a more permanent correction. Other tests included in this group, such as the system resolution test (§ 900.12(e)(5)(iii)—called the focal spot condition test in the final regulations) are early warning tests that give an indication of possible approaching problems. In the case of the system resolution test, FDA has accepted the argument of the NMQAAC physicist who believed that, unless the system resolution was so poor as to lead to failure also of the image quality test, some time could be permitted for the correction of the resolution problem. Of course, if the image quality test is failed, the piece of equipment will be taken out of service until the problem is corrected. Finally, this group includes the artifact test (§ 900.12(e)(xi)), for which there are no objective action limits against which to compare the test results.

Although problems revealed by the tests in the second group are not considered serious enough to take a piece of equipment out of service until corrected, FDA believes that they must not be allowed to exist indefinitely. Therefore, § 900.12(e)(8)(ii)(B) requires that when tests in this group are failed, the problems must be evaluated and corrected within 30 days.

l. *Surveys (§ 900.12(e)(9))*

This paragraph required that a facility survey be performed by a medical physicist no less often than once a year. The tests and reviews that, at a minimum, were to be included in the survey were specified along with requirements that the medical physicist provide a survey report to the facility within 30 days of the survey. Identification of those who performed the survey was to be provided in the report.

(Comment 536). Two comments were received on § 900.12(e)(9)(i), which specified that the surveys should be conducted annually. One comment indicated confusion about the requirement by stating that an annual FDA inspection was not needed if a certified physicist conducted biannual surveys. The other comment asked that the requirement be modified to allow the annual surveys to take place in a year plus or minus a reasonable period.

FDA notes that an inspection is not a survey but rather is a check by an independent authority on how well the facility is meeting the requirements. An inspection and a survey serve different functions and are both required under the MQSA. Furthermore, the inspection does not duplicate the physicist's work. The inspection involves conducting only the tests that provide the most general picture of the equipment performance but also includes review of other aspects of the facilities performance such as personnel qualifications and reporting and recordkeeping practices, which are not considered by the physicist during the survey. Recognizing the unique characteristics of both the survey and the inspection, and the benefits of multiple oversight mechanisms, Congress required that each be conducted annually. Performance of more frequent surveys, semi-annually, e.g., does not eliminate the need for inspections. FDA has retained the requirement for an annual survey in accordance with 42 U.S.C. 263b(e)(1)(B)(iv). This requirement does not prohibit the facility from having a survey more frequently if it wishes. In response to the second comment, FDA notes that it has exercised its enforcement discretion under the interim regulations, and intends to continue to do so under the final regulations, to permit short periods of additional time beyond 12 months for the facility to obtain a survey under certain circumstances. The agency has done so in recognition of the difficulty that facilities that rely on contract physicists have in scheduling surveys. However, this exercise of enforcement discretion in a particular year is not intended to set a pattern that will permit facilities to impemissibly lengthen the timeframes between surveys to longer than annually.

(Comment 537). Several comments were received on the survey report required under § 900.12(e)(9)(iii). One comment recommended that a standard physicist report format should be required to facilitate review. Another stated that there should be provision for identification of units if the facility has more than one unit or has installed a new unit in an old room. A third comment stated that the report should include the calibration dates of the exposure measuring instruments.

FDA recognizes the advantages of a standardized report and in the past has encouraged the use of the report format recommended in the ACR quality assurance manuals. This format includes provision for identification of the unit being evaluated; such information has been and will continue to be implicitly required, because without it, the facility is unable to prove that a particular unit was included in the survey. FDA also believes that there has been a move towards standardization under the interim regulations because reports that inadequately provide the information needed during inspections have created extra work for facilities and physicists who must provide the information. This has led to improvements in later reports. However, while there are advantages to a standardized report, FDA also recognizes the need to allow flexibility in this respect to cover special situations and to permit the use of individual initiative in developing improved formats. The agency concludes, therefore, that it is both unnecessary and needlessly restrictive to require a specific report format by regulation.

