regulations. Furthermore, this interpretation does not apply to presidential or vice presidential campaigns that are covered by the Presidential Election Campaign Fund Act, 26 U.S.C. 9001 *et seq.* (general elections) or the Presidential Primary Matching Payment Account Act, 26 U.S.C. 9031 *et seq.*[3] Finally, the Commission notes that the use of Federal funds is governed by general appropriations law and is subject to Congressional oversight.[4]

Dated: February 1, 2002.

David M. Mason,

Chairman, Federal Election Commission.

[FR Doc. 02–2858 Filed 2–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 900

[Docket No. 99N–4578]

RIN 0910–AB98

State Certification of Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations governing mammography. The amendments implement the ''States as Certifiers'' (SAC) provisions of the Mammography Quality Standards Act of 1992 (MQSA). These amendments permit FDA to authorize individual States to certify mammography facilities, conduct facility inspections, enforce the MQSA quality standards, and administer other related functions. The amendments establish the standards to be met by States receiving this authority. They also establish procedures for application, approval, evaluation, and withdrawal of approval of States as certification agencies. FDA retains oversight responsibility for the activities of the States to which this authority is given. Mammography facilities certified by those States must continue to meet the quality standards established by FDA for mammography facilities nationwide.

DATES: This rule is effective May 7, 2002. Submit written comments on the information collection requirements by March 8, 2002.

ADDRESSES: Submit written comments on the information collection requirements to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy A. Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Kaye F. Chesemore, Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3332, FAX 301–594–3306.

SUPPLEMENTARY INFORMATION:

I. Background

MQSA (Public Law 102–539) was enacted on October 27, 1992. The purpose of the legislation was to establish minimum national quality standards for mammography. To provide mammography services legally after October 1, 1994, MQSA requires all mammography facilities, except facilities of the Department of Veterans Affairs, to be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to FDA. MQSA replaced a patchwork of Federal, State, and private standards with uniform minimum Federal standards designed to ensure that all women nationwide receive adequate quality mammography services. On October 9, 1998, the Mammography Quality Standards Reauthorization Act (MQSRA) (Public Law 105–248) was enacted to extend MQSA through fiscal year (FY) 2002.

A. Provisions of MQSA

In order to receive and maintain FDA certification, facilities must meet key requirements of MQSA, which include:

1. Compliance with quality standards for personnel, equipment, quality assurance programs, and reporting and recordkeeping procedures.

2. Accreditation by private, nonprofit organizations or State agencies that have been approved by FDA as meeting MQSA standards for accreditation bodies and that continue to pass annual FDA performance evaluations of their activities. As part of the accreditation process, the accreditation body must evaluate actual clinical mammograms from each unit in the facility for quality. The accreditation body determines whether or not the facility quality standards have been met.

3. Demonstration of continued compliance with the facility quality standards through annual inspections performed by FDA-certified Federal or State inspectors.

B. Accomplishments to Date

Interim facility quality standards were published in the **Federal Register** of December 21, 1993 (58 FR 67558), and used as the basis for the initial certification of mammography facilities under MQSA beginning October 1, 1994. By that date, mammography facilities had to have a FDA certificate in order to continue to lawfully provide mammography services. In the **Federal Register** of October 28, 1997 (62 FR 55852), more comprehensive facility quality standards and accreditation body requirements were published and became effective on April 28, 1999. FDA has approved five accreditation bodies: American College of Radiology (ACR) and the States of Arkansas, California, Iowa, and Texas. The number of certified mammography facilities varies with time but typically is about 10,000. FDA has trained and certified Federal and State inspectors to conduct MQSA inspections, and the sixth year of inspections is underway.

C. Standards for Certification Agencies

State agencies have played a very important role in the development and implementation of the MQSA program. As already noted, four of the five accreditation bodies are States, thus providing an alternative to the ACR for accreditation of facilities within those four States. Most of the FDA-certified inspectors are State personnel who, under contract with FDA, have conducted the great majority of MQSA inspections. FDA currently has contracts for the performance of inspections with 47 States, the District of Columbia, Puerto Rico, and New York City. Mammography facilities in States without inspection contracts and all Federal facilities are generally inspected by FDA.

MQSA also provides for an even more significant State role in the MQSA program. Section 354(q) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(q)) permits FDA to authorize qualified States to: (1) Issue, renew, suspend, and revoke certificates;

[3] The Commission's regulations governing travel by presidential and vice presidential candidates who receive federal funds are found at 11 CFR 9034.7 and 9004.7, respectively. These regulations differ from 11 CFR 106.3 in several ways. See, for example, 11 CFR 9004.7(b)(5) and 11 CFR 9034.7(b)(5), which address reimbursement requirements for use of a government airplane to travel to or from a campaign-related stop.

[4] Both the Senate and the House of Representatives have provided specific guidance to their members regarding mixed-purpose travel. *See* page 118 of the *Senate Ethics Manual* (September 2000) and page 95 of the *Rules of the House of Representatives on Gifts and Travel* (April 2000).

(2) conduct annual facility inspections and followup inspections; and (3) implement and enforce the MQSA quality standards for mammography facilities operating within the qualified State. This rule puts into effect 42 U.S.C. 263b(q) by establishing the requirements that must be met by the States acting as certification agencies (commonly known as SACs) and the procedures for the application, approval, evaluation, and withdrawal of approval of SACs.

To be approved as a certification agency, a State must: (1) Have enacted laws and issued regulations at least as stringent as the MQSA standards and regulations, (2) have the legal authority and qualified personnel to enforce those laws and regulations, (3) devote adequate funds to the administration and enforcement of those laws and regulations, and (4) provide FDA with information and reports, as required.

By statute, FDA and SAC States each have authority in the areas of compliance and the suspension or revocation of certificates. Should there ever be a need, FDA is able to take administrative, judicial, or other actions against facilities within an approved State, regardless of whether a State takes such action. FDA retains exclusive responsibility for: (1) Establishing quality standards, (2) approving and withdrawing approval of accreditation bodies, (3) approving and withdrawing approval of State certification agencies, and (4) maintaining oversight of State certification programs.

D. Development of the SAC Proposed Rule

In the **Federal Register** of March 30, 2000 (65 FR 16847), FDA published a proposed rule for the implementation of the SAC provisions of MQSA and sought public comment. FDA's National Mammography Quality Assurance Advisory Committee (NMQAAC) and a SAC working group aided in the development of the proposed rule.

NMQAAC is a committee of health professionals and representatives of consumer groups and State agencies with responsibility for advising FDA on regulatory requirements implemented under MQSA. NMQAAC provided advice about the direction of the SAC program and the content of the proposed rule at meetings held in September 1994 and July 1996.

FDA's partnership with the States will be an essential key to the future success of the SAC program. To begin building that partnership, FDA formed a working group in accordance with 21 CFR 20.88(e). Working group participants have included regional and headquarters FDA staff, representatives of the States of Arkansas, California, Florida, Illinois, Iowa, Massachusetts, Nevada, New Hampshire, New Jersey, and Texas, and the American College of Radiology. FDA chose the State participants with the goal of obtaining input from all regions of the country and from States that are MQSA accreditation bodies. Since its first meeting in June 1996, the working group has contributed greatly to the development of the proposed rules.

The agency has also utilized knowledge gained from its experience in working with the accreditation bodies over the past several years and from a SAC Demonstration Project. Experience with the accreditation bodies has greatly influenced the proposed rule because of the similarity to the: (1) Objectives targeted, (2) problems to be solved, and (3) agency oversight needed.

The SAC Demonstration Project, established by FDA in August 1998, gave certification authority to approved States for a 1-year trial period that was later extended for a second and third year. The States of Illinois and Iowa applied for and received approval from FDA to participate in the SAC Demonstration Project. The experience proved valuable in the development of the national regulatory SAC program.

The proposed rule's 90-day comment period ended on June 28, 2000. FDA analyzed the comments received and responds to them in sections III, V, and VI of this document. As noted, FDA made some changes to the proposed rule in response to those comments.

II. Provisions of the Final Rule

FDA is adding subpart C, entitled ''States as Certifiers,'' to part 900 (21 CFR part 900—Mammography). This subpart contains sections defining: (1) The requirements for a State to apply to become a certification agency, (2) the requirements to be met by and the responsibilities of the States that receive certification authority, (3) the processes to be used by FDA in evaluating the performance of each certification agency, (4) the criteria for and the process to be followed to withdraw approval of a certification agency, and (5) the opportunities for hearings and appeals related to adverse actions taken by FDA with respect to certification agencies. FDA is also amending § 16.1(b)(2) (21 CFR 16.1(b)(2)), which addresses hearing procedures, and § 900.2 (Definitions) to bring the regulations into conformance with subpart C.

The intent of MQSA, which is to assure high quality mammography services for all women in the United States, led FDA to add subpart C. FDA believes that these amendments will provide women, in States with certification authority, with the same assurance of high quality mammography as women in States for which FDA retains that authority. There are also potential cost savings to the facilities and the public through a reduction in the facility inspection fees in SAC States. This will occur in SAC States whose inspection costs are lower than the national average that is used to calculate the present national inspection fee.

A. Scope

Section 900.20 describes the scope of subpart C. The new subpart establishes procedures for a State to apply to become a FDA-approved certification agency for mammography facilities. It further defines the responsibilities to be met by certification agencies and the oversight procedures that FDA will use to ensure that these responsibilities are met.

B. Application for Approval as a Certification Agency

Section 900.21 summarizes the information to be provided by the State to enable FDA to make an informed decision about the State's ability to adequately carry out certification responsibilities. The application must include a detailed description of the mammography quality standards the applicant will require facilities to meet. If these standards are different from FDA's quality standards, the application must include information to show that they are at least as stringent as FDA standards. The application also must include information about the applicant's decisionmaking process for issuing, suspending, and revoking a facility's certificate as well as its procedures for notifying facilities of inspection deficiencies and the monitoring of the correction of those deficiencies. Finally, the State must provide information about the resources it can devote to the program, including the: (1) Qualifications of the State's professional staff; (2) adequacy of the State's staffing, finances, and other resources; (3) ability of the State to provide data and reports in an electronic format compatible with FDA data systems; and (4) adequacy of the State's enforcement authority and compliance mechanisms.

Section 900.21(c) provides a general description of the process that FDA will follow to decide whether or not to accept a State as a certification agency. Section 900.21(d) notes that FDA may limit the types of facilities for which

FDA is granting certification authority; for example, FDA does not expect to grant certification authority to States for Federal facilities. It should be noted also that 42 U.S.C. 263b(q) does not permit FDA to grant a State authority to certify facilities outside of the State's borders.

C. Standards for Certification Agencies

Section 900.22 establishes the requirements and responsibilities to be met by States that have been approved as certification agencies.

Section 900.22(a) requires the certification agency to have FDA-approved measures to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the agency's behalf.

Section 900.22(b) requires that the statutory and regulatory requirements used by the certification agencies for the certification and inspection of mammography facilities be those established by FDA in part 900 or other appropriate, but at least as stringent, requirements.

Section 900.22(c) requires that the scope, timeliness, disposition, and technical accuracy of completed inspections and related enforcement activities conducted by the certification agencies be adequate to ensure compliance with the MQSA quality standards.

Section 900.22(d) requires that the certification agencies have appropriate criteria and processes for the suspension and revocation of certificates and that the certification agencies promptly investigate and take regulatory action against facilities that operate without a certificate.

Section 900.22(e) requires that there be means by which facilities can appeal adverse certification decisions made by a certification agency.

Section 900.22(f) requires that approved certification agencies have processes for requesting additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice.

Section 900.22(g) requires that the certification agencies have procedures for patient and physician notification in situations where the certification agency has determined that mammography quality has been compromised to the extent that there may be a serious risk to human health.

Section 900.22(h) requires that certification agencies have processes to ensure the timeliness and accuracy of electronic transmission of inspection data and facility certification information in a format and timeframe determined by FDA.

Section 900.22(i) requires FDA authorization for any changes a certification agency proposes to make in any standards that FDA previously accepted under § 900.21 or § 900.22. FDA believes that this process is necessary to assure that standards for certification agencies remain at least as stringent as the FDA standards.

D. Evaluation

Section 900.23 establishes standards for the annual performance evaluation of each certification agency. The evaluation will be based on indicators related to the adequacy of the certification agency's performance in the areas of certification, inspection, and compliance.

During the evaluation, FDA will consider the timeliness and effectiveness with which the certification agencies meet their various responsibilities. The evaluation also will include a review of any changes in the standards or procedures that the certification agency has made in the areas listed in §§ 900.21(b) and 900.22. The evaluation will include a determination of whether there are major deficiencies in the certification agency's performance that, if not corrected, would warrant FDA withdrawal of the State agency's approval. The evaluation will also include identification of any minor deficiencies that require corrective action.

E. Withdrawal of Approval

Section 900.24 provides for the actions to be taken if evaluations carried out under § 900.23, or other information, leads FDA to determine that a State certification agency is not adequately carrying out its responsibilities. If FDA determines that there are major deficiencies in the certification agency's performance, FDA may withdraw its approval. Examples of major deficiencies include: (1) Commission of fraud, (2) willful disregard for the public health, (3) failure to provide adequate resources for the program, (4) performing or failing to perform a delegated function in a manner that may cause serious risk to the public health, or (5) the submission of material false statements to FDA.

For minor or less serious deficiencies, FDA will establish a definite time period for the certification agency to take corrective measures as directed by FDA or to submit the State's own plan of corrective action for FDA approval. FDA may place the certification agency on probationary status while the agency is addressing the minor deficiencies. The agency would utilize probationary status in situations where the certification agency is not implementing the corrective action satisfactorily or within the established schedule. FDA also may withdraw approval from the certification agency if: (1) Corrective action is not taken or (2) the identified minor deficiencies have not been eliminated within the established timeframe.

While a certification agency is developing and carrying out its corrective action plan, even if on probationary status, it will retain its certification authority. If a certification agency loses its approval, it must notify all facilities certified or seeking certification by it. In addition, the certification agency must notify the appropriate accreditation bodies with jurisdiction in the State of its change in status. These requirements, however, would not preclude FDA notification. A certification agency that has lost its approval must also transfer facility records and other information required by FDA to a location and according to a schedule approved by FDA.

F. Hearings/Appeals

Under § 900.25, FDA provides an opportunity for a certification agency to challenge in an informal hearing an adverse action taken by FDA with respect to approval or withdrawal of approval. The agency provides the opportunity for a hearing in accordance with part 16 (21 CFR part 16). Certification agencies also are required to provide facilities that have been denied certification with the opportunity to appeal that decision. Each certification agency shall specify in writing its appeals process for approval by FDA in accordance with § 900.21.

