(g) *Where can I get information about any already-approved alternative methods of compliance?* Contact the Small Airplane Directorate, 901 Locust, Room 301, Kansas City, Missouri 64106; telephone: (816) 329-4121; facsimile: (816) 329–4091.

(h) *What if I need to fly the airplane to another location to comply with this AD?* The FAA can issue a special flight permit under sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate your airplane to a location where you can accomplish the requirements of this AD.

Issued in Kansas City, Missouri, on March 22, 2000.

Michael Gallagher,

Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 00–7878 Filed 3–29–00; 8:45 am]

BILLING CODE 4910–13–U

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: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to implement the patient notification provisions of the Mammography Quality Standards Act of 1992 (the MQSA). This action will permit FDA to authorize individual States to certify mammography facilities, to conduct the inspection of the facilities, to enforce the MQSA quality standards, and to administer other related functions. FDA retains oversight responsibility for the activities of the States to which this authority has been delegated and mammography facilities certified by those States must continue to meet the quality standards established by FDA for mammography facilities nationwide. The document proposes procedures for application, approval, evaluation, and withdrawal of approval of States as certification agencies. It also proposes standards to be met by States receiving this authority.

DATES: Submit written comments on the proposed rule by June 28, 2000. Written comments on the information collection requirements should be submitted by May 1, 2000.

ADDRESSES: Submit written comments on the proposed rule to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. 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. The Regulatory Impact Study (RIS) and cost analysis is available at the Dockets Management Branch for review between 9 a.m. and 4 p.m., Monday through Friday. Requests for copies of the RIS should be submitted to the Freedom of Information Staff (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A-16, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Ruth A. Fischer, 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

The 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. The MQSA required that to provide mammography services legally after October 1, 1994, all mammography facilities, except facilities of the Department of Veterans Affairs, had 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. 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. On October 9, 1998, the Mammography Quality Standards Reauthorization Act (the MQSRA) (Public Law 105–248) was enacted to extend the MQSA through fiscal year 2002.

A. Provisions of the MQSA

The key requirements of MQSA to be met by the facilities in order to receive and maintain their FDA certification 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 standards established by the agency for accreditation bodies and that continue to pass annual FDA reviews of their activities. As part of the accreditation process, the accreditation body must evaluate for quality actual clinical mammograms from each unit in the facility, and determine that 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 by October 1, 1994, the date by which mammography facilities had to have an FDA certificate in order to continue lawfully providing mammography services. In the **Federal Register** of October 28, 1997 (62 FR 55852), more comprehensive facility quality standards and accreditation body requirements were published, which became effective on April 28, 1999. Five accreditation bodies, the American College of Radiology (ACR) and the States of Arkansas, California, Iowa, and Texas, have been approved by FDA to accredit mammography facilities. Approximately 250 Federal and State inspectors were trained and certified to conduct the MQSA inspections, and the 5th year of inspections has now begun. The number of certified mammography facilities varies with time but typically is slightly under 10,000.

C. Role of the States

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 the borders of the accrediting States. Most of the FDA-certified inspectors are State personnel who, working under contract with FDA, have conducted the great majority of the inspections. FDA currently has contracts for the performance of inspections with 46 States, the District of Columbia, Puerto Rico, and New York City.

MQSA also provides for an even more significant State role in the MQSA program. In accordance with section 354(q) of the Public Health Service Act (the PHS Act) (42 U.S.C. 263b(q)), States

may become the certifying agency for mammography facilities operating within their borders and also may be delegated other important responsibilities, such as the conduct of the inspections of the facilities they certify and enforcement of MQSA quality standards. The purpose of this proposed rule is to establish the requirements to be met by States as Certification Agencies (commonly known as and hereafter referred to as States as Certifiers (SAC's)) and the procedures for the application, approval, and withdrawal of approval of SAC's.

D. The Patient Notification Provisions

Section 354(q) of the PHS Act allows FDA to delegate to qualified States, the authority for: (1) Issuing, renewing, suspending, and revoking certificates, (2) conducting annual facility inspections and followup inspections, and (3) implementing and enforcing the MQSA quality standards for mammography facilities within the jurisdiction of the qualified State.

To be approved, a State must: (1) Have enacted laws and issued regulations equivalent to 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.