Because the calibration requirement for exposure measuring instruments (§ 900.12(e)(12)) is a new requirement, this information has not been checked during inspections under the interim regulations. Because it is now a requirement under the final regulations, FDA expects that, in most cases, this information will be included in the survey report and that there is no need for a specific regulation requiring it to be there. However, if the facility wishes to provide the information in some other format, it will have the flexibility to do so.

(Comment 538). Four comments were related to the requirement of § 900.12(e)(9)(iv) that the report be provided to the facility within 30 days of the survey. One comment suggested shortening the interval to 2 weeks. Another stated that Massachusetts had found that a requirement that the facility's lead interpreting physician sign the report within 30 days had been effective in ensuring that the findings of the medical physicist were implemented. A third comment proposed that the deficiencies noted by the medical physicist be corrected within 1 month. The fourth comment urged that if the report is not received within 30 days, the facility be required to take the equipment out of service. This, it was believed, would stimulate the physicist to be timely.

FDA believes that a shorter time period would be unreasonable in situations where contract physicists might do several surveys in a several day trip before returning to his or her office to complete the reports. The agency also believes that it is common practice that before leaving the facility, the physicist gives a preliminary report to the facility staff, which would include identifying conditions that require prompt action. The new provisions of § 900.12(e)(8), which require correction of certain serious test failures before the failed equipment is used for further examinations, will further stimulate the provision of

preliminary reports. The agency continues to believe, therefore, that the 30-day timeframe is reasonable. With respect to the second and third comments, the agency believes that the new § 900.12(e)(8) adequately ensures that the more serious failures are corrected before the equipment is used again and that all identified problems are corrected within 30 days. A separate requirement is not needed here. With respect to the fourth comment, FDA believes that there is already sufficient incentive for the facility to make sure it receives its report within the 30 days without need for the drastic action suggested.

(Comment 539). The last comment on this paragraph endorsed the requirement in § 900.12(e)(v), that not only the physicist, but anyone who is performing part of the survey under the physicist's direct supervision be identified.

FDA retained this requirement when the regulations were codified.

m. *Mammography equipment evaluations (§ 900.12(e)(10))*

FDA proposed this provision to resolve several somewhat conflicting concerns. The basic goal was to ensure that newly installed equipment or equipment that had undergone major changes is tested for adequate performance by a qualified person before the equipment is used for examinations. However, this goal had to be achieved within the statutory limitations that provide for the issuance of provisional certificates prior to the completion of the survey and that require review of QC data as part of the survey. Such data cannot be generated unless the unit is in clinical use (42 U.S.C. 263b(c)(2)). The agency was also concerned about the costs that might be incurred by a facility that required two visits by the physicist, one visit for the original equipment check and the second for the full survey. There was also concern about the possibility of reduced access attributable to delays in putting the equipment into use due to inability to arrange for a visit by a physicist for some period of time.

Proposed § 900.12(e)(10) was an attempt to balance these conflicting concerns by requiring a mammography equipment evaluation of units or processors that were either new or had undergone major changes before those units were put to use in performing examinations. The evaluations were to be done by a qualified person, who could be a physicist or could be another individual, such as an installer or manufacturer's representative, and any problems found were to be corrected before the equipment was used clinically.

(Comment 540). One comment supported this paragraph as written, but 27 comments opposed allowing anyone but a medical physicist who met the requirements of § 900.12(a)(3) to perform the mammography equipment evaluation. NMQAAC also supported requiring that the physicist perform this evaluation.

In view of these comments, FDA has changed the wording to limit the performance of the mammography equipment evaluation to a medical physicist or someone under the direct supervision of a medical physicist. As noted above, this may mean a delay of some weeks in the use of the equipment at some facilities until a medical physicist can be scheduled for the evaluation. However, the agency has been persuaded by the unanimity of the public comments and the advice of NMQAAC that the benefits of having a medical physicist perform the evaluation outweighs the disadvantage of a possible delay. The agency also notes that by planning ahead, the facility may be able to minimize this delay.