G. Conforming Amendments

A conforming amendment to § 16.1 adds § 900.25 to the list of provisions under which regulatory hearings are available.

Conforming amendments to § 900.2 state that the definitions in that section apply to subpart C, as well as to subparts A and B of part 900. Three definitions, ''§ 900.2 (zz) Certification agency,'' ''(aaa) Performance indicator,'' and ''(bbb) Authorization'' are added to the definition list. In adding these definitions, FDA departs from its earlier practice of placing the definitions in alphabetical order to add the new definitions to the end of the list. This placement was done to avoid the necessity of making numerous changes in the citations of the definitions in subparts A and B and to avoid the potential for confusion and error. A

change has also been made in the definition of ''Certification'' to recognize the role of States as certification agencies. A similar conforming amendment was made to § 900.11(a).

III. Public Comments on Provisions of the Final Rule

FDA received eight responses to the request for comments on the proposed regulations for State certification of mammography facilities. They were from representatives of a mammography facility, the ACR, the Conference of Radiation Control Program Directors, Inc. (CRCPD), and five representatives of individual State radiation control programs. Each response contained a number of individual comments. A large number of these comments were related to the cost analysis and will be addressed in section V of this document (Analysis of Impacts). A few of the comments dealt with paperwork issues and will be discussed in section VIII of this document (Paperwork Reduction Act of 1995). The remaining comments addressed: (1) The general concept of SAC, (2) individual provisions of the proposed regulations, and (3) possible additions to the regulations. FDA responds to these comments as follows.

A. General Comments

General comments were those that raised issues or concerns that were broader in scope than any specific provisions.

(Comment 1) One comment reminded FDA that ''MQSA was established to create and maintain a minimum national quality standard in mammography.'' The authors went on to laud the ''strict requirements'' and the procedures of the agency for their effectiveness in achieving this goal. However, they expressed concerns about continuing to meet the intent of MQSA in a consistent fashion without undue burdens on facilities if certification authority was given to a number of agencies (States). Although the authors did not appear to be opposed in principle to the concept of certification authority being given to the States, they made it clear that their support was contingent on the resolution of these concerns. Another comment expressed confidence that States could manage certification responsibilities efficiently and effectively.

The agency agrees that the basic intent of MQSA is to ensure that the performance of mammography meets uniform minimum national standards of quality. FDA believes that the proposed regulations and the associated agency oversight actions provide adequate assurance that this intent will continue to be met after certification authority is given to individual States. In response to the first comment, however, the agency has made changes in the regulations to further strengthen this assurance.

FDA made five changes in §§ 900.21 and 900.22 to make it easier for FDA to determine if an applicant's standards of quality meet or exceed the uniform minimum national standards. The first, in § 900.21(a), replaced the words ''substantially equivalent to'' with ''at least as stringent as.'' The second, in § 900.21(b)(3)(ii), replaced the words ''their equivalence to'' with ''that they are at least as stringent as.'' The third, in § 900.21(c), replaced the words ''substantially equivalent'' with ''at least as stringent as.'' A similar change in § 900.22(b) replaced the words ''equivalent to'' with ''at least as stringent as.'' These four changes were intended to clarify the nature of the information that the agency is seeking. The fifth change adds a new § 900.21(b)(3)(iii)(O) to ensure that the SAC State will make it clear to FDA and to the affected facility when an action taken against a facility is based upon more stringent State standards. This addition was made to clarify that a State may only impose the more stringent requirements under State law.

In addition, two changes were made to emphasize that after approval as a certification agency, a State must continue to ensure that the intent of MQSA is met. The words ''regulations or'' have been inserted in § 900.23 to emphasize that the annual evaluation of certification agencies will include a review of the certification agency's regulations to ensure that they remain adequate for MQSA purposes. Also, the words ''has failed to achieve the MQSA goals of quality mammography and access'' were added to § 900.24(a) to make it clear that FDA can withdraw approval of a certification agency should a SAC State fail to achieve the MQSA goals.

FDA will cover the oversight actions, which FDA believes help ensure that uniform national minimum standards of quality will be met, in more detail with the discussion of the comments on specific provisions of the regulations. In addition, comment 14 of this document discusses a change made in § 900.24(b) in order to minimize a potential burden on facilities.

(Comment 2) One person noted that his present understanding of FDA's intent regarding data transmission between accreditation bodies and State certifying agencies is that the accreditation bodies would provide data to FDA and FDA would then pass it on to the State certifying agencies. The comment approved of this planned flow and urged that it be specified in the regulations.

The comment does correctly describe FDA's intent with respect to electronic transmission of data. The agency believes that this pathway is much more efficient and cost effective than if multiple pathways had to be developed between accreditation bodies and certifying States. It is also the most effective way of maintaining the national database required for MQSA activities. However, FDA does not believe that it is necessary to specify this intent in the regulations and so rejects this comment.

(Comment 3) One comment noted that there are very minimal differences between the content of the proposed regulations for State certification of mammography facilities and the existing requirements met by accreditation bodies.

This similarity was intentional on the agency's part. FDA recognized that the information needed to determine if FDA could approve a State as a certification agency was similar in many respects to that required to determine if FDA could approve an accreditation body. Furthermore, the responsibilities of, the procedures to be followed by, and the resources needed by SAC States and accreditation bodies show many similarities. It seems most efficient for both FDA and the States, especially States that might wish to be both an accreditation body and a certification agency, to pattern the requirements for certification agencies on those for accreditation bodies. In addition, patterning the proposed SAC requirements on those for accreditation bodies permitted the SAC effort to benefit from the experience gained from the agency's work with the accreditation bodies. The accreditation body requirements have been able to ensure uniform accreditation standards, even though five accreditation bodies are presently involved. Similar certification requirements will help achieve continued assurance that all mammography facilities will meet a uniform minimum national standard of quality with multiple certification agencies.

(Comment 4) One comment noted that State radiation control agencies have requested implementation of MQSA (42 U.S.C. 263b(q)) which provides for certification authority to be given to the States, almost since the implementation of MQSA in 1994. It went on to say, ''We feel it is important to note the fact that the proposed regulations are neither

complex nor sufficiently voluminous to require more than five years to achieve publication in the **Federal Register**.''

FDA has been aware since the early days of the program that some States have been very interested in seeing 42 U.S.C. 263b(q) implemented. At a Dallas, TX meeting convened by FDA and the CRCPD in January 1994 to obtain comments from the State radiation control programs on the agency's plans to implement MQSA, representatives of some States urged FDA to make the implementation of 42 U.S.C. 263b(q) its highest priority.

In establishing its priorities for the implementation of MQSA, the agency had to first focus on those actions required by law. These actions included: (1) Developing quality standards, (2) approving accreditation bodies, (3) certifying facilities, and (4) establishing an inspection program. Other permitted actions, including the transfer of certification authority to interested States, had to be given a lower priority in order to accomplish these mandates. Had FDA focused its attention on implementing 42 U.S.C. 263b(q) rather than on its mandates, access to mammography could have been seriously compromised.

After October 1, 1994, FDA had other legislative mandates to meet that would have a more immediate impact in ensuring quality mammography and were viewed by Congress to be of greater urgency than implementing 42 U.S.C. 263b(q). One of the mandates included the establishment of the annual inspection program, which involved developing criteria and training and equipping a corps of 250 inspectors. Also, in granting FDA special authority for interim regulations, Congress sent a clear message as to the importance it attached to quickly replacing the interim regulations with more comprehensive final regulations. Again, FDA focused its resources toward meeting these mandated requirements. In August 1998, with the final regulations published, FDA increased its efforts to implement 42 U.S.C. 263b(q) by establishing a SAC Demonstration Project based upon valuable information provided by a SAC working group of State, Federal, and professional personnel assembled in June 1996.

The agency believes that its order of priorities was also advantageous for future SAC certification agencies. If the agency had first implemented 42 U.S.C. 263b(q) and then developed its inspection program and the final regulations, State certification agencies would have had to constantly adjust their programs as the FDA efforts unfolded. The agency also believes that the information gained from preliminary activities in the Demonstration Project will, in the long run, save both time and effort for the SAC States and the facilities under the regulatory program. In addition, FDA believes that its implementation priorities will help ensure that the SAC program will be immediately effective in maintaining uniform minimum national standards of quality for mammography.

B. Comments on Application for Approval as a Certification Agency (§ 900.21)

Section 900.21 defines State eligibility for becoming a certification agency, outlines the required content of the application, and provides details on the general framework for the processing of the application. Some of the comments received on this section were related to the paperwork burden and FDA will discuss them under section VIII of this document. FDA's response to the other comments follows.

(Comment 5) One respondent suggested that § 900.21(a) be reworded to indicate that States must have the authority to enter into an agreement with FDA, as this implied more than simply saying that the State is capable of entering into an agreement. A second comment stated that FDA should clarify this section.

FDA agrees that clarification is needed. However, the agency believes that the rewording suggested by the first respondent is too limited in that it focuses only on the State having the authority to enter into a legal agreement. The phrase ''capable of meeting the requirements'' was also intended to mean that the State must have the resources needed to carry out the agreement. Therefore, FDA has revised this provision to read: ''(a) *Eligibility*. State agencies may apply for approval as a certification agency if they have standards at least as stringent as those of § 900.12 of subpart B of this part, qualified personnel, adequate resources to carry out the States as Certifiers' responsibilities, and the authority to enter into a legal agreement with FDA to accept these responsibilities.''

(Comment 6) One comment noted that § 900.21(b)(3)(iii)(F) requires an applicant to submit to FDA information on the qualifications of the applicant's professional and supervisory staff but does not specify the minimum criteria for these qualifications. The author asked how applicants would know if members of their staff were qualified.

FDA agrees that an interested State might need more information on qualification criteria. However, the agency believes it would be preferable to provide this information through guidance and direct consultation instead of codifying a set of minimum criteria in the regulations. Position categories differ greatly from State to State in their requirements and descriptions. Also, individuals with a variety of backgrounds can perform some of the tasks required of a certification agency. In light of these differences, FDA believes that it needs flexibility in handling the issue of personnel qualifications that would not be available if minimum criteria were established by regulation.

To improve clarity, FDA also made minor editorial changes in some of the provisions of § 900.21.

C. Comments on Standards for Certification Agencies (§ 900.22)

Section 900.22 outlines the responsibilities of the SAC States and requires them to implement FDA-approved measures to ensure that there will be no conflict of interest or facility bias in carrying out these responsibilities.

(Comment 7) Two comments urged FDA to delete or modify § 900.22(c) so that the certifying agency would not have the responsibility of ensuring that facilities are in compliance with the quality standards. One author went further and made the conflicting statement that ''Given that Section 900.23 will ensure that a certifying State meets its responsibilities, subsection (c) is unnecessary.'' It was not explained how § 900.23 would ensure that the SAC State would carry out its compliance responsibilities if the author's previous suggestion were followed that such responsibilities should not be given.

FDA was surprised to receive these comments from representatives of State radiation control programs. Compliance with the quality standards by the facilities is the key factor in achieving the MQSA goal of quality mammography nationwide. Ensuring that the facilities they certify are in compliance with the quality standards is by far the most significant of the activities that the agency is proposing to give to the SAC States. If FDA does not give this authority, it would have to remove not only § 900.22(c) but also § 900.22(d), (e), (f), and (g), which are activities to ensure compliance with the quality standards. This would limit the new responsibilities given to the SAC States to the point that there would be little incentive for States to join the program. From the information supplied by the working group and informal contacts with State personnel, FDA

believes that most of the States interested in becoming certification agencies want the responsibility for ensuring that the facilities they certify are in compliance with the quality standards. The agency also notes that 42 U.S.C. 263b(q) specifically references the compliance activities as one of the responsibilities that may be given to States. FDA believes that compliance activities by SAC States are appropriate and therefore did not accept these comments.

(Comment 8) One comment expressed concern about how appeals of any adverse accreditation decisions based on failure of clinical images would be handled by certifying States. The authors recommended that § 900.22(e) should in some way ensure that such appeals do not result in less qualified personnel in a SAC State overruling the ''highly qualified'' ACR personnel who made the original decision.

FDA agrees that interpreting physicians participating in the appeals process or in decisions about additional mammography review or patient notification should be adequately qualified for those duties. However, FDA believes that it is more appropriate for the agency to ensure that the SAC State has adequately qualified review interpreting physicians through FDA's application review and oversight functions rather than through regulations.

(Comment 9) One comment expressed concern about the criteria being used to initiate additional mammography review (AMR). The authors stated that they believed that requests for AMR were increasing. They recommend that, as stated in the current MQSA regulations, such reviews should be limited to cases where ''mammography quality at a facility has been compromised and may present a serious risk to human health * * *.''

FDA agrees that the above statement is the criterion in § 900.12(j) for the initiation of an AMR. The agency believes that, in accordance with the goal of ensuring uniform minimum standards for quality mammography nationwide, this criterion should continue to apply within the SAC States as well as in the non-SAC States. To ensure that there is no misunderstanding on this point, FDA is modifying § 900.22(f) to the following:

> There shall be a process for the certification agency to request additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice. The certification agency should request additional mammography review only when it believes that mammography quality at a facility has been compromised and may present a serious risk to human health.

(Comment 10) One comment stated that § 900.22(g) should require patient notification to take place whenever an uncertified facility is found to be operating, regardless of the clinical image review determination of pass or fail. A second comment went further in arguing that if a facility has performed mammography without certification, ''additional clinical image review is irrelevant.'' The author of that comment urged that the ''underlying assumption should be that if a facility has not complied with the fundamental legal requirement of obtaining a certificate prior to performing mammography, there is no assurance that the facility has met any of the applicable standards for certification.'' The author went on to say ''if standards were not met in obtaining images, additional image review is not going to rectify the problem. Delaying notification of affected patients until additional clinical image review is conducted unnecessarily puts those patients at risk.''

FDA believes that the ''underlying assumption'' of the author of the second comment is not necessarily correct, especially when a facility has been previously certified, passed its inspections, and the time of operation without a certificate was short. On the other hand, the agency understands the concern about possible risk to patient health if notification is delayed in cases where the facility not only operated without a certificate, but also failed to meet other quality standards, thus resulting in poor quality mammography. This concern, however, must be balanced against the unnecessary stress and alarm that could be caused if patients are notified of the lack of certification when an AMR would have shown that the quality of mammography was acceptable. Furthermore, if this alarm caused patients to undergo unnecessary repeat examinations, additional radiation exposure and expense would result.