FDA is to retain exclusive responsibility for: (1) Establishing quality standards, (2) approving accreditation bodies, (3) approving and withdrawing approval of State certification agencies, and (4) maintaining oversight over State certification programs. Moreover, FDA retains authority to suspend or revoke the certificate of facilities within an approved State, and to take other administrative and judicial actions against such facilities provided for in the MQSA.

E. Development of the SAC Proposed Rule

This proposed rule covers procedures for application for FDA approval as a certification agency and the requirements and responsibilities of such agencies. It also establishes procedures for oversight of approved States and for withdrawal of approval. Four sources of information were relied upon by FDA in developing these regulations, in addition to the expertise and research of FDA personnel.

First, the proposed SAC program was discussed with the National Mammography Quality Assurance Advisory Committee (NMQAAC). NMQAAC is a committee of health professionals, whose work focuses significantly upon mammography, and of representatives of consumer groups and State agencies. This committee has the responsibility of advising FDA on regulatory requirements implemented under the MQSA. Advice about the direction of the SAC program and the content of the proposed rule was provided by NMQAAC at meetings held in September 1994 and July 1996. NMQAAC has received updates on the proposed program at subsequent meetings.

Second, the SAC program and the proposed rule were discussed in meetings of a SAC Working Group formed by FDA in accordance with 21 CFR 20.88(e). Although NMQAAC was a source of valuable information from a wide segment of the mammography community, FDA partnership with the States would be an essential key to the future success of the SAC program. This second group was intended to serve as a means to begin building that partnership. 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. The State participants were chosen with the goal of obtaining input from all regions of the country and from States that are MQSA accreditation bodies. The Working Group met in June 1996, January and September 1997, May and November 1998, and May 1999 and has contributed greatly to the development of the proposed rules.

Third, FDA's experience over the last 4 years with the accreditation bodies has greatly influenced the proposed rule because there is similarity with respect to the objectives targeted, the problems to be solved, and the oversight needed for the delegation of accreditation and certification authority.

Finally, in August 1998, FDA established a SAC Demonstration Project in which certification authority was delegated to approved States for a 1 year period, with the possibility of renewal for a second year. The States of Illinois and Iowa applied for and received approval from FDA to participate in the demonstration project. The experience gained proved to be valuable in the development of the long term SAC program.

II. Provisions of the Proposed Rule

FDA is proposing to add subpart C, entitled States as Certifiers, to part 900 (21 CFR part 900—Mammography). This subpart will contain sections defining: (1) The requirements for application by a State for approval as a certification agency, (2) the requirements to be met and the responsibilities of the States delegated certification authority, (3) the process 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 State as a certification agency, and (5) opportunities for hearings and appeals related to adverse actions taken by FDA with respect to certification agencies. FDA is also proposing conforming amendments to § 16.1(b)(2) (21 CFR 16.1(b)(2)), which deals with hearing procedures, and to § 900.2 Definitions.

In proposing this rule, and in all activities related to MQSA, FDA is guided by the intent of the MQSA to ensure access to high quality mammography services for all women in the United States. FDA believes that women in States with certification authority can be provided 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 inspection fee in States whose inspection costs are lower than the national average that is used to calculate the present national inspection fee. Other cost savings may be achieved through States being able to combine the MQSA program with other State mammography initiatives.

A. Scope

Proposed § 900.20 describes the scope of subpart C. The new subpart establishes procedures for a State to apply to become an FDA-approved certification agency for mammography facilities. It further defines the responsibilities to be met by the certification agencies and the oversight procedures to be used by FDA to ensure that the responsibilities are adequately fulfilled.

B. Application for Approval as a Certification Agency

Before FDA can approve a State as a certifying agency, the agency must have assurance that the State can adequately meet the associated responsibilities. Proposed § 900.21 summarizes the information to be provided by the State to FDA to enable the agency to make an informed decision on the likelihood that the State will be able to adequately carry out certification responsibilities. Under section 354(q) of the PHS Act, only FDA may establish quality standards. States

retain authority under paragraph (m), however, to enact and enforce standards ''as stringent as'' those established under MQSA. The application must include a detailed description of the mammography quality standards the applicant will require facilities to meet and, if different from FDA's quality standards, information substantiating the equivalence of those standards to FDA standards. The application also must include information about the applicant's decision making process for issuing, suspending, and revoking a facility's certificate and its procedures for notifying facilities of inspection deficiencies and the monitoring of the correction of those deficiencies. Finally, information must be provided about the resources the State can devote to the program, including information about: (1) The qualifications of the State's professional staff; (2) adequacy of the State's staffing, finances, and other resources; (3) the State's ability to provide data and reports in an electronic format compatible with FDA data systems; and (4) the adequacy of the State's enforcement authority and compliance mechanisms.