(Comment 541). Several comments addressed the issue of the content of the mammography equipment evaluation. Two comments urged that this be a complete survey but a third noted that the equipment would have to be in use for a period of time before the complete evaluation could be done. Four other comments suggested some specific tests to be included in the evaluation, but two more comments recommended leaving the decision about necessary testing to the person doing the testing.

As noted above, the MQSA provisions relating to provisional certificates and the physical impossibility of checking QC data before the equipment is put into use preclude the possibility that the mammography equipment evaluation can be the full survey required by the statute. Although the agency agrees that it may be beneficial to do a variety of tests at the time of the equipment evaluation, it does not intend to designate particular tests in the regulations. The revised provision simply requires that the evaluations determine if the new or changed equipment meets the applicable requirements of § 900.12(b) and (e), thereby focusing on the primary public health concern, which is to establish that units are not put into clinical use without proper testing. This more general wording, the agency believes, also eliminates the need to consider processors and mammography units separately with respect to this evaluation, as suggested by six comments.

Related to the content of the mammography equipment evaluation is FDA's concern, mentioned earlier, about the expense to the facility if two physicist visits are required, one for a mammography equipment evaluation and another, later, for the survey. The agency's original efforts to reduce costs was its proposal to permit the mammography equipment evaluation to be performed by qualified individuals other than physicists. The revised final regulations eliminate this possibility. In a different approach to limiting costs to the facility, FDA plans to permit the initial survey of the new or changed equipment to be done in two stages. The first stage, the mammography equipment evaluation, will obviously require a facility visit by the physicist. If the facility and physicist can cooperate to produce adequate documents, FDA will permit the second stage, the review of the QC data after it is available, to be done by mail. Presumably, this will cost the facility less than two onsite visits to the facility by the physicist. The agency stresses that this two-stage process is intended to help contain costs associated with a facility's initial survey of new or changed equipment and is entirely optional and within the discretion of the facility and its physicist. The agency will require subsequent annual surveys of that equipment to be done at one time through an onsite visit.

The proposal required a mammography equipment evaluation for new equipment and also after major components of the equipment were changed. FDA specifically asked for comments on what should be considered to be ''major components'' but received relatively few responses.

(Comment 542). One comment suggested processor rollers in the case of the processor. For the X-ray unit, two comments suggested the X-ray tube and one of these went on to add the bucky, the screen-film system, and the photo-timing system. Two comments also suggested changes in the ventilation system because such changes can cause major artifact problems. Another comment simply suggested that repairs by service personnel should require testing.

FDA found these suggestions useful and will take them into account in determining what constitutes a major component. With respect to the regulations themselves, in view of the limited number of comments, the agency decided to continue to keep the wording general.

(Comment 543). One comment opposed the entire idea of a mammography equipment evaluation before the equipment was put into use, stating that it would only increase the cost of installation. Another comment, however, strongly supported the correction of all problems before any equipment was put into use. FDA agrees that there will be some cost associated with mammography equipment evaluations, but believes that the dangers inherit in permitting the use of untested equipment in patient examinations more than justifies this requirement. Therefore, the agency has retained the requirement in the final rules and clarified that the evaluation is also required for new and reassembled equipment, or whenever a major component is changed or repaired.

n. *Facility cleanliness (§ 900.12(e)(11))*

This proposed paragraph required the facility to establish and implement protocols for maintaining darkroom, screen, and view box cleanliness and to document that the protocols were followed.

(Comment 544). Six comments stressed the importance of darkroom, screen, and view box cleanliness, primarily because of the likelihood that dirty conditions will lead to artifacts. Three comments took the opposite position, stating that the section should be deleted due to lack of evidence of a hazard. Seven comments urged FDA to go further and establish protocols for cleaning in the regulations. On the other hand, 13 identical comments questioned whether it would be possible for FDA to establish regulations on cleanliness.

FDA believes that proper standards of cleanliness contribute to quality mammography; e.g., they do reduce undesirable effects associated with artifacts. However, as the agency stated in the preamble to the proposed regulations, there are a variety of cleaning protocols and a variety of circumstances affecting the cleaning needs of a facility. FDA continues to believe that facilities must be given the flexibility to establish cleaning protocols that best fit their needs. The presence and use of such protocols can easily be determined during inspections and their effectiveness, or lack thereof, will be demonstrated by the results of the QC tests, such as the artifact test.