Because of the need to balance these two concerns, FDA and the State certification agencies need to have the flexibility to deal with such situations on a case-by-case basis. For this reason, the agency has rejected the suggestion for mandatory patient notification in every case where a facility has operated without a certificate.

(Comment 11) One comment suggested a change in § 900.22(i), which requires certification agencies to obtain FDA authorization ''for any changes it proposes to make in any standards that FDA has previously accepted under § 900.21 of this section.'' The comment urged that the words ''obtain FDA authorization'' be changed to ''coordinate with FDA to ensure comparability with MQSA requirements.'' The reason given was that they did not feel that FDA could ''authorize'' a State to make changes in its regulations. A second comment expressed a similar concern. The author noted that it would be prudent for a certification agency to discuss contemplated changes in State standards with FDA. FDA then had the right to make it known to the certification agency if it found the changes inconsistent with MQSA. The author also acknowledged that if the certification agency did not cooperate in removing the inconsistency, ''FDA can take appropriate action.'' The comment concluded with the statement that it would be ''inappropriate and unacceptable'' for FDA to require formal authorization for changes a State agency may want to make in its standards.

FDA notes that 42 U.S.C. 263b(q) gives the agency the authority to ''authorize'' a State to ''implement the standards'' established by FDA. The agency believes that to ensure that these minimum standards are implemented uniformly nationwide, in both SAC States and non-SAC States, the SAC States must have standards in their regulations that are at least as stringent as the MQSA quality standards. This stringency level must exist at the time the State receives certification authority. Therefore, as part of its application, prospective certification agencies must submit their facility mammography standards for review. The State standards must also remain as stringent as the MQSA quality standards for as long as the State is a certification agency. However, this cannot be guaranteed if the State is free to change its standards after only ''discussion'' or ''consultation'' with FDA. Therefore, the agency believes that it is not only appropriate, but also required under 42 U.S.C.263b(q), that FDA authorize changes in State standards before they are put into use by the State in its activities as a certification agency.

At the same time, the agency recognizes that the term ''authorize,'' used in the statute and repeated in the regulations, may be contributing to the concerns of those making the comments because they may be interpreting it as meaning more than is intended. FDA does not intend to say that a State needs ''authorization'' from the agency to make changes in its regulations. The agency does intend to say, for the reason just discussed, that a SAC State needs FDA approval of its changed regulations

before it can use them in the exercise of its SAC authority. To clarify this point, FDA has added a definition of ''authorization'' as a new § 900.2(bbb).

As further clarification of what was intended with this requirement, the words ''before requiring facilities to comply with the changes'' have been added at the end of § 900.22(i). This further clarification was prompted by the second comment, which seems to suggest that FDA take action to correct inappropriate State regulation changes, which would affect a State's SAC role, after they are put into effect, instead of requiring agency authorization before they are put into effect. FDA does recognize that, as suggested by the comment, there are actions available to it, including withdraw the certification agency's authority to certify, if ''discussion'' and ''coordination'' are not effective in maintaining consistency between the State's standards and the MQSA standards. However, to take such action after the State standards are put into use would be very disruptive to the facilities certified within the State. In most States, it would require some time for the State regulations to be amended to remove the inconsistencies so that the State could become a SAC State again. FDA believes it would be preferable to prevent such problems from occurring rather than to correct them afterward. The most effective way of doing this is to require States to obtain FDA ''authorization,'' to use the terminology in MQSA, for changes in State standards before using them in their certification activities.

(Comment 12) Two comments urged that inspector training be delegated to the SAC States as a cost saving measure. Although these comments are outside the scope of the regulations, FDA has provided the following answer. As previously stated, the goal of the MQSA program is to ensure that all mammography facilities nationwide meet uniform minimum quality standards. A key factor in achieving this assurance is the uniform application of the MQSA quality standards during inspections. To achieve this uniform application, it is crucial that all inspectors have a uniform training experience. FDA doubts that uniformity of training can be achieved if multiple independent training centers are used in the place of a single center.

The agency also questions whether States can provide training of the same quality and quantity as the FDA training at less cost. FDA provides 6 weeks of specialized training for prospective inspectors. By the completion of their training, the inspectors have benefitted from contact with over a dozen instructors and received about the same number of hours of instruction as given in a typical year of graduate school. In addition, they are required to complete mentored inspections in the field before FDA certifies them as MQSA inspectors. Because the States are already providing the field training, there would be no increase or decrease in cost for that component if the SAC States were given full responsibility for training their inspectors. Any possibility of cost savings by the States would have to come in providing the basic classroom training.

Now that FDA has completed the initial buildup of approximately 250 inspectors, a single series of classes per year, graduating approximately 20 inspectors, is generally sufficient for replacement purposes. Individual States rarely find it necessary to have more than one inspector trained a year. It is unlikely that State training programs would be able to provide comparable training to that described above at a per inspector cost less than that of FDA, because such programs would lose the benefit of economy of scale.

Neither of the comments advocating training of inspectors by States provided any details on the nature of the training they envisioned. Only one provided a cost figure but it contained no details on how it was estimated. The two comments failed to provide a basis for concluding either that State training of inspectors would be less costly than the FDA training or that training at multiple independent centers can be conducted in such a way as to ensure uniform training of inspectors. Therefore, FDA concludes that, for the present, the agency should retain responsibility for training as well as certifying inspectors. However, FDA will re-evaluate this position after the SAC program expands and additional experience is gained.

(Comment 13) One comment noted that in the list of the authorities to be delegated to the States in the preamble to the proposed regulations, the authority for certification is included but a short while later it is stated that ''FDA retains authority to suspend or revoke the certificate of facilities within an approved State.'' The authors believed that this was in conflict with the law and noted that no reason was given for this decision. The comment asked ''What if a State has been given that authority by State law?''

The MQSA statute has provisions for both States and the agency to suspend or revoke certificates in SAC States. States may be approved to carry out the certification program requirements under 42 U.S.C. 263b(q)(1)(A), which includes the suspension and revocation of certificates. As a condition for becoming a State certification agency, an agency must have authority under State statute to accept and carry out the SAC responsibilities. However, 42 U.S.C. 263b(q)(3)(B) specifically states that, in a State given certification authority, FDA may take action under 42 U.S.C. 263b(i), which is the part of 42 U.S.C. 263b giving authority to suspend and revoke certificates. Consequently, there is no conflict with the law.

FDA has written and spoken about dual authority in many public forums. The agency has always asserted that it does not intend to exercise its certification authority in SAC States except in rare circumstances. Thus far, the agency has not used this authority during the SAC Demonstration Project. FDA would also like to make it clear that should it suspend or revoke a certificate in a SAC State on its own authority, the implications of that action are limited to the facility losing its certificate. FDA's action should not be construed as meaning that it is ''taking back'' the general authority of the SAC State to suspend or revoke certificates of facilities within its borders. Such a general resumption of authority would occur only if the agency withdraws its approval of the SAC State as a certification agency.

To improve clarity, FDA also made minor editorial changes in some of the provisions of § 900.22.

D. Comments on Evaluation (§ 900.23)

Section 900.23 of the proposed regulations provides for annual evaluation of the certification agencies by FDA and describes some of the details of the evaluation.

(Comment 14) One comment warned that, to ensure consistency, continuity, and the quality of mammography, FDA would have to impose an extensive and active review of the State certification authorities. The authors believed that the extent of this evaluation was not made clear in the regulations and asked questions about: (1) Whether FDA would conduct followup inspections to validate the certification agency inspections, (2) how frequent the followup inspections would be, and (3) how discrepancies between the State inspections and followup inspections would be handled. The comment also included an expression of concern about the possibility that the cost of an adequate evaluation program might be unreasonable.

FDA notes that FDA auditors accompany State inspectors on selected inspections to observe and, if necessary, correct their performance. In this way,

the agency increases the probability that the quality standards are enforced correctly and uniformly throughout the country. Currently one audit inspection is conducted for each State inspector annually. FDA may do additional reviews of specific inspections if there are questions about an inspector's performance. These audit inspections have been conducted in the SAC States as well as the non-SAC States. Because such inspections are already being performed, there will be no new costs for their performance in SAC States.

The agency also expects to evaluate the performance of the certification agencies through mechanisms similar to those currently used for accreditation bodies. These include reviews of annual reports and other documents provided by the certification agencies. An FDA evaluation team will conduct periodic site visits to the certification agency. At present, quarterly performance reports are required from the SAC States participating in the Demonstration Project. If FDA determines that performance of the certification agency is unsatisfactory, § 900.24 provides the agency with the authority to take appropriate action.

(Comment 15) One comment urged that ''The mentioned performance indicators should be delineated in the rule or developed as guidance and available for review and comment and not developed at a further date. Guidance on complying with these indicators could be developed at a later date, but the indicators themselves should be contained within the rule.''

FDA notes that performance indicators were developed for use in the SAC Demonstration Project with the aid of review and comments from the SAC working group. As FDA gained experience from that project, the indicators were modified to make them more appropriate. Further modification may be necessary as the program grows. Consequently, FDA believes that it is premature to codify the performance indicators in regulation. Greater flexibility is available through the guidance process to make adjustments to the indicators more rapidly, should that be necessary.

To improve clarity, FDA also made minor editorial changes in some of the provisions of § 900.23.

E. Comments on Withdrawal of Approval (§ 900.24)

Section 900.24 makes a range of actions available to FDA for use when a certification agency is not in substantial compliance with the regulations.

The words ''after providing notice and opportunity for corrective action'' have been added in the first sentence of § 900.24(a) in order to incorporate a requirement from the statute itself. This requirement was mistakenly left out of the proposed regulation.

(Comment 16) One comment supported implementation of the SAC program providing that it can be carried out ''without incurring an undue financial, compliance, or legal burden on the mammography facilities or public.'' Under § 900.24(a), FDA may withdraw approval of a certification agency if it fails to correct major deficiencies. Under § 900.24(b), FDA may place a certification agency on probation while it corrects minor deficiencies in the performance of its responsibilities. If a certification agency fails to correct these deficiencies while under probation, FDA may withdraw its approval of the agency. If FDA withdraws approval of a certification agency under either of these circumstances, the facilities certified by the agency would again have to become certified by FDA. There would be some burden on the facilities in making such transfers. FDA will develop administrative procedures for the transfer to minimize the burden to the extent possible. In addition, FDA believes that giving the facilities advanced notice that such a transfer may be necessary, so that the facility may be prepared for the possibility will further minimize the burden. Therefore, a sentence has been added to § 900.24(a) requiring a certification agency that has been ordered to carry out corrective actions for major deficiencies to notify all facilities certified or seeking certification by it of this order. Similarly, a new paragraph (b)(1) has been added to § 900.24 requiring a certification agency to notify all facilities certified or seeking certification by it during the probation period if the agency is placed on probation.

(Comment 17) The introduction to this section states that if ''a certification agency is not in substantial compliance with this subpart, FDA may initiate the following action * * *.'' One comment urged that the agency define ''substantial compliance'' or delete the word ''substantial.''

FDA believes that to make either of these changes would remove the flexibility that it needs to respond appropriately to a wide variety of conditions. Deleting the word ''substantial'' would mean that any deviation from the requirements, no matter how minor, would require action against the certification agency. On the other hand, because it would be impossible to foresee all possible situations in which action might have to be considered, any definition of ''substantial compliance'' would inevitably be incomplete. In order to retain the flexibility to evaluate each individual situation and to arrive at the course of action most appropriate for it, FDA rejects this comment.

F. Suggestions for Additions to the Regulations

(Comment 18) One comment urged FDA to address the use of ''interim notices'' in the regulations instead of in guidance, as it is at present. The authors noted that their State planned on promulgating regulations to include criteria and processes for issuing interim notices and stated the opinion that most State administrative procedure statutes would require similar regulations for their certification agencies. They urged FDA to include the interim notice process in its own rules to serve as a model for the State rules. A second comment suggested clarifying the term ''interim notice'' by terming it ''interim notice of certification.'' A third comment urged FDA to differentiate between the issuance of interim notices to new facilities under a provisional status and existing facilities that receive interim notices due to delays or failure in the accreditation process.

Interim notices are issued by FDA or a certification agency to a facility in a variety of situations, including accreditation delays, nonreceipt of a certificate, and to bridge the gap of time between certificate issuance and facility receipt of a certificate. The notice permits a facility to perform mammography while waiting for the certificate to arrive by mail. FDA devised this process as a way to handle the immense task of completing the accreditation and certification of thousands of facilities in a relatively short period of time during the early days of the MQSA program. FDA retained the process after those early years as the accreditation bodies continued to make adjustments to their fluctuating workload. Situations sometimes arose where without such a mechanism, a facility would have to cease operating for a period of time, even though its staff had carried out their responsibilities properly and promptly.

FDA notes that it is reconsidering the future use of interim notices separately from the development of the SAC regulations. Therefore, it is premature to respond to this issue. However, in its examination of the interim notice issue,

FDA will consider the specific comments made.

The agency also notes that interim notices are not presently mentioned in the SAC regulations. The interim notice process could not be added to the regulations without giving the public the opportunity to comment. If such regulations were incorporated into the SAC regulations, they would have to be reproposed. Thus, the publication of the final SAC regulations would be delayed for at least 6 months to 1 year, which many States would find unacceptable. If FDA determines that there is a need to add regulations on interim notices, the agency will publish a proposal and give the public an opportunity to comment. With respect to the plans of one State to issue regulations of its own with respect to interim notices, the agency notes that the mammography regulations of a State acting as a certification agency must continue to be at least as stringent than those of FDA. If a State proceeds with its own interim notice regulations, it may have to amend those regulations after FDA makes its decision on the future of interim notices or may find that its regulations do not satisfy MQSA's SAC requirements because they are less stringent than the MQSA regulations. With these considerations in mind, States interested in such regulations may wish to wait until FDA makes a final decision on this issue.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(g) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612 (as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Public Law 104–121)), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA published an impact analysis in association with the proposed regulations. After a thorough analysis of the comments received on the impact analysis as described below, FDA concluded that none of the comments made a convincing case for changing either the methods used in the cost analysis or the conclusions drawn from it. Therefore, FDA has concluded that this final rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the final rule is not a significant regulatory action as defined by the Executive order and so is not subject to review under the Executive order. A full discussion of the comments FDA received on the analysis follows.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule will have no significant economic impact on a substantial number of small entities because it applies only to States wishing to become certification agencies. However, as part of its Regulatory Impact Study, FDA did analyze the potential for changes in costs to facilities. As will be discussed later in the worst case revealed by the analysis, some mammography facilities may experience a small increase in cost. However, because States are not likely to enter the program unless their entry will be of benefit to the facilities within their borders, a cost savings to the public as a whole and to mammography facilities is more likely to occur. Therefore, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

A. Scenarios Used

FDA realized that the cost impact of these regulations would be heavily dependent upon the number and characteristics of the States that choose to participate in the SAC program. However, because participation is entirely voluntary on the part of the States, FDA could not determine in advance which States would decide to become SAC States. The first assumptions made, therefore, were related to which States might become SAC States. FDA used three scenarios to establish the possible range of the impact of these regulations.