FDA also plans to issue application guidance to prospective State certification agencies to further assist them in preparing the necessary materials and supporting documentation.

Proposed § 900.21(c) also provides a general description of the process that FDA will follow in arriving at a decision on whether or not to accept a State as a certification agency. Proposed § 900.20(d) notes that FDA may limit the types of facilities for which certification authority is being granted; for example, FDA does not expect to grant certification authority for Federal facilities to States.

FDA specifically invites comments on the nature and extent of the information collection burden that is included in § 900.21

C. Standards for Certification Agencies

Proposed § 900.22 proposes requirements and responsibilities to be met by States that have been approved as certification agencies.

Proposed § 900.22(a) would require 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.

Proposed § 900.22(b) would require that the statutory and regulatory requirements used by the certification agencies for the certification and inspection of mammography facilities be those of MQSA and part 900 or appropriate more stringent requirements.

Proposed § 900.22(c) would require 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 MQSA quality standards.

Proposed § 900.22(d) would require 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.

Proposed § 900.22(e) would require that there be means by which facilities can appeal adverse certification decisions made by a certification agency.

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

Proposed § 900.22.(g) would require that the certification agencies have procedures for patient notification for situations when the certification agency has determined that mammography quality has been compromised to the extent that there may be a serious risk to human health.

Proposed § 900.22(h) would require that approved certification agencies have processes to ensure the timeliness and accuracy of electronic transmission of inspection data and facility certification status in a format and timeframe determined by FDA. FDA believes that such electronic transfer is necessary in view of the need to transmit large amounts of data rapidly among the accreditation bodies, certification agencies, FDA, and other involved agencies such as the Health Care Financing Administration (HCFA). Without a rapid transfer of certification information, facilities may not be able to operate for a period of time or may face delays for Medicare and Medicaid reimbursement because HCFA has not been informed of their certification status. Similarly, without rapid transfer of data concerning inspection deficiencies and corrective actions, members of the public may be put at risk for an unacceptable period.

Proposed § 900.22(i) would require FDA authorization for any changes a certification agency proposes to make to any standards FDA previously accepted under § 900.21 or § 900.22. FDA believes that this is necessary to assure the standards for certification agencies continue to be met.

D. Evaluation

Section 900.23 proposes standards for the annual evaluation of the performance of each certification agency. The evaluation will be based on performance indicators related to the adequacy of the certification agency's performance in the areas of certification, inspection, and compliance. FDA plans to provide further guidance on the nature of these performance indicators. The experience gained during the SAC Demonstration Project is expected to be of significant value in developing this guidance.

During the evaluation, FDA will consider the responsiveness, 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 shall include a determination of whether there are major deficiencies in the certification agency's performance that, if not corrected, would warrant withdrawal by FDA of the agency's approval. The evaluation will also include identification of any minor deficiencies that require corrective action. In performing these evaluations, FDA will use the results of annual inspections, information from required reports from certification agencies, and any other appropriate source of information. For example, the agency may visit facilities or certification agencies as part of the evaluation and may request additional information from the certification agency or other sources.

E. Withdrawal of Approval

In § 900.24, FDA has proposed actions to be taken if evaluations carried out under proposed § 900.23 or other information leads to a determination that a 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 approval of the certification agency. Examples of major deficiencies include commission of fraud, willful disregard for the public health, failure to provide adequate resources for the program, performing or failing to perform a delegated function in a manner that may cause serious risk to the public health, or the submission of material false statements to FDA. If there are less serious deficiencies, termed minor deficiencies in the

regulations, FDA will establish a definite time period during which the certification agency must either take corrective measures as directed by FDA or submit to FDA for its approval the certification agency's own plan of corrective action. FDA may place the certification agency on probationary status while the minor deficiencies are being addressed. Probationary status would be used in situations where the certification agency is not implementing the corrective action satisfactorily or within the established schedule. FDA also may withdraw approval of the agency as a certification agency if corrective action is not taken or if the identified minor deficiencies have not been eliminated within the established schedule.