(Comment 545). Six comments stated that FDA was paying attention to disinfecting the equipment but not to screen cleanliness, apparently a reference to § 900.12(e)(13), discussed below.

FDA disagrees with these comments and believes that adequate attention has been paid to both areas. The agency also notes that the infection control requirements will also address the concerns raised by the comment, which stated that cleanliness requirements for bucky and compression paddle and examination room cleanliness should be added.

o. *Calibration of air kerma (exposure) measuring instruments (§ 900.12(e)(12))*

This paragraph, as proposed, required calibration of the instruments used by medical physicists in their annual surveys to measure exposure, at least annually. Ten years after publication of the regulation, additional requirements would have to be met by those doing the calibration.

(Comment 546). Numerous comments urged FDA to change the required frequency of calibration to once every 2 years. A few comments opposed the requirement entirely, while others suggested calibration more frequently than annually. In response to these comments, FDA changed the required frequency to once every 2 years as a normal practice, but also retained the requirement for calibration after a repair of the instrument.

As discussed in connection with the definitions of kerma and air kerma, the agency has also introduced the quantity of air kerma into this rule in accordance with the move towards use of SI units. Also in accordance with the agency cost concerns discussed earlier, the requirements proposed in § 900.12(e)(12)(ii) to be phased-in over 10 years have been eliminated.

p. *Infection control (§ 900.12(e)(13))*

This paragraph was proposed in recognition of the fact that, while transfer of disease caused by blood borne pathogens during mammography has never been reported, it is theoretically possible. Therefore, the agency concluded that appropriate precautions should be taken. Because FDA believes that this concern is not unique to mammography, it did not propose specific requirements for mammography equipment but stated instead that the facility should follow the general requirements for infection control related to medical devices.

(Comment 547). Seven comments opposed this requirement. Reasons given included that it was redundant, unnecessary, and time-consuming; would create needless paperwork; and did not deal with a radiation control problem. Two comments, however, urged additional measures, such as requiring informed consent and the use of protective covers. Another comment warned that any material placed between the breast and the image receptor would cause increased dose and degradation of image quality.

FDA believes that the comments do not provide convincing arguments for a change in the agency's position in either direction. The agency continues to believe that at least a theoretical concern about disease transmission exists and that the best way to deal with this concern is to address it as part of infection control procedures to be followed during the use of medical devices in general.

6. Quality Assurance-Mammography Medical Outcomes Audit (§ 900.12(f))

This paragraph requires that every mammography facility establish and maintain a mammography medical outcomes audit program for followup on mammographic assessments and correlation of pathology results with the interpreting physician's recommendations. This program should be designed to ensure the reliability, validity, and accuracy of interpretation of mammograms.

a. *General comments on medical outcomes audit*

(Comment 548). A single comment was received on the general difficulty in conducting a medical outcomes audit faced by facilities that rely on contract interpreting physicians. Specifically, the comment noted that there would be a higher potential for bias in medical outcomes audits conducted for small facilities that employed a relatively greater number of interpreting physicians.

FDA disagrees that the use of a number of contract interpreting radiologists will necessarily result in biases in medical outcomes data. Data should be calculated both for the aggregate facility data base of patients and again for each interpreting physician. Because the data are to be calculated for individual physicians, any particular set of data that represents unusual or anomalous results will be readily identified and additional calculations can be performed by the facility to project average outcomes without that outlying data. The benefit of tracking these results, therefore, includes the ability to identify problems and find trends. The facility will be required to designate a reviewing interpreting physician to review these data and to notify all interpreting physicians, including contract interpreting radiologists, of both aggregate and individual results. Such analyses may require followup actions, which are to be documented by the reviewing interpreting physician.

b. *Confidentiality*

The issue of maintaining confidentiality of medical outcomes audit information collected by the