Scenario 1—FDA assumed only the States of Iowa and Illinois, the current participants in the SAC Demonstration Project, would choose to participate in the program.

Scenario 2—FDA assumed that six additional States, which have in the past indicated significant interest in becoming SAC States, would join Iowa and Illinois in the SAC program.

Scenario 3—FDA assumed that seven additional States would join the eight States included in the scenario 2 analysis. These additional States have indicated some interest in becoming SAC States when the program is fully implemented.

The selection of the States for these scenarios does not indicate either a commitment by the States to participate or a commitment by FDA to accept their participation in a future SAC program. Both the six States added in scenario 2 and the seven added in scenario 3 have a wide geographic distribution and the number of mammography facilities within their borders ranges from relatively large to relatively small. Although the basis of selection was FDA's perception of States' interest, the resulting groups are representative of the country as a whole.

B. Pre-SAC and Post-SAC Funding of MQSA Activities

Funding to support the MQSA activities pre-SAC comes from two sources: Inspection fees and federally appropriated funds. By statute, FDA must pay for all inspection costs by collecting fees from the mammography facilities. The present inspection fee is $1,549 per facility plus an additional $204 per mammography unit for each unit beyond the first at the facility. Appropriated funds support all activities other than those that are covered by this fee. In addition, an amount equal to the inspection fee for each governmental entity is allotted from appropriated funds to support the inspection program for those facilities. These sources of funding will continue to be relied upon for support of MQSA activities in States that choose notto enter the SAC program.

If a State becomes a SAC State, the nongovernmental facilities within that State will pay an inspection support fee to FDA to reimburse the agency, as required by statute, for the inspection support services that the agency will continue to provide. This inspection support fee has been initially set at $509 per facility, regardless of the number of mammography units in the facility. As with the inspection fees in non-SAC States, this fee will be collected in a given year only from those facilities in SAC States that were actually inspected during that year. The same amount will also be provided from appropriated funds for each governmental entity inspection within the SAC States.

The SAC State will determine how the responsibilities that it has assumed will be funded. For example, the

funding could come from State appropriations, a certification fee charged by a SAC State, registration fees, or a combination of sources.

C. Phases of the Analysis

FDA carried out the cost impact analysis in several phases. In phase 1, the costs or savings from the SAC program to the public as a whole were estimated by comparing FDA's pre-SAC costs (for performing various functions that would be given to the States) with the post-SAC costs for FDA and SAC States in each of the three scenarios. In this initial analysis, the agency assumed that the inspection fee would remain unchanged from the present value. The results of this phase are shown in tables 1 through 3 of this document.

The second phase of the analysis looked at the impact that would result on the costs or savings to the public as a whole if inspection fees had to be changed. As States enter the SAC program, their facilities will be paying FDA the lower inspection support fee instead of the inspection fee. The funds available for the FDA inspection program thus will decrease as more States become SAC States. On the other hand, the cost of the FDA inspection program will also decrease because it will no longer include the cost of contracting with the States for inspecting facilities in the SAC States. The relative amounts of the decreases in funds available and inspection costs will be highly dependent upon which States enter the SAC program. If a State with a low inspection cost per facility becomes a SAC State, the decrease of funds available to FDA will be more than the decrease in program costs. As a result, the inspection fee in the non-SAC States will have to increase in order to provide sufficient funds to FDA to fulfill its MQSA inspection responsibilities. If a State with a high inspection cost per facility enters the SAC program, the reverse will be true. Table 4 of this document shows the estimated change in the funds needed from inspection fees in each of the three scenarios, and the impact this would have on the savings or cost to the public as a whole.

In the third phase of the analysis, attention turned from the economic impact of the SAC regulations on the public as a whole to the impact on that portion of the public represented by small entities, as required by the Regulatory Flexibility Act. The agency considered all of the approximately 10,000 mammography facilities in the country to be small entities for the purposes of the analysis. In the case of facilities in the non-SAC States, this impact would manifest itself as an increase or decrease in the inspection fee, depending upon whether the second phase of the analysis showed that more or less money was needed to support the FDA inspection program.

In the case of facilities in the SAC States, the analysis first involved determining the difference between the savings to facilities from no longer having to pay the FDA MQSA inspection fee to the costs to the facilities for the inspection support fee and the State costs. The difference was then divided by the number of SAC State facilities. Table 5 of this document shows the savings or costs to the small facilities in the non-SAC and SAC States under each of the three scenarios.

The third phase of the analysis estimated the average impact on the SAC State facilities. The fourth phase showed that depending upon the State in which it was located, the actual impact upon an individual facility could vary widely. The amount of this impact was again highly dependent upon the cost of inspections within each State. The range of the impact was determined by comparing the situations for the lowest and highest inspection cost States among the 15 States included in scenario 3.

The fifth phase of the analysis recognized the fact that although all mammography facilities are assumed to be small entities, they actually vary greatly in size. To further evaluate the impact on the smallest of the mammography facilities, the increase or decrease in per facility costs under the SAC program were compared to the facility revenues derived from mammography for a low volume mammography facility. For this comparison, a model developed by the Eastern Research Group was used. This model estimated that the lowest volume mammography facility (performing less than 300 mammograms annually) would have approximately $24,000 in annual revenues from mammography.

The projected reporting and recordkeeping for SAC States is discussed in detail in the Paperwork Reduction Act (the PRA) of 1995 section. The rule imposes no new reporting and recordkeeping requirements on mammography facilities, and, thus, no additional professional skills are necessary.

D. Discussion of Results

Tables 1 through 3 of this document give the results from the first phase of the analysis. These results support the initial statement that the potential net savings or cost to the public from the SAC program is heavily dependent upon the number and characteristics of the States that choose to become SAC States. All three of the scenarios show that there is the potential for savings to the public from the SAC program. However, the estimated amount of the savings is not proportional to either the number of States in the program or the number of facilities.

TABLE 1.—COST TO THE PUBLIC OF MQSA FUNCTIONS IN NON-SAC[1] STATES

Scenario	Non-SAC States Facilities (Percent of National Total)	Non-SAC States Cost
Baseline	100	$16,067,499
1	94.1	$15,140,562
2	73.8	$11,841,663
3	46.0	$7,394,421

[1] SAC means States as Certifiers.

TABLE 2.—COST TO THE PUBLIC OF MQSA FUNCTIONS IN SAC[1] STATES

Scenario	Facilities (Percent of National Total)	SAC States Cost
Baseline	0	$0
1	5.9	$709,870
2	26.2	$3,650,563

TABLE 2.—COST TO THE PUBLIC OF MQSA FUNCTIONS IN SAC[1] STATES—Continued

Scenario	Facilities (Percent of National Total)	SAC States Cost
3	54.0	$8,180,723

[1] SAC means States as Certifiers.

TABLE 3.—SAVINGS TO THE PUBLIC—FIRST PHASE ANALYSIS

Scenario	Non-SAC[1] State Cost	SAC State Cost	Total Costs	Savings to Public
Baseline	$16,067,499	$0	$16,067,499	$0
1	$15,140,562	$709,870	$15,850,432	$217,067
2	$11,481,663	$3,650,563	$15,492,226	$575,273
3	$7,394,421	$8,180,723	$15,575,444	$492,055

[1] SAC means States as Certifiers.

Whether the SAC program will save (or cost) the public more money than the pre-SAC program depends upon whether SAC States can carry out their SAC functions more or less economically than these functions were carried out within their borders pre-SAC. The biggest component of the cost to the public pre-SAC is the inspection fee. This fee is a national average fee that is the same for all facilities no matter where they are located. On the other hand, the actual cost of performing the inspection varies widely from State to State. If a State whose inspection cost is significantly lower than the national average becomes a SAC State, there is an increased probability that the total cost per facility for inspections, the other State functions, and the inspection support fee will be less than the inspection fee that the facility paid pre-SAC. If so, there will be net savings to the public from that State becoming a SAC State. On the other hand, in States with high inspection costs, the combined cost per facility of the inspections, the other functions, and the inspection support fee may exceed the inspection fee, in which case there will be a net cost to the public arising from that State being in the SAC program.

The bulk of the SAC facilities in scenario 1 are in a State with an inspection cost below the national average. It is not surprising then to find net savings in scenario 1. The inspection costs in the States added in scenario 2 range from slightly lower than to a little higher than the average. Again, it is not surprising to find that there is a net savings and, because the number of facilities in SAC States is greatly increased, it is also not surprising to find that the total net savings is significantly increased over scenario 1. On the other hand, in scenario 3, three of the States added have per facility inspection costs that are well above the national average. Thus, there is an increase in cost to the public arising from these States being in the program. The impact of their participation is magnified because these three States include over two thirds of the facilities added in scenario 3. As a result, there are lower net savings in scenario 3 than in scenario 2.

The agency based the savings estimated in the first phase of the analysis upon the assumption that the inspection fee would not increase with the implementation of the SAC program. In the second phase of the analysis, however, FDA estimated additional amounts of $127,593, $563,710, and $605,208, in scenarios 1, 2, and 3, respectively, would have to be raised by increasing fees in order to provide sufficient funds for the FDA inspection program. Table 4 of this document shows the effect of applying these corrections to the previously estimated savings to the public as a whole. The savings to the public in scenario 1 are reduced but still significant, those in scenario 2 virtually disappear, and in scenario 3 there would be an increase in cost.

TABLE 4.—IMPACT OF INSPECTION FEE INCREASE ON THE PUBLIC AS A WHOLE[1]

Scenario	Savings Before Fee Change	Savings/(Cost) After Fee Change
1	$217,067	$89,474
2	$575,273	$11,563
3	$492,055	($113,173)

[1] SAC means States as Certifiers.

Beginning with phase 3 of this analysis, the agency turned its attention from the economic impact on the public as a whole to the impact on that portion of the public represented by the mammography facilities. Table 5 of this document shows the estimated per facility savings or increased costs for facilities in both SAC and non-SAC States under the three scenarios.

TABLE 5.—ESTIMATED PER FACILITY SAVINGS OR (COSTS) RESULTING FROM THE SAC[1] PROGRAM

Scenario	Non-SAC State Facility Savings (Cost)	SAC State Facility Savings (Cost)
1	($16.52)	$150.45
2	($93.16)	$.03
3	($160.23)	($128.67)

[1] SAC means States as Certifiers.

In all three scenarios, estimated costs increased for the non-SAC State facilities due to the need to increase the inspection fee to raise the necessary funds to support the FDA inspection program. However, even the largest of estimated increases was only about 10 percent of the present fee.

In the case of the facilities in the SAC States, there is an estimated per facility savings in scenario 1 but an estimated increased cost in scenario 3. The average cost per facility in scenario 2 is essentially unchanged. Again, this variation in impact from scenario to scenario is primarily due to the difference in inspection costs among the included States.

As previously noted, however, the actual impact on an individual facility varies widely with the State. Phase 4 of the analysis illustrates the extremes of this variation among the States by comparing the situation in the State with the highest inspection contract cost per facility from among the 15 States to the situation in the State with the lowest inspection contract cost per facility. The facilities in the State with the lowest inspection cost would save, on the average, an estimated $200 per facility per year, which is a decrease of over 10 percent of the FDA inspection fee, if that State became a SAC State. Facilities in the State with the highest inspection cost, however, would have to pay an average of over $507 additional per year, an increase of one-third over the FDA inspection fee, if their State became a SAC State. Interestingly, both of the States joined the SAC program in scenario 3, where the second and third phases of the analysis showed that there was an overall increase in the cost to both the public as a whole and to the part of the public represented by the mammography facilities. Thus, even under scenarios where there is an overall cost increase, there may be savings in individual States.

This great variation is a major reason why the nearly $700,000 cost to facilities in scenario 3 is a ''worst case'' situation that will probably never be reached. The States included in this analysis were States that had shown some level of interest in becoming a SAC State. The primary basis of this interest was a belief that by becoming a SAC State they could provide a service to the facilities and mammography patients within their borders. They expected to be able to provide an assurance of quality mammography at least equal to that under the national program but at a lower cost. If such a belief proves to be too optimistic in a particular State, due to high inspection costs or any other reason, it is unlikely that they will apply to become SAC States.The fifth and final phase of the analysis considers the potential impact of the SAC program on the smallest of the small entity mammography facilities (those with approximately $24,000 in annual revenues from mammography). Tables 6 and 7 of this document present the average facility costs in both non-SAC and SAC States as a percentage of low volume facility revenues in situations where there is an increased cost (all 3 scenarios for facilities in non-SAC States and scenario 3 for facilities in SAC States).

TABLE 6.—COST/SAVINGS PER FACILITY IN NON-SAC[1] STATES

Scenario	Per Facility Increase in Inspection Fee	Inspection Fee Increase as Percentage of Facility Revenue
1	$16.52	0.1%<
2	$93.16	0.5%<
3	$160.23	1.0%<

[1] SAC means States as Certifiers.

TABLE 7.—COST/SAVINGS PER FACILITY IN SAC STATES

Scenario	Net (Cost)/Savings to SAC[1] Small Entities	Average per Facility Net (Cost)/ Savings	Cost as a Percentage of Facility Revenues[2]
1	$87,710	$150.45	NA
2	$838	$0.33	NA
3	($691,595)	($128.69)	1.0%<

[1] SAC means States as Certifiers.
[2] Revenues for a facility performing less than 300 mammograms annually with revenues of approximately $24,000.

Even the largest of the estimated increased costs represented less than 1 percent of the facility's revenue from mammography.

E. Unfunded Mandates

The Unfunded Mandates Reform Act requires that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure of $100 million or more in any one year by State, local, and tribal governments in the aggregate or by the private sector. Because participation in the SAC program is entirely voluntary on the part of the State and not mandated, and because the costs of those who choose to participate will be far less than $100 million, FDA concluded that the proposed SAC regulation is consistent with the principles of the Unfunded Mandates Reform Act without the need for further analysis.