While an 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 and appropriate accreditation bodies of its change in status. 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. The goal will be to return the facilities within its jurisdiction to the FDA certification program without an interruption in their certification status.

F. Hearings/Appeals

Under proposed § 900.25, FDA will provide 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 of that certification agency. The opportunity for a hearing shall be provided in accordance with 21 CFR part 16. Certification agencies also are required to provide facilities that have been denied certification with the opportunity to appeal that decision. The appeals process of each certification agency shall be specified in writing and shall have been approved by FDA in accordance with proposed § 900.21.

G. Conforming Amendments

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

Conforming amendments to § 900.2 are also proposed to indicate that the definitions in that section applied to subpart C, as well as to subparts A and B of part 900. Two definitions, § 900.2 (zz) *Certification agency* and (aaa) *Performance indicator*, are proposed for addition to the definition list. In adding these definitions, FDA proposes to depart from its earlier practice of placing the definitions in alphabetical order and to simply add the new definitions to the end of the list. This was done to avoid the necessity of making numerous changes in the citations of the definitions in subparts A and B with all the potential for confusion and error that such citation changes would entail.

III. 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.

IV. Analysis of Impacts

FDA has examined the impact of the proposed rule under Executive Order 12866, under the Regulatory Flexibility Act (Public Law 96–354), and under the Unfunded Mandates Reform Act (Public Law 104–4). 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 (including potential economic, environmental, public health and safety, and other advantages, distributive impacts, and equity). The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. The Unfunded Mandates Reform Act requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million (adjusted annually for inflation). The agency has conducted preliminary analyses of the proposed rule, and has determined that the proposed rule is consistent with the principles set forth in the Executive Order and in these two statutes. The regulatory impact study and cost analysis that details the agency's calculation of these economic aspects is available at the Dockets Management Branch for review.

FDA realized from the beginning 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 will be entirely voluntary on the part of the States, FDA cannot determine in advance which States will decide to become SAC States. The first assumptions that had to be made, therefore, were related to which States might become SAC States. Three separate scenarios were used to establish the possible range of the impact of these proposed regulations.

In scenario 1, FDA assumed only the States of Iowa and Illinois would choose to participate in the program. Iowa and Illinois are the current participants in the SAC Demonstration Project and have indicated a strong interest in continuing. In scenario 2, FDA assumed that Iowa and Illinois would be joined in the SAC program by six additional States. The States chosen have in the past indicated significant interest in becoming SAC States when the program is fully implemented. In 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 geographical distribution and the number of mammography facilities within their borders ranges from relatively large to relatively small. Thus, although the basis of selection was FDA's perception of the State's interest, the resulting groups are representative of the country as a whole.

The costs or savings from the SAC program were estimated by comparing the pre-SAC costs for performing the functions that would be affected by the program with the costs of performing them under each scenario. The proposed regulations would permit FDA to delegate to the SAC States the responsibility (with FDA oversight) for the function of MQSA certification as it applies to non-Federal mammography facilities within their borders, and shared responsibility for other functions such as enforcement. Control and execution of the annual inspections of mammography facilities also would be delegated to the SAC States; however, to permit effective oversight of an SAC State's inspection program, FDA would retain responsibility for inspection-related support functions including training the inspectors, calibration of their equipment, and functions related to the transfer of information

electronically between the States and FDA. Underlying all of these functions is the significant task of keeping the public and facilities informed about the MQSA activities. Because of the importance of this public information task, its cost was considered separately in the analysis.

Funding to support the MQSA activities pre-SAC comes from two sources: User fees and appropriated funds. Paragraph (r) of the MQSA provides for user fees to cover costs related to inspections, which FDA collects from each non-governmental mammography facility inspected in a year. Presently, the inspection fee is $1,549 per facility plus an additional $204 per mammography unit for each unit beyond the first 1 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 facility 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 not to enter the SAC program.

If a State becomes a SAC State, the non-governmental facilities within that State will pay an inspection support fee to FDA to reimburse the agency, as required by the statute, for the inspection-related services that the agency has provided. This 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 of $509 will also be provided from appropriated funds for each governmental facility inspection within the State.

The SAC State will determine how the responsibilities that it has assumed will be funded. The funding could come from State appropriations, from a fee charged by the State either under its own authority or under paragraph (r) of the MQSA, or some combination of these sources.