F. Alternative Regulatory Approaches

In addition to the impact analyses discussed above, Executive Order 12866 requires agencies to select regulatory approaches that maximize net benefits. To fulfill these obligations, FDA considered and rejected the following three alternatives:

1. Not Implementing Section 354(q) of the PHS Act

Section 354(q) of the PHS Act states that FDA (with authority delegated from the Secretary of the Department of Health and Human Services) ''may'' authorize a State to carry out the certification and other functions listed above. FDA thus had the option of not implementing section 354(q) of the PHS Act and instead retaining the present centralized certification program. However, many States have indicated a strong interest in increasing their participation in the MQSA program to improve the quality of mammography. The analysis discussed above illustrates that such increased State participation

has the potential for economic savings to the public as a whole. In some States, there are also the potential economic savings for that portion of the public represented by the mammography facilities. In view of these factors, not implementing section 354(q) of the PHS Act could be justified only if its implementation would impede the basic objective of MQSA, the improvement of the quality of mammography. FDA has no evidence to indicate that this would be the case. On the contrary, increased State participation appears to have the potential of accelerating the improvement in the quality of mammography. Because of these considerations, FDA rejected this alternative.

2. Recognizing Existing State Certification Programs

Several States already have programs in place for the certification of mammography facilities. FDA considered recognizing such existing and possible future programs in lieu of the approach taken in the proposed regulations, which is to require a State to establish a program as stringent as the national program in order to be authorized as a SAC. This alternative would have the advantage of lessening the effort the State would have to invest in meeting the requirements to be a SAC and would eliminate the need for facilities to have both MQSA and State certification. However, the existing State certifications vary in nature and extent and it would be expected that such a variation would increase if future State programs are created without the establishment of a consistent set of national standards for such programs. MQSA was designed to replace the existing patchwork of private and government efforts to improve the quality of mammography with a nationwide program that would ensure patients that the mammography they receive meets the same standards of quality, no matter where in the country they receive it. FDA concluded that this could not be guaranteed if existing and future State certification programs were simply recognized without the need to meet national standards.

3. Implementing Section 354(q) of the PHS Act Through the Issuance of More Detailed Regulations

The approach taken in the proposed regulations is to seek to ensure that State certification programs that receive the delegated authority provide guarantees of quality mammography that are as stringent as those provided by FDA's national program but to allow the State programs some flexibility in the means used to achieve this goal. An alternative to this approach would be to impose more detailed requirements that would have to be met for a State to receive certification authority. FDA rejected this approach because it was believed that this would sacrifice the advantages to be gained by giving the State programs the flexibility to tailor their program to best fit the local conditions in the State.

G. Comments Received on the Impact Analysis

FDA published a preliminary impact analysis in association with the proposed SAC regulations on March 30, 2000 (65 FR 16847). The following public comments were received on the methodology and projections included in that analysis.

General Comments

(Comment 19) One comment asked, ''Will FDA proceed with SAC if a cost savings cannot be achieved?'' The authors added, ''The cost passed on to the public may be beneficial if the FDA approved mammography sites had distinct advantage and endorsement from the FDA. This would serve to enhance and improve quality.''

Although 42 U.S.C. 263b(q) only states that FDA ''may'' authorize States to carry out certification functions and not that it is required to do so, the agency has decided to make this option available to interested States. This will not change even if it turns out that the costs savings estimated under some scenarios in the cost analysis are actually cost increases or if the minor cost increases estimated in other scenarios are more than expected.

The agency would like to point out again, however, that participation in the SAC program is voluntary on the part of the States. The States that have expressed interest in becoming certification agencies have in general done so because they believe that they can affect cost savings for their facilities while continuing to ensure that national standards for mammography are met. If they find that they are unable to achieve these cost savings, FDA believes that they will not apply to become SAC States or, if they are already SAC States under the Demonstration Program, they will withdraw from the program.

Use of Nationwide Average Inspection Fees

(Comment 20) One comment noted that the use of the nationwide average per facility cost as the basis for the inspection fee has resulted in States with lower costs supporting States with higher costs and facilities in the lower cost States shouldering an unfair proportion of the fees. A second comment expressed the author's fear that this disproportionate financial burden would become greater for small States who did not become certifiers as the pool of non-certifying States becomes smaller.

FDA agrees that the use of the nationwide inspection fee has resulted in the consequences noted in the first comment. The inspection support component of the inspection fee (for activities such as training and equipping inspectors) is the same for each facility no matter where it is located. The direct cost of the inspections, however, which is by far the single biggest component of the national inspection fee, does vary greatly from State to State. The use of the nationwide average fee has resulted in facilities in low inspection cost States bearing a disproportionate part of the costs. FDA was aware from the beginning of the MQSA program that this situation would be the case. However, uncertainties and variables associated with the cost of inspection make it difficult to establish a single national fee that would, as required by the law, cover the inspection costs without overcharging the facilities in the aggregate. To establish a separate fee for each State would have vastly magnified the difficulty of this task.

FDA disagrees with the comment that initiation of the SAC program, along with the resultant decrease in the pool of non-certifying States, will increase the disproportionate financial burden of facilities in small States. The agency does recognize that the facilities in the remaining non-certifying States, large or small, may have to pay a higher inspection fee. As part of the cost analysis, FDA estimated increases in the facility inspection fee of approximately $16.52, $93.16, and $160.23 would be needed under the conditions of scenarios 1, 2, and 3, respectively. However, any such increase would actually reduce the ''disproportionate'' burden that facilities in some States pay as a result of the use of a nationwide inspection fee.

The reason for this is that, as noted in the cost analysis and in the previous answer, the States that are most likely to become SAC States are those who by doing so will be able to save their facilities money. Thus the States, large or small, with the lower inspection fees will most likely be the ones to become SAC States while those with the higher inspection fees will likely not. This means that while the burden may increase in non-SAC States, its disproportionality will decrease.

Perceived Errors in the Cost Analysis

(Comment 21) One comment stated that the inspection-related functions that FDA provides are the same, regardless of whether the facility is located in a SAC or non-SAC State. Therefore, the cost associated with these functions and the fee charged should be the same regardless of SAC status.

FDA notes that this is indeed the case. In the SAC States, facilities reimburse FDA only for inspection support services through the $509 inspection support fee. In the non-SAC States, facilities pay an inspection fee of $1,549 per facility plus $204 for each additional unit. The inspection fee includes the $509 for the services covered by the inspection support fee plus an additional amount to cover the average national direct cost of the inspections. Thus, the amount charged for inspection support functions is the same whether the facility is in a SAC or non-SAC State.

(Comment 22) One comment stated that FDA did not account for the reduction of some of its costs for activities such as issuing certificates and performing enforcement activities and, similarly, did not account for increased State costs for taking on these functions.

FDA disagrees. As explained in the preamble to the proposed SAC regulations and in more detail in the Regulatory Impact Study, FDA estimates in each scenario the reduced costs to FDA of conducting functions transferred to the SAC States on a proportional basis. Pre-SAC, the FDA cost for certification, enforcement, and public information was $2,192,000. In scenario 1, for example, FDA would be responsible for only 94.1 percent of the pre-SAC facilities, a 5.9 percent reduction. FDA assumed that its post-SAC costs of these activities would be 94.1 percent of the pre-SAC cost or $2,063,143. Scenarios 2 and 3 made similar proportional reductions, based upon the number of facilities that would be in SAC States. FDA used these reduced costs in estimating the savings or increased costs from the SAC program. Thus, the statement that FDA did not account for reduced costs due to a reduction in its activities is incorrect.

FDA also took the increased State costs into account. In scenario 1, where the SAC States were those in the Demonstration Project, the agency assumed that the fees charged by the two States involved equaled their exact costs for performing the inspections and for handling the SAC activities and, therefore, covered their increased costs. FDA queried the States that were added in scenarios 2 and 3 to determine if they had estimates of what it would cost them to perform SAC activities. Unfortunately, although those States were selected on the basis of having indicated some interest in becoming certification agencies, their planning had not reached the point where they felt comfortable providing a cost estimate. Therefore, it was again necessary to fall back on proportional costs. If a possible SAC State contained 3.6 percent of the nation's mammography facilities, FDA assumed as a first estimate that the State could perform its new activities, such as issuing certificates, for 3.6 percent of FDA's pre-SAC baseline costs. FDA further refined this first estimate in each State by adjusting the personnel component of the costs to account for the difference between the cost of a full time equivalent (FTE) in that State and the cost of a FDA FTE.

The agency acknowledged in its Regulatory Impact Study, that this estimation process did not take into account the loss of economy of scale that would result from spreading these functions from one large entity to several smaller ones. However, there was no valid basis available for estimating the impact of the loss of economy of scale.

(Comment 23) One comment stated that the cost analysis did not consider that a State might have costs associated with the performance of the MQSA inspections that are not currently being recovered from the contract with FDA; if the State became a SAC State, it might want to recover these added costs from the facilities. Therefore the potential savings to the facilities were overestimated in the cost analysis.

FDA agrees that this point is a potential source of error but again would mention that the agency queried the States for cost information and did not get any, except that available for the two States in the Demonstration Project from their fee structure. Even in this comment, the author gave no indication of how much more reimbursement the States might seek from facilities. Without such information, FDA had no basis for including a value for the costs mentioned in the comment.

Suggestions for Reducing Costs

Besides the comment suggesting that training of the inspectors be turned over to the SAC States, which we addressed earlier, respondents made the following cost saving suggestions.

(Comment 24) One comment suggested that FDA should review its nationwide database and software systems to determine whether such elaborate and costly systems are really necessary.

FDA notes that such reviews have been carried out and will be repeated periodically in the future. However, the agency also points out that the requirements of MQSA put limitations upon possible reductions in its software system. For example, the Senate report accompanying the original act indicates that the intent of 42 U.S.C. 263b(d)(1)(B) is that the agency should avoid, where possible, requiring facilities to provide duplicate information to their accreditation body and to FDA. This means that the agency's information management system must permit electronic transfer of information between the accreditation bodies and FDA, because the mechanical transfer and organization of such information for 10,000 facilities would be extremely cumbersome and expensive. With the accreditation bodies, SAC States, and FDA directly connecting to the centralized database, interoperability among data systems is increased considerably.

Another advantage to the centralized database is the ability of the software system to interface with the Centers for Medicare and Medicaid Services' (CMS') data system, which allows facilities to be reimbursed under Medicare. FDA also interacts with the National Cancer Institute's Cancer Hotline to help women find facilities located near them. The agency believes that a centralized database is more effective and efficient in carrying out these important functions.

(Comment 25) One comment noted that FDA should reduce the cost, scope, and time of the inspection, recognizing the role of the accreditation bodies and medical physicists, and the number and types of inspection deficiencies currently being cited.

FDA believes that there is a misunderstanding on the part of the author of this comment as to the intent of Congress in establishing both accreditation and inspection functions. The two systems are not duplicative but rather complementary. Accreditation bodies are responsible for the initial review of mammography facilities, and they repeat these evaluations every 3 years for compliance with the quality standards established by FDA. They also have unique responsibility for conducting reviews of clinical images from the facilities to determine if the images meet the image quality standards established by the accreditation body.

Accreditation agencies base their evaluations on material sent to them by the facilities. Inspectors, on the other hand, visit the facilities and are able to

check more closely for compliance with these standards. In addition, while the accreditation bodies evaluate the facilities every 3 years, the inspections are conducted on an annual basis.

FDA believes that there is great value in having the inspection act as an independent check upon the work of the physicist. It is not necessary for the inspector to completely duplicate the work of the physicist. In fact, the inspection only involves measuring the more general indicators of quality, such as phantom image quality and dose. These general measurements are sufficient to give an indication if there are problems with the equipment performance that had been overlooked during the physicist survey or had developed since that survey. This permits a more prompt correction of the problems than would occur if they were not detected until the next physicist survey.

FDA does not believe shifting additional responsibilities to the accreditation body or physicist will provide the same assurance that facilities are meeting uniform minimum national quality standards for mammography as does the present division of responsibilities. Moreover, the cost reductions from such shifts would be limited since some of the larger components of the inspection costs, such as travel to and from the facility, will not change even if the inspection is shortened.

The agency does note, however, that in accordance with MQSA, planning is under way for a Demonstration Project to examine the question of whether the frequency of the inspections can be reduced without compromising mammography quality. Should the study show that it is possible to reduce inspection frequency, the cost of inspections would be reduced proportionally.

Comments Related to the Inspection Support Fee

(Comment 26) One comment stated the belief that FDA did not have the statutory authority to charge an inspection support fee. The author added further that he knew of no other case where a Federal program has been delegated to the States where the Federal program still assesses the fee to the facilities in the State.

FDA notes that 42 U.S.C. 263b(r) requires that the agency ''assess and collect'' fees to cover the ''costs of inspections * * *'' FDA reviewed the question of what costs could be included in the costs of inspections at the time the initial inspection fees were established in 1995 and, most recently, when FDA revised them in 1998 (63 FR 2245, January 14, 1998). FDA may seek reimbursement through fees for the costs of the actual performance of the inspection (travel costs, personnel time, etc.), as well as other inspection costs. These other costs include: (1) Overhead costs (on both the State and Federal levels); (2) costs of equipping inspectors with measuring instruments; (3) calibration and maintenance of those instruments; (4) design, programming, and maintenance of data systems for inspection tracking and data collection during inspections; (5) training and certification of inspectors; and (6) costs of billing facilities for the fees. Inspection fees include all of these costs.

The largest component of the ''costs of inspection,'' the actual performance of the inspections and the State overhead related to them, will not be FDA expenses in the SAC States. Therefore, it would not be lawful for the agency to bill the facilities for them. However, the remaining activities included in the ''costs of inspections'' remain FDA's responsibility and, by law, facilities must reimburse the agency for them. To fulfill this legal requirement, FDA has established the inspection support fee.

FDA conducted research on three major Federal-State programs that were similar in scope to the SAC program: Nuclear Regulatory Commission, Occupational Safety and Health Administration, and Environmental Protection Agency. FDA did not conduct an exhaustive study of other Federal agencies that have delegated functions to the States. Therefore, FDA is unable to confirm or reject the statement that no other Federal agency charges such a fee. The agency notes, however, that the activities of each Federal agency are governed by its own legislation. Federal agencies that delegate authority must do so in accordance with the legislation governing that delegation and FDA is no exception. Because MQSA (42 U.S.C. 263b(q)) requires FDA to seek reimbursement for all costs of inspections from the facilities, it has done so for facilities in SAC States by establishing the inspection support fee.

(Comment 27) Two comments asked for a justification/explanation of how the figure of $509 was arrived at for the inspection support fee.

In October of 1999, FDA sent a letter to all of the State Program Directors explaining how FDA determined this fee, including the State program that submitted these comments. The starting point for the determination was the inspection fee, which had been increased to $1,549 per facility (plus $204 for each mammography unit beyond the first) in January 1998. FDA explained the basis of that fee in a notice published in the **Federal Register** of January 14, 1998 (63 FR 2245). FDA then determined the aggregate costs attributable to the State inspection contracts and to the FDA field inspection costs and found them to account for $1,040 of the basic fee. The remainder of the $1,549, or $509 was thus attributable to FDA's inspection-related activities described above (training and equipping of inspectors, etc.). Just as FDA periodically re-evaluates its inspection fee in light of changing circumstances and costs, it will periodically re-evaluate its inspection support fee with the result that it may go up or down in the future.

(Comment 28) One comment stated that ''the $509 assessment by FDA will result in no cost reduction and as stated could and probably will result in higher costs. This is contrary to the statement in the Analysis of Impact section that their proposal complies with Executive Order 12866 and the Regulatory Flexibility Act.'' A second comment likewise stated that the inspection support fee would result in higher facility costs. The author pointed out that the cost per inspection in his State was $1,421.25; thus, if facilities in his State had to pay a $509 inspection support fee, their total costs would have to go up from the present inspection fee of $1,549 per facility plus $204 for each unit beyond the first.

FDA disagrees with the first comment's contention that the agency's analysis was not in accordance with Executive Order 12866 and the Regulatory Flexibility Act. The author of the comment did not provide an explanation of why he believed this to be so. The agency thus is unable to address any specific concerns on his part but will review its analysis process in general.

Executive Order 12866 directs agencies to prepare an assessment of all anticipated costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits. The Regulatory Flexibility Act requires determination of whether a proposed regulation may have a significant effect on small entities. As summarized in the preamble to the proposed SAC regulations, FDA did carry out the required analysis. The agency first looked at the cost impact on the public as a whole and then at the impact on that portion of the public represented by the mammography facilities, all of which the agency deemed to be small entities.

The Regulatory Impact Study contains this detailed analysis, which was summarized in the preamble to the proposed regulations and within this present preamble. Its principal findings were that on a nationwide basis there was a potential for reduced costs for mammography facilities and the public as a whole from the SAC program. However, the agency warned that the potential for savings varies greatly from State to State. The reason for the variation was not due to the inspection support fee. That fee is the same for all facilities, whether located in a SAC State or a non-SAC State where it is a component of the inspection fee. The reason for the variation is that the costs of doing the inspections themselves vary greatly from State to State.

In particular, the agency found that while facilities in States with low inspection costs would see savings, States with high inspection costs would probably see a cost increase for their facilities. This conclusion is borne out by the second comment, whose author is correct in saying that if his State were to become a SAC State, the costs to the facilities in that State would most likely go up. But again, the reason for this increase is not the inspection support fee but instead is the above average cost of inspections in his State. Presently, the facilities in his State benefit from the fact that a nationwide inspection fee is charged to facilities in non-SAC States. As other comments previously noted, this benefit means that facilities in States with lower than average inspections costs pay more than their share of the inspections costs while facilities in States with higher than average inspection costs pay less than their share. If the State referred to in the second comment entered the SAC program, the facilities in that State would have to pay the actual inspection costs in their State, not the reduced figure made possible by the use of an average national fee. Unless that State could find a way to trim its inspection costs, the cost to the facility would likely increase.

In its analysis, FDA also noted that States are not required to become certification agencies either by law or the proposed regulations. The agency further noted that it is unlikely that a State will become a certification agency unless such an action would lead to cost savings to its facilities. The author of the second comment also supported this belief by stating that if there were an increase in cost to their facilities, his State would be unlikely to become a SAC State. Again, participation in the SAC program is voluntary.

In addition, as required by Executive Order 12866, FDA examined possible alternatives to the approach laid out in the proposed regulations. For reasons given in detail in the Regulatory Impact Study, the agency rejected these alternatives. The author of the comment did not indicate disagreement with the rejection of the alternatives.

FDA believes that the above information, provided in more detail in both the Regulatory Impact Analysis and the preamble to the proposed regulations, illustrates that the agency did fulfill its obligations under Executive Order 12866 and the Regulatory Flexibility Act.

(Comment 29) One comment urged that training of the inspectors be delegated to the States as a way of reducing the inspection support fee. A second comment stated that information transfer was not related to inspections but to the maintenance of a national database, therefore its costs should not be included in the inspection support fee. A third comment disagreed with a FDA statement that a lack of rapid transfer of data to FDA from the certification agencies could put the public at risk. A fourth comment charged that the costs included in the inspection support fee are overestimates, because they were based on the start-up costs of training and equipping the initial corps of inspectors and initial software development. The comment added that the maintenance costs will be much less.

The agency has previously addressed the first comment in detail. A summary of that previous response is that the agency does not believe that, given the loss of economies of scale, an individual State can provide training of equal quality and breadth but at less cost than the FDA program. If more information had been provided on the proposed State training program, FDA might have come to a different conclusion, but the comment provided no details to support the author's belief that money could be saved in this way. In addition, inspector training was one of the major topics discussed at a 1998 SAC working group meeting in Louisville, KY. The majority of States expressed their desire for continued FDA training. FDA remains open to training alternatives after the SAC program has been implemented.

Regarding the second comment, FDA notes that the information transfer includes such important components as notifying the State inspection programs that a particular facility is certified and thus should be inspected. In addition, the uploading of the inspector report to the database is the indicator that the facility has been inspected. FDA again notes that MQSA seeks to minimize facilities' obligation to submit duplicate information; that is, facilities should not be required to provide the same information to both the accreditation body and the certification agency that is responsible for the inspection program. For this reason, the inspection program's only source for information on the location, contact person, and other characteristics that were provided by the facility to the accreditation body and by that body to FDA is from FDA. Therefore, the transfer of that information to the certifying State for use in its inspection program is another way in which information transfer and inspections are related. A third, and perhaps the most important, connection between information transfer and the inspection program is the transfer of inspection results from an inspector to FDA and the transfer of those results back to the inspectors who inspect the facility in following years. This last transfer avoids the need to repeat components of the inspection, such as review of initial qualifications of personnel that would not have changed in the intervening year, and thus permits a more streamlined inspection. The information transferred back to the inspectors also alerts them to problems that the facility has had in the past so that they may determine if the problems have been adequately corrected. These examples show that information transfer is closely related to the inspections; it, therefore, is appropriate to include it in the inspection support fee. SAC States could develop their own data systems also, but that would mean increased costs as well as problems of interoperability with MQSA's largest accreditation body.

In answer to the third comment, FDA would first mention one important example to show that the speed of data transmission is important to the public health. Mammography facilities can not be reimbursed for examinations under Medicare unless FDA has informed CMS that the facility has been given a certificate as an indication that it meets the standards. Similarly, if a facility's certificate is suspended or revoked or is not renewed, FDA must inform CMS of this before reimbursement of the facility under Medicare can be stopped. If information from the certification agency concerning the facility's certification is delayed in transmission to FDA, unsatisfactory facilities may continue to be reimbursed and thus continue to provide unsatisfactory examinations. Conversely, facilities that meet the standards may be delayed in being cleared for reimbursement, thus

reducing the availability of adequate mammography.

Delayed transfer of inspection data also would inhibit FDA's effort to ensure that uniform minimum national quality standards are met. It would make the national inspection database less effective as a tool for speedy identification of undesirable trends related to compliance with the quality standards. If an inspection in one State finds a problem with personnel or mobile facilities that operate in more than one State, delays in transmitting that data to FDA will delay notifying the other States of the problem. Finally, it should be mentioned again that FDA has an obligation to protect the public health by ensuring through its oversight activities that the same uniform minimum national quality standards are met in the SAC States as in the non-SAC States. Delay in the transmission of inspection data from the SAC States would hamper these oversight efforts.

FDA disagrees with the fourth comment as it applies to training costs. The initial task of training approximately 250 inspectors was completed in FY 97. As noted in the analysis, the inspection support fee was based on FY 98 costs, by which time the training program was in the maintenance stage. FDA does agree that the information transfer software is still under development and that the costs of the information transfer system will decrease when this task is completed. There are likely to be other changes as well with the passage of time and so FDA does and will continue to periodically reassess the inspection support fee, as it does the inspection fee, to see if the amount should be adjusted.

(Comment 30) One comment asked whether certain specific costs related to training were included in the training component of the inspection support fee. These were: (1) Initial training, (2) continuing education and travel for continuing education, (3) travel that is currently included under the contract, and (4) annual evaluation of the certifying body.

FDA notes that those initial training costs for new inspectors that are related to the actual instruction process are included in the inspection support fee. These costs included the expense of the contract with a university to provide the first segment of the training. These costs also include the cost of providing a training facility, mammography units for practice surveys, equipment, and other supplies for the last two segments of the training as well as the instructor's salaries for those segments.

The inspection support fee does not include student travel and per diem expenses for the training. In addition, it does not include the continuing education costs for all inspectors, which is currently limited to $1,300 per 3-year period per inspector. The agency is not certain what the authors of the comment meant by item 3. If they are referring to the costs of the inspector traveling to and from inspection sites, the inspection support fee does not cover these expenses. All of these costs are, and will continue to be, covered under the inspection contracts in the non-SAC States; thus, they are not part of the inspection support services. Since State certification agencies will not have inspection contracts, they would need to cover these costs from fees to facilities or from State appropriations.

The fourth item asks about FDA's exercise of its oversight function through annual evaluations. To date, the cost of oversight functions has been covered by Federal appropriations. In order to assure the quality and consistency of inspections nationwide, FDA currently conducts oversight of all MQSA-certified inspectors and their inspections whether they are in an inspection contract State or a SAC State. While FDA recovers its inspection oversight costs by fees in inspection contract States, FDA presently does not recover them in SAC States. In the future, FDA may consider the possibility of transferring inspection oversight costs from the inspection fee to the inspection support fee.

H. Summary

The analysis described above shows that the SAC program's economic impact on the public and the small entities will vary with how many and which States become SAC States. However, even in the scenario with the greatest adverse impact, the increased cost to the public was estimated to be less than 1 percent of the present cost of the MQSA activities that would be transferred to SAC States. The situation with respect to the cost to individual mammography facilities was more complicated. For facilities in non-SAC States, it appears that the SAC program might lead to an increase in their inspection fee. The estimated amount of the increase ranges from about 1 percent of the present fee (scenario 1) up to approximately 10 percent of the present fee (scenario 3). For facilities in the SAC States, the estimated impact ranged from the total of their inspection support fee and any fee paid to the State being about 10 percent less than the present inspection fee (scenario 1) to being about 8 percent greater (scenario 3). When the average cost increase for either SAC or non-SAC facilities in the various scenarios was compared to the revenues of a very small mammography facility, it never exceeded 1 percent of the facility revenues.

Although the estimated average savings or increases for facilities in both the non-SAC and SAC States vary with the scenario, they all represent small changes in the pre-SAC costs to the facilities from the inspection fee. However, these averages mask much greater State by State variations in savings or added costs. As discussed above, FDA believes that a State is unlikely to apply to become a SAC State if the costs to its facilities will be significantly increased by that action. The facilities in the States that do become SAC States are likely to experience a more favorable economic impact than that estimated in this analysis. FDA also believes that both quality mammography and the reduction of breast cancer mortality will be no less after these proposed regulations are implemented than before. Facilities in SAC States will have to meet at least the same quality standards as facilities in non-SAC States. They will be accredited by the same FDA-approved accreditation bodies and they will be inspected by the same MQSA-certified inspectors whether in the SAC program or not. Implementing these regulations will bring the administration of the delegated MQSA functions closer to the facilities and the public. With their closer proximity, State agencies may be able to respond more rapidly to help mammography facilities to improve the quality of their services or take enforcement actions against the few facilities that present serious public health threats.

After thorough analysis of the comments received on the impact estimates, as described above in comments 19 through 30, FDA concluded that none of the comments made a convincing case for changing either the methods used in the cost analysis or the conclusions drawn from it.

Therefore, FDA determines that this rule is consistent with the principles set forth in Executive Order 12866, the Regulatory Flexibility Act, and the Unfunded Mandates Act. The economic impact on the public represented by the mammography facilities will depend upon which States choose to enter the program. In the worst case revealed by the analysis, a small increase in costs may be experienced. However, because States are not likely to enter the program unless such entry will be of benefit to

the facilities within their borders, a cost savings to the public as a whole and to mammography facilities is more likely to occur. Finally, because participation in this program is voluntary on the part of the States and costs incurred by the SAC States can be recouped through user fees, there are no unfunded mandates.

VII. Executive Order 13132—Federalism

Executive Order 13132, dated August 4, 1999, establishes the procedures that Federal agencies must follow when formulating and implementing policies that have federalism implications. Federalism is described as the belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people. Regulations have federalism implications whenever they have a substantial direct effect on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Whenever a regulation has this result, the agency must prepare a federalism assessment.

The Executive order directs Federal agencies to:

1. Encourage States to develop their own policies to achieve program objectives and to work with appropriate officials in other States;

2. Where possible, defer to the States to establish standards;

3. In determining whether to establish uniform national standards, consult with the appropriate State and local officials as to the need for national standards and any alternatives that would limit the scope of national standards or otherwise preserve State prerogatives and authority; and

4. Where national standards are required by Federal statutes, consult with appropriate State and local officials in developing those standards.

As noted above, the purpose of the legislation was to establish minimum national quality standards for mammography. The MQSA replaced a patchwork of Federal, State, and private standards with uniform Federal standards designed to ensure that all women nationwide receive adequate quality mammography services. FDA has worked very closely with State officials in developing the national standards for the MQSA program, and has sought and obtained input from States at every step of the process.

As noted above, section 354(q) of the PHS Act permits FDA to authorize qualified States to: (1) Issue, renew, suspend, and revoke certificates; (2) conduct annual facility inspections; and (3) enforce the MQSA quality standards for mammography facilities within the jurisdiction of the qualified State. FDA retains responsibility for: (1) Establishing quality standards, (2) approving accreditation bodies, (3) approving and withdrawing approval of State certification agencies, and (4) maintaining oversight of State certification programs.