The baseline value (given in tables 1 and 2 of this document) used for the pre-SAC cost of the MQSA functions to be delegated to the SAC States is a total of the costs of the individual functions pre-SAC determined from review of recent FDA budgets. The total costs to the public as a whole under each of the three scenarios will be:

Post-SAC Costs to the public = Costs in non-SAC States + Costs in SAC States

The costs in non-SAC States are calculated as follows:

Costs in non-SAC States = Inspection Program Costs + Certification Costs + Compliance Costs + Public Information Costs

The Inspection Program Costs term was estimated for non-SAC States by subtracting from the baseline inspection costs the total of the inspection fees that will no longer be paid by the facilities (or, in the case of governmental facilities, from appropriated funds) located within the SAC States in each scenario. The other costs were obtained by multiplying the baseline costs for those functions by the percentage of the nation's mammography facilities remaining in non-SAC States. In other words, it was assumed, for example, that if only 80 percent of the nation's facilities remain in non-SAC States, the cost of carrying out these functions would be only 80 percent of the pre-SAC cost.

The costs in SAC States are calculated as follows:

Costs in SAC States = FDA Inspection Support Costs + State Costs

FDA's Inspection Support Costs term was obtained by multiplying the inspection support fee by the number of facilities within the SAC States that would be expected to be inspected during the year (in all these calculations an inspection rate of 82.8 percent was assumed in both non-SAC and SAC States, for reasons discussed in the regulatory impact study and cost analysis available at the Dockets Management Branch). The State Costs assumed by the SAC States could be funded either by State appropriations or a fee charged by the State under State law or the MQSA. If fees are used, they could be State certification fees, inspection fees collected by States under State law, inspection fees collected by States under MQSA, or some combination of these.

The two States currently in the SAC Demonstration Project both decided to fund their activities through a fee. Iowa set its fee at $850 per facility plus $300 for each additional unit beyond the first in the facility. Illinois's fee is $750 per facility. Both States decided to charge these fees to all non-Federal facilities within their borders, whether they were inspected in a given year or not, since the functions being funded are not all related to inspections. For scenario 1, the Total of Other Fees term was obtained by multiplying the number of facilities in the two States (and in Iowa, the number of additional units) by the fee or fees of that State.

The SAC States in scenarios 2 and 3, other than Iowa and Illinois, are not presently SAC States. There is no established fee, therefore, to serve as the basis for estimating their costs. The State Costs term thus had to be estimated using a series of assumptions. The equation used for the estimation was:

State Costs = Inspection Costs + Inspection Support Costs + Certification Costs + Enforcement Costs + Public Information Costs

To obtain the inspection costs term, it was assumed that the average cost per inspection would be the same as the State is presently receiving for performing inspections under contract with FDA; the inspection cost term would be the average per facility cost times the number of facilities inspected. The inspection support costs was the cost of the inspection-support services included in the delegation to the States. Like the last three terms in the equation, this cost related to functions that were new to the States. For all four of these terms, the estimate of cost was made by multiplying the pre-SAC baseline cost for the function by the percentage of the nation's facilities in each SAC State. For example, if 5 percent of the nation's facilities were located in a particular SAC State, the Certification Cost in that State would be estimated as five percent of the pre-SAC cost for the entire nation. For the personnel components of the costs of these functions, further correction factors were applied to take into account the fact that the cost of a State Full Time Employee (FTE) is typically less than that of a Federal FTE.

The analysis results summarized in tables 1 and 2 of this document 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 that savings is not proportional to either the number of States in the program or the number of facilities. In fact, the estimated savings in scenario 3, with 15 SAC States including 54 percent of the nation's facilities, is less than in scenario 2, with 8 States and a little more than 26 percent of the facilities.

TABLE 1.—COST OF CERTIFICATION IN NON-SAC[1] STATES

Scenario	Non-SAC States Facilities (%)	Non-SAC States Cost
Baseline	100.0	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 OF CERTIFICATION IN NON-SAC[1] STATES

Scenario	SAC States Facilities (%)	SAC States Costs	Total Costs	Savings to Public
Baseline	0	0	16,067,499	0
1	5.9	709,870	5,850,432	217,067
2	26.2	3,650,563	15,492,226	575,273
3	54.0	8,180,723	15,575,444	492,055

[1] SAC means States as certifiers.