FDA believes that this division of responsibilities provides for necessary uniformity of minimum national standards and, at the same time, provides States with maximum flexibility in administering the SAC program within their State.

Also, as previously noted, interested States have had several opportunities to participate in the development of this program through NMQAAC, the SAC working group, the SAC Demonstration Project and as accreditation bodies. States had an additional opportunity to participate by submitting comments on the proposed rule. FDA directed a mailing of the proposed rule to State health officials to encourage their comments on the proposed rule. Comments from the States were generally supportive of the rule. As discussed above, where appropriate, FDA has revised the final rule to accommodate State concerns.

Participation in the SAC program is voluntary on the part of each State but subject to approval by FDA. The Federal Government will perform all the necessary functions for implementation of MQSA in States that choose not to serve as certification agencies. If a State becomes a SAC State, the facilities within its borders will pay only the inspection support fee. Further, federally appropriated funds will not be used by the SAC State to support the inspection of governmental facilities within that State. Facilities will pay an inspection support fee to FDA to reimburse the agency, as required by statute, for the inspection-related functions that FDA has retained. A State that becomes a certification agency will determine how to fund the SAC responsibilities. The funding could come from State appropriations, a certification fee charged by a SAC State, registration fees or from some combination of those sources.

For the reasons discussed above, FDA believes that this final rule is consistent with the federalism principles expressed in Executive Order 13132.

VIII. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown below with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Requirements for States As Certification Agencies.

Description: These information collection requirements apply to State certification agencies. In order to be an approved certification agency, State agencies must submit an application to FDA and must establish procedures that give adequate assurance that the mammography facilities they certify will meet minimum national standards for mammography quality. The certifying agency also must provide information about its electronic data management system as well as any other information needed by FDA to carry out its ongoing responsibility to ensure that the certification agency is complying with the requirements. These actions are being taken to ensure the continued availability of safe, accurate, and reliable mammography on a nationwide basis.

Respondent Description: State Governments.

In the proposed rule of March 30, 2000 (65 FR 16847), FDA invited comments on the proposed collection of information provisions of the SAC regulations. FDA received two public comments addressing these provisions. In addition, on May 3, 2000, OMB filed comment.

One comment recommended that the information collection burden be lessened by reducing the amount of information required by § 900.21(b)(iii) in the application of a State applying to be a certification agency. OMB likewise stated that FDA should consider ways to reduce burdens to the States when submitting information for this collection. The authors of the public comment suggested that the requirements be reduced to:

(A) Requiring rules and regulations equivalent to subpart B of FDA's part 900;

(B) Information on the education, experience, and training requirements of the applicant's professional staff;

(C) Statement of policies to avoid conflict of interest;

(D) Description of the applicant's mechanism for handling facility inquiries and complaints; and

(E) Any other information FDA identifies as necessary to make a

determination on the approval of a State as a certifying agency.

The authors added that such a change would help correct what they perceived to be an undue emphasis on paperwork in the proposed regulations at the expense of adequate concern for the health and safety of the public.

A second comment noted that additional mammography review and patient notification are two processes for which FDA should not require written policies and procedures. The comment also suggested that FDA allow State agencies to attest to having adequate staffing, finances, and other resources to implement and maintain a mammography certification program.

FDA again notes that the purpose of MQSA is to ensure that uniform minimum national standards of quality are met for mammography. Comments discussed earlier in the preamble of this final rule expressed concerns about whether this goal would continue to be achieved if multiple agencies were allowed to carry out the SAC activities. If the goal is no longer achieved when a State is authorized as a SAC, then the public health and safety would suffer.

In responding to these comments earlier in this final rule, FDA emphasized the importance of its oversight activities in assuring that uniform minimum national standards of quality continue to be met for mammography. The agency further stressed that this oversight began with the review of the original application for approval as a certification agency. FDA believes that if there are problems that could hamper the State agency from functioning effectively as a certification agency, to the extent possible, those problems should be detected and corrected before, not after, a State is authorized to be a SAC.

FDA has been conscious of the paperwork burden from the start and has worked to reduce it for States applying to become certification agencies under MQSA. At the present time, FDA allows attestation for several areas of the SAC application including: (1) Availability of sufficient funding and resources to carry out certification activities, (2) maintenance of sufficient staffing levels, and (3) several inspection and compliance-related provisions. Experience with the MQSA accreditation bodies has shown that initial attestation to adequate staffing can be problematic. There have been occasions when the accreditation body's attestation that it had sufficient staffing later proved to be incorrect, perhaps due to insufficient prior analysis of its needs. As a result, the accreditation body's efforts to effectively carry out its functions were hampered for a period of time until it could obtain adequate resources. Learning from its experience with accreditation bodies, FDA is seeking assurance that a certification agency has adequate staff in place at the time of approval, not several months or 1 year later.

FDA also disagrees with the comment suggesting that FDA reduce the information it required to the few categories listed. Under such an approach, FDA would have to base a decision on whether to approve the State agency as a certification agency without any information about the agency's application review and decisionmaking process for facility certification. FDA would have no information on whether the State agency had policies and procedures governing the notification of facilities of certificate denials and expirations or for suspending or revoking a facility certificate. The agency would have no information on how the State agency planned to ensure that certificates are processed within a reasonable timeframe or whether the State had any timeframe at all for such actions. FDA would have no information on what process, if any, was available for a facility to utilize in appealing adverse accreditation decisions.

Furthermore, the agency would have to make its decision without any information about the State agency's plans to inspect facilities according to the statutory requirements. There would be no information available on how the State agency planned to ensure that deficiencies discovered during inspections were corrected. There would be no information available on the State agency plans, if any, to apply such enforcement actions as additional mammography review or patient notification; issues that, as earlier comments showed, are of increasing concern. On the support side, there would be no information available to FDA to determine if the State's electronic data management and analysis system is adequate. FDA's experience with accreditation bodies shows that this is an area where there can be major problems that can hamper the entire program. In short, if the application were reduced to the extent recommended by the comments, FDA would have to make its decision on the acceptability of the State agency as a certification agency based upon inadequate information. Even the most basic information about how the State proposes to conduct its major activities (certification, inspection, and compliance) would be missing completely.

FDA further notes that the estimated amount of time to provide the information requested was minimal, a one time investment of 50 hours per State. Even if the comments were accepted, the potential time saving is small and certainly not sufficient to justify the potential risk to the public should inadequate information lead the agency to approve an applicant that could not carry out its responsibilities. The agency concludes, after consideration of the possible options, that it has achieved the best possible compromise between the desire to minimize the information collection burden and the need to have adequate information to carry out its public health responsibilities. After considering ways to reduce the burden to the States, FDA has concluded that, without the information included in the proposal, the agency will be unable to make a valid assessment of the State agency's capability to adequately perform the functions outlined above. If the agency approves a certification agency that is unable to effectively perform these functions, the public health and safety will be adversely impacted within that State, perhaps significantly.

TABLE 8.—REQUIREMENTS FOR STATES AS CERTIFIERS DURING INITIAL YEAR

(Estimated Annual Reporting Burden)[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
900.21(b)	13	1.0	13	50	650	$130.00
900.21(c)(2)	13	1.0	13	25	325	$65.00
900.22(i)	2.0	0.1	0.2	5	1.0	$2.00
900.23	2.0	1.0	2.0	20	40.0	$20.00
900.24(a)	2.0	0.05	0.1	62	6.2	$22.00

TABLE 8.—REQUIREMENTS FOR STATES AS CERTIFIERS DURING INITIAL YEAR—Continued

(Estimated Annual Reporting Burden)[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
900.24(a)(2)	2.0	0.025	0.05	52	2.6	$10.00
900.24(b)	2.0	0.2	0.4	20	8.0	$4.00
900.24(b)(1)	2.0	0.05	0.1	52	5.2	$22.00
900.24(b)(3)	2.0	0.05	0.1	52	5.2	$20.00
900.25(a)	2.0	0.25	0.5	5	2.5	$5.00
Total					1,045.7	$300.00

[1] There are no capital costs associated with this collection of information.

TABLE 9.—REQUIREMENTS FOR STATES AS CERTIFIERS DURING INITIAL YEAR

(Estimated Annual Recordkeeping Burden)[1]

21 CFR Section	No. of Recordkeepers	Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.22(a)	2.0	1.0	2.0	1.0	2.0	$5.00
900.22(d) through (h)	2.0	1.0	2.0	1.0	2.0	$5.00
900.25(b)	2.0	1.0	2.0	1.0	2.0	$5.00
Total					6.0	$15.00

[1] There are no capital costs associated with this collection of information.

TABLE 10.—REQUIREMENTS FOR STATES AS CERTIFIERS DURING SECOND AND LATER YEARS

(Estimated Annual Reporting Burden)[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Operating & Maintenance Costs
900.21(i)	15.0	1.0	1.5	5	7.5	$15.00
900.23	15.0	1.0	15.0	20	300.0	$150.00
900.24(a)	15.0	0.05	0.75	62	46.5	$157.50
900.24(a)(2)	15.0	0.025	0.375	52	19.5	$75.00
900.24(b)	15.0	0.2	3.0	20	60.0	$30.00
900.24(b)(1)	15.0	0.05	0.75	52	39.0	$150.00
900.24(b)(3)	15.0	0.05	0.75	52	39.0	$150.00
900.25(a)	15.0	0.25	3.75	5	18.75	$60.00
Total					530.25	$787.50

[1] There are no capital costs associated with this collection of information.

TABLE 11.—REQUIREMENTS FOR STATES AS CERTIFIERS DURING SECOND AND LATER YEARS

(Estimated Annual Recordkeeping Burden)[1]

21 CFR Section	No. of Recordkeepers	Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating & Maintenance Costs
900.22(a)	15	1.0	15.0	1.0	15.0	$37.50
900.22(d) through (h)	15	1.0	15.0	1.0	15.0	$37.50
900.25(b)	15	1.0	15.0	1.0	15.0	$37.50
Total					45	$112.50

[1] There are no capital costs associated with this collection of information.

In contrast to the situation with the economic impact analysis, the additional reporting and recordkeeping burden will fall to the State Governments that choose to become certification agencies and not the approximately 10,000 mammography facilities in the country (all of whom are considered to be small entities). The mammography facilities will continue to provide the same reports that they are presently providing. The bulk of these reports will continue to go to the accreditation bodies that are currently receiving them. The occasional report (for example, if a facility appeals an adverse decision) that presently goes to FDA will, in SAC States, go to the State. The facility recordkeeping requirements also are unchanged.

The total additional reporting and recordkeeping burden on State Governments from these regulations depends on the States that choose to become certification agencies. Since this choice is voluntary on the part of the States, it is impossible to say with certainty how many will seek these responsibilities. However, to estimate the possible maximum impact, FDA

assumes that the 15 States used in scenario 3 of the economic impact analysis will become certification agencies. This number included the 2 States currently participating in the SAC Demonstration Project (Iowa and Illinois) and 13 additional States.

Because of the different nature and time, two sets of tables are provided. Tables 8 and 9 of this document provide estimates of the burden during the first year of the program. During this year, the agency assumed that the 13 new States will apply for and obtain approval as certification agencies. During that year they will bear the initial one time burden associated with application and approval process under § 900.21. FDA assumed that the 13 new States will not be approved in time to be subject to the ongoing burden associated with the evaluation process of § 900.23 during the first year of the program. In contrast, Iowa and Illinois, having already received approval during the Demonstration Project, will not have to provide materials previously submitted, so will not have to bear the initial burden associated with § 900.21. However, during the first year, they will have the ongoing burdens of the evaluation process (§ 900.23).

Tables 10 and 11 of this document provide estimates of the recordkeeping and reporting burden in succeeding years. As it was assumed that all 15 States will have completed the application and approval process by the end of the first year, no State will have the initial burden associated with § 900.21 in the succeeding years. All will experience the burden associated with the evaluation process (§ 900.23) and some are expected to have additional burdens associated with actions under §§ 900.22, 900.24, and 900.25.

With respect to the ongoing burden, based upon FDA's experience with accreditation bodies, which must meet a similar requirement, the agency estimated that a SAC State would seek approval for a change in previously approved standards once every 10 years. The frequency per response for reporting under § 900.22(i) thus would be 0.1. Each SAC State will be evaluated annually so the frequency per response under § 900.23 will be 1.0.

The agency estimated that each State will have to respond to major deficiencies under § 900.24(a) only once every 20 years and minor deficiencies under § 900.24(b) only once every 5 years. The frequency per response under those requirements are 0.05 and 0.2, respectively.

The hourly reporting burden per response for the State certification agency in responding to major deficiencies was estimated in the proposed regulations to be 10 hours. This burden is increased because of the addition of the requirement that the State certification agency inform the facilities that it certifies of the need for it to take corrective action. It was assumed that this would be carried out by mail and would entail an hourly reporting burden per response of 2 hours to produce the letter plus a burden of 15 minutes per facility to mail it out. The total burden would depend upon the number of facilities in the State, which cannot be predicted in advance, so for estimation purposes, 200 facilities (approximately the average number of facilities per State in the United States) was used. This added requirement was thus estimated to increase the hourly reporting burden per response by 52 hours, bringing the total hourly reporting burden per response under § 900.24(a) to 62 hours.

In addition, if the State certification agency is unable to correct its major deficiencies to FDA's satisfaction and its approval is withdrawn, under § 900.24(a)(2), it would have to notify the facilities that it has certified. It was assumed that in 50 percent of the situations where major deficiencies occurred, the State would be unable to correct them, thus the frequency per response of having to notify facilities of withdrawal of approval would be 0.05 x 0.50 = 0.025. The associated hourly reporting burden per response would be the same as sending out the original notification to the facilities of the State certification agency's need for corrective action, that is, 52 hours.

In the cases where there are minor deficiencies, the hourly reporting burden per response associated with responding to minor deficiencies was estimated in the proposed regulations as 20 hours. FDA assumed that the State will, in most cases, make the necessary corrections but that once every 20 years (or once out of every four times the State has minor deficiencies), the State would face possible withdrawal of approval under § 900.24(b)(3). Therefore the frequency per response would be 0.05. It was assumed that in all such cases, the State certification agency would first be placed on probation, to give it the opportunity to correct the deficiencies, before withdrawal of approval would be considered. If placed on probation, under § 900.24(b)(1), it must notify the facilities that it has certified or that seek certification from it, of its probationary status. As with previous facility notification letters, it was assumed that the hourly reporting burden per response would be 2 hours to produce the letter plus 15 minutes per facility to mail it to 200 facilities or 52 hours total. In addition, if the State certification agency failed to correct its deficiencies and FDA had to withdraw its approval, under § 900.24(b)(3), the State certification agency would have to notify its facilities of this. The hourly reporting burden per response of this notification was again estimated to be 52 hours total, using the same assumptions as with the other notification letters.