The explanation of why these results show the pattern that they do begins with the realization that the SAC program will save (or cost) the public more money than the pre-SAC program depending upon whether SAC States can carry out their delegated functions more economically than they 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 a 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 a net savings in scenario 1. The inspection costs in the States added in scenario 2 range from lower than to a little higher than the average. Again, it is not surprising to find that there is a net savings and, since 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, three of the States added to scenario 3 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.

One additional factor had to be taken into account to provide a more accurate evaluation of the cost to the public of the proposed SAC regulations. The initial round of calculations assumed that the inspection fee charged to the facilities in the non-SAC States will not change as the result of some States becoming SAC States. This is not necessarily true. The funds available for the FDA inspection program in the non-SAC States will decrease as more States become SAC States because facilities in SAC States will only be paying FDA the inspection support fee instead of the higher inspection fee. On the other hand, the cost of the FDA inspection program will also decrease because it will no longer include the cost of inspecting the facilities in the SAC States. However, as noted, the inspection cost varies greatly from State to State. If predominantly low inspection cost States become SAC States, the reduction in cost of the MQSA inspection program in the non-SAC States plus the inspection support fee paid by the SAC State facilities may not be as great as the reduction in the funds available to FDA to fulfill its MQSA inspectional responsibilities. In that case it will be necessary to raise the inspection fees in the non-SAC States or the inspection support fee for SAC State facilities, or both, because the FDA inspection program must be fee supported. On the other hand, if predominantly high inspection cost States become SAC States, the reverse would be true and it may be possible to reduce the inspection fees in the non-SAC States.

To refine the analysis, the funds needed by FDA to carry out its post-SAC MQSA inspection responsibilities were compared to the funds that would be available if the inspection and inspection support fees remained unchanged. It was found that 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. The following table 3 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 3.—IMPACT OF NON-SAC[1] STATE INSPECTION FEE CHANGE

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.

The above discussion provides estimates of the economic impact of the proposed SAC regulations on the public in general. In accordance with the Regulatory Flexibility Act, the economic impact on the portion of the public represented by the small entities was also evaluated. All of the approximately 10,000 mammography facilities in the country were considered to be small entities for the purposes of the analysis.

In the case of facilities in non-SAC States, any economic impact in the scenarios examined would appear as an increase or decrease in their inspection fee. As noted above, with the scenarios used in the analysis, additional funds would be needed for FDA's post-SAC MQSA inspection program. The decision on whether these additional funds would come from an increase in the inspection fee paid by non-SAC State facilities, the inspection support fee paid by SAC State facilities, or both would depend upon which fee(s) was (were) failing to cover the cost of the activities for which it was being assessed. However, as a worst case estimate for non-SAC State facilities, it was assumed that 100 percent of the needed funds would have to come from an increase in inspection fee. If the changes in fee are limited to changes in the facility inspection fee, leaving the fee for extra units unchanged, increases of $16.52, $93.16, and $160.23 respectively would be needed in scenarios 1, 2, and 43. Even the largest estimated increase, that for scenario 3, was only about 10 percent of the present $1,549 inspection fee.

Turning to the impact on State facilities, as of August 3, 1998, the SAC States in the three scenarios had within their borders 583; 2,613; and 5,374 mammography facilities respectively. The analysis of the economic impact on these small entities was performed by comparing their savings arising from no longer paying the FDA inspection fee to their costs for the inspection support fees and the State costs.

TABLE 4.—SMALL ENTITY ECONOMIC IMPACT

Scenario	SAC[1] State Facility Savings	SAC State Facility Costs	Net Cost to Small Entities	Net Savings to Small Entities
1	$797,580	$709,870		$87,710
2	$3,651,401	$3,650,563		$838
3	$7,489,128	$8,180,723	$691,595	

[1] SAC means States as certifiers.

If the savings/cost is divided by the number of facilities in each scenario, it is found that, on the average, a facility in scenario 1 would save about $150 per year, as compared to the present inspection fee. On the other hand, the average cost to a facility in scenario 3 would increase about $129 per year. The average cost per facility in scenario 2 is essentially unchanged.