Finally, the agency assumed that once every 4 years (a frequency per response of 0.25) each SAC State would seek an informal hearing under § 900.25(a) in responding to some adverse action against it.

The estimated recordkeeping burden was related to the maintenance of standard operating procedures (SOPs) in several areas. It was assumed that each State would spend 1 hour per year maintaining each SOP. All of these SOPs would be related to ongoing tasks under §§ 900.22 through 900.25. During the first year (see table 9 of this document) the recordkeeping burden would be borne by Iowa and Illinois only, in the second and succeeding years (see table 11 of this document), by all 15 States. FDA also has corrected an error in the proposed rule where it inadvertently omitted § 900.22(h) from the recordkeeping tables (see tables 9 and 11 of this document). There is no change in burden due to this correction.

The total estimated annual burden for the final MQSA regulations that went into effect on April 28, 1999, was 184,510 hours. Adding a subpart C to part 900 (Mammography) to incorporate these proposed regulations would lead to an estimated additional annual burden of 1,051.7 hours during the first year after the regulations were effective and an estimated additional burden of 575.25 hours in each succeeding year. Again, the actual total annual burden is dependent upon how many States voluntarily choose to enter the SAC program. These estimates are based upon 15 States becoming SAC States. The estimates would be reduced or increased if less than or more than 15 States join the program.

In compliance with the PRA (44 U.S.C. 3507(d)), the agency has submitted the information collection provisions of the final rule to OMB for review. Prior to the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 900

Electronic products, Health facilities, Medical devices, Radiation protection, Reporting and recordkeeping requirements, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 16 and 900 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 continues to read as follows:

Authority: 15 U.S.C. 1451–1461; 21 U.S.C. 141–149, 321–394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201–262, 263b, 364.

2. Section 16.1 is amended in paragraph (b)(2) by numerically adding an entry for § 900.25 to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

§ 900.25, relating to approval or withdrawal of approval of certification agencies.

* * * * *

PART 900—MAMMOGRAPHY

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

Authority: 21 U.S.C. 360i, 360nn, 374(e); 42 U.S.C. 263b.

4. Section 900.2 is amended by revising the introductory paragraph and paragraph (i), and by adding paragraphs (zz), (aaa), and (bbb) to read as follows:

§ 900.2 Definitions.

The following definitions apply to subparts A, B, and C of this part:

* * * * *

(i) *Certification* means the process of approval of a facility by FDA or a certification agency to provide mammography services.

* * * * *

(zz) *Certification agency* means a State that has been approved by FDA under § 900.21 to certify mammography facilities.

(aaa) *Performance indicators* mean the measures used to evaluate the certification agency's ability to conduct certification, inspection, and compliance activities.

(bbb) *Authorization* means obtaining approval from FDA to utilize new or changed State regulations or procedures during the issuance, maintenance, and withdrawal of certificates by the certification agency.

5. Subpart C, consisting of §§ 900.20 through 900.25, is added to read as follows:

Subpart C—States as Certifiers

Sec.

Subpart C—States as Certifiers

§ 900.20 Scope.

The regulations set forth in this part implement the Mammography Quality Standards Act (MQSA) (42 U.S.C. 263b). Subpart C of this part establishes procedures whereby a State can apply to become a FDA-approved certification agency to certify facilities within the State to perform mammography services. Subpart C of this part further establishes requirements and standards for State certification agencies to ensure that all mammography facilities under their jurisdiction are adequately and consistently evaluated for compliance with quality standards at least as stringent as the national quality standards established by FDA.

§ 900.21 Application for approval as a certification agency.

(a) *Eligibility.* State agencies may apply for approval as a certification agency if they have standards at least as stringent as those of § 900.12, qualified personnel, adequate resources to carry out the States as Certifiers' responsibilities, and the authority to enter into a legal agreement with FDA to accept these responsibilities.

(b) *Application for approval.* (1) An applicant seeking FDA approval as a certification agency shall inform the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health (HFZ–240), Food and Drug Administration, Rockville, MD 20850, marked Attn: SAC[1] Coordinator, in writing, of its desire to be approved as a certification agency.

(2) Following receipt of the written request, FDA will provide the applicant with additional information to aid in the submission of an application for approval as a certification agency.

(3) The applicant shall furnish to FDA, at the address in paragraph (b)(1) of this section, three copies of an application containing the following information, materials, and supporting documentation:

(i) Name, address, and phone number of the applicant;

(ii) Detailed description of the mammography quality standards the applicant will require facilities to meet and, for those standards different from FDA's quality standards, information substantiating that they are at least as stringent as FDA standards under § 900.12;

(iii) Detailed description of the applicant's review and decisionmaking process for facility certification, including:

(A) Policies and procedures for notifying facilities of certificate denials and expirations;

(B) Procedures for monitoring and enforcement of the correction of deficiencies by facilities;

(C) Policies and procedures for suspending or revoking a facility's certification;

(D) Policies and procedures that will ensure processing certificates within a timeframe approved by FDA;

(E) A description of the appeals process for facilities contesting adverse certification status decisions;

(F) Education, experience, and training requirements of the applicant's professional and supervisory staff;

(G) Description of the applicant's electronic data management and analysis system;

(H) Fee schedules;

(I) Statement of policies and procedures established to avoid conflict of interest;

(J) Description of the applicant's mechanism for handling facility inquiries and complaints;

(K) Description of a plan to ensure that certified mammography facilities will be inspected according to MQSA (42 U.S.C. 263b) and procedures and policies for notifying facilities of inspection deficiencies;

(L) Policies and procedures for monitoring and enforcing the correction of facility deficiencies discovered during inspections or by other means;

(M) Policies and procedures for additional mammography review and for requesting such reviews from accreditation bodies;

(N) Policies and procedures for patient notification;

(O) If a State has regulations that are more stringent than those of § 900.12, an

[1]SAC means States as Certifiers.

explanation of how adverse actions taken against a facility under the more stringent regulations will be distinguished from those taken under the requirements of § 900.12; and

(P) Any other information that FDA identifies as necessary to make a determination on the approval of the State as a certification agency.

(c) *Rulings on applications for approval.* (1) FDA will conduct a review and evaluation to determine whether the applicant substantially meets the applicable requirements of this subpart and whether the certification standards the applicant will require facilities to meet are the quality standards published under subpart B of this part or at least as stringent as those of subpart B.

(2) FDA will notify the applicant of any deficiencies in the application and request that those deficiencies be corrected within a specified time period. If the deficiencies are not corrected to FDA's satisfaction within the specified time period, FDA may deny the application for approval as a certification agency.

(3) FDA shall notify the applicant whether the application has been approved or denied. The notification shall list any conditions associated with approval or state the bases for any denial.

(4) The review of any application may include a meeting between FDA and representatives of the applicant at a time and location mutually acceptable to FDA and the applicant.

(5) FDA will advise the applicant of the circumstances under which a denied application may be resubmitted.

(d) *Scope of authority.* FDA may limit the scope of certification authority delegated to the State in accordance with MQSA.

§ 900.22 Standards for certification agencies.

The certification agency shall accept the following responsibilities in order to ensure quality mammography at the facilities it certifies and shall perform these responsibilities in a manner that ensures the integrity and impartiality of the certification agency's actions:

(a) *Conflict of interest.* The certification agency shall establish and implement measures that FDA has approved in accordance with § 900.21(b) to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the certification agency's behalf.

(b) *Certification and inspection responsibilities.* Mammography facilities shall be certified and inspected in accordance with statutory and regulatory requirements that are at least as stringent as those of MQSA and this part.

(c) *Compliance with quality standards.* The scope, timeliness, disposition, and technical accuracy of completed inspections and related enforcement activities shall ensure compliance with facility quality standards required under § 900.12.

(d) *Enforcement actions.* (1) There shall be appropriate criteria and processes for the suspension and revocation of certificates.

(2) There shall be prompt investigation of and appropriate enforcement action for facilities performing mammography without certificates.

(e) *Appeals.* There shall be processes for facilities to appeal inspection findings, enforcement actions, and adverse certification decision or adverse accreditation decisions after exhausting appeals to the accreditation body.

(f) *Additional mammography review.* There shall be a process for the certification agency to request additional mammography review from accreditation bodies for issues related to mammography image quality and clinical practice. The certification agency should request additional mammography review only when it believes that mammography quality at a facility has been compromised and may present a serious risk to human health.

(g) *Patient notification.* There shall be processes for the certification agency to conduct, or cause to be conducted, patient notifications should the certification agency determine that mammography quality has been compromised to such an extent that it may present a serious risk to human health.

(h) *Electronic data transmission.* There shall be processes to ensure the timeliness and accuracy of electronic transmission of inspection data and facility certification status information in a format and timeframe determined by FDA.

(i) *Changes to standards.* A certification agency shall obtain FDA authorization for any changes it proposes to make in any standard that FDA has previously accepted under § 900.21 before requiring facilities to comply with the changes as a condition of obtaining or maintaining certification.

§ 900.23 Evaluation.

FDA shall evaluate annually the performance of each certification agency. The evaluation shall include the use of performance indicators that address the adequacy of program performance in certification, inspection, and enforcement activities. FDA will also consider any additional information deemed relevant by FDA that has been provided by the certification body or other sources or has been required by FDA as part of its oversight mandate. The evaluation also shall include a review of any changes in the standards or procedures in the areas listed in §§ 900.21(b) and 900.22 that have taken place since the original application or the last evaluation, whichever is most recent. The evaluation shall include a determination of whether there are major deficiencies in the certification agency's regulations or performance that, if not corrected, would warrant withdrawal of the approval of the certification agency under the provisions of § 900.24, or minor deficiencies that would require corrective action.

§ 900.24 Withdrawal of approval.

If FDA determines, through the evaluation activities of § 900.23, or through other means, that a certification agency is not in substantial compliance with this subpart, FDA may initiate the following actions:

(a) *Major deficiencies.* If, after providing notice and opportunity for corrective action, FDA determines that a certification agency has demonstrated willful disregard for public health, has committed fraud, has failed to provide adequate resources for the program, has submitted material false statements to the agency, has failed to achieve the MQSA goals of quality mammography and access, or has performed or failed to perform a delegated function in a manner that may cause serious risk to human health, FDA may withdraw its approval of that certification agency. The certification agency shall notify, within a time period and in a manner approved by FDA, all facilities certified or seeking certification by it that it has been required to correct major deficiencies.

(1) FDA shall notify the certification agency of FDA's action and the grounds on which the approval was withdrawn.

(2) A certification agency that has lost its approval shall notify facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, that its approval has been withdrawn. Such notification shall be made within a timeframe and in a manner approved by FDA.

(b) *Minor deficiencies.* If FDA determines that a certification agency has demonstrated deficiencies in performing certification functions and responsibilities that are less serious or more limited than the deficiencies in

paragraph (a) of this section, including failure to follow the certification agency's own procedures and policies as approved by FDA, FDA shall notify the certification agency that it has a specified period of time to take particular corrective measures as directed by FDA or to submit to FDA for approval the certification agency's own plan of corrective action addressing the minor deficiencies. If the approved corrective actions are not being implemented satisfactorily or within the established schedule, FDA may place the agency on probationary status for a period of time determined by FDA, or may withdraw approval of the certification agency.

(1) If FDA places a certification agency on probationary status, the certification agency shall notify all facilities certified or seeking certification by it of its probationary status within a time period and in a manner approved by FDA.

(2) Probationary status shall remain in effect until such time as the certification agency can demonstrate to the satisfaction of FDA that it has successfully implemented or is implementing the corrective action plan within the established schedule, and that the corrective actions have substantially eliminated all identified problems, or

(3) If FDA determines that a certification agency that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the certification agency. The certification agency shall notify all facilities certified or seeking certification by it, as well as the appropriate accreditation bodies with jurisdiction in the State, of its loss of FDA approval, within a timeframe and in a manner approved by FDA.

(c) *Transfer of records.* A certification agency that has its approval withdrawn shall transfer facility records and other related information as required by FDA to a location and according to a schedule approved by FDA.

§ 900.25 Hearings and appeals.

(a) Opportunities to challenge final adverse actions taken by FDA regarding approval of certification agencies or withdrawal of approval of certification agencies shall be communicated through notices of opportunity for informal hearings in accordance with part 16 of this chapter.

(b) A facility that has been denied certification is entitled to an appeals process from the certification agency. The appeals process shall be specified in writing by the certification agency and shall have been approved by FDA in accordance with §§ 900.21 and 900.22.

Dated: October 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–2750 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride Soluble Powder; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Agri Laboratories, Ltd. The ANADA provides for a revised withdrawal time for use of oxytetracycline (OTC) hydrochloride (HCl) soluble powder in the drinking water of turkeys and swine.

DATES: This rule is effective February 6, 2002.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Agri Laboratories, Ltd., P.O. Box 3103, St. Joseph, MO 64503, filed a supplement to ANADA 200–066 that provides for use of AGRIMYCIN 343 (oxytetracycline HCl) Soluble Powder for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for a zero-day withdrawal time after the use of the product in the drinking water of turkeys and swine. The supplemental application is approved as of October 4, 2001, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

Section 520.1660d is also being amended to reflect approval of a 5-pound pail size, which was approved under ANADA 200–066 on June 15, 1994.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1660d is amended in paragraph (a)(6) by adding ''; pail: 5 lb'' after ''oz.''; in paragraphs (d)(1)(ii)(A)(*3*), (d)(1)(ii)(B)(*3*), and (d)(1)(ii)(C)(*3*) in the sixth sentence by removing '', 057561,'' and in the eighth sentence by numerically adding ''057561,''; and in paragraph (d)(1)(iii)(C) by revising the last sentence to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

* * * * *

(d) * * *

(1) * * *

(iii) * * *

(C) * * * Administer up to 5 days; do not use for more than 5 consecutive days; withdraw zero days prior to slaughter those products sponsored by Nos. 046573, 057561, and 061133.

* * * * *

Dated: January 11, 2002.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 02–2589 Filed 2–5–02; 8:45 am]

BILLING CODE 4160–01–S