The actual impact on an individual facility varies widely with the State. The extremes of this variation among the States in the analysis are illustrated by comparing the situation in the State with the highest inspection cost from among the 15 with the State with the lowest inspection cost. The facilities in the State with the lowest inspection cost would save, on the average, an estimated $200 per facility per year, over 10 percent of the FDA inspection fee, if their State became a SAC State. Facilities in the State with the highest inspection cost, however, would have to pay an average of about 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, showing how much the impact varies with the State. Even with an overall increase in the cost to the public as a whole and to the part of the public represented by the mammography facilities, some facilities will see savings.

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. This interest was primarily based on a belief that by becoming a SAC State they could provide a service to the facilities and mammography patients within their borders. The service that they expect to be able to provide was an assurance of quality mammography at least equal to that under the national program but at a lower cost. The analyses above indicate that such a belief may be too optimistic in the case of the States whose inspection costs are significantly higher than the national average. If such States realize that this is indeed the case when they conduct their own analysis, it is unlikely that they will apply to become SAC States unless there are other benefits to compensate for the increased costs.

Another encouraging factor is that there were still net savings to the small entities in scenario 1. Scenario 1, it should be remembered, is the scenario where the cost in the SAC States could be based upon the actual fees charged by the States in the Demonstration Project. It would be expected that this would lead to more accurate cost estimates than in scenarios 2 and 3 where a number of assumptions had to be substituted for actual experience. It is possible that these assumptions led to an overestimation of the costs and as other States enter the program they may be able to set their fees so as to adequately fund their activities but at a lower cost than in these estimates.

The evaluations discussed above are based on evaluating the average impact on the mammography facilities in the non-SAC and SAC States. However, mammography facilities, even though

all are considered to be small entities, vary greatly in size and thus their ability to bear additional costs of complying with the MQSA requirements. To further evaluate the impact on small entities, facility compliance costs were compared with 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 following tables 5 and 6 present the average facility costs for facilities in both non-SAC and SAC States as a percentage of low volume facility revenues. For the non-SAC State facilities, the additional costs to the facilities through a worst case increase in the inspection fee (where all of the additional funds needed by FDA to fulfill its responsibilities for the MQSA inspection program must be raised by an increased inspection fee) is used for the comparison. It should be remembered that only the 82.4 percent of the non-SAC facilities inspected will see this impact. The 17.6 percent of these facilities that are not inspected in the year under consideration will pay no inspection fee and will not feel any impact from the increase. For the SAC State facilities, the average per facility cost in scenario 3 (as shown above, there would be a savings in scenarios 1 and 2) is compared to the facility revenues. These costs would be borne by all SAC State facilities.

TABLE 5.—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	<1.0%
3	$160.23	<1.0%

[1] SAC means States as certifiers.

TABLE 6.—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.

The third aspect of the economic impact to be considered is the issue of 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 in any one year by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million. 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.

Finally, in addition to the impact analyses discussed above, Executive Order 12866 requires agencies to select regulatory approaches that maximize net benefits while the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. To fulfill these obligations, FDA considered and rejected the following three alternatives to the approach taken in the proposed rule: (1) Not implementing section 354(q) of the PHS Act; (2) recognizing existing State certification programs; and (3) implementing section 354(q) of the PHS Act through the issuance of more detailed regulations. The reasons for these rejections are discussed in detail in the regulatory impact study and cost analysis which is available at the Dockets Management Branch.

In summary, this analysis shows that the economic impact on both the public and the small entities from the SAC program 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 as a whole was estimated to be less than 1 percent of the present cost of the MQSA activities that would be affected by the SAC program. The situation with respect to the component of the public represented by the 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 in scenario 1 up to approximately 10 percent of the present fee in 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 in scenario 1 to being about 8 percent greater in scenario 3. When the average cost for either SAC or non-SAC facilities in the various scenarios was compared to the revenues of a very small mammography facility, in no case did it exceed 1 percent of the facility revenues.

Although the estimated average savings or increases for the facilities in both the non-SAC and SAC States vary with the scenario, they have in common the fact that they all represent small changes in the pre-SAC costs to the facilities from the inspection fee. However, it should be kept in mind that these averages camouflage 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 thus likely to experience a more favorable economic impact than that estimated in this analysis.

FDA also believes that the expected benefits that will be achieved in guaranteeing quality mammography and reducing breast cancer mortality will be no less after these proposed regulations are implemented than before. Facilities in SAC States will have to meet 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 FDA-trained and equipped inspectors as would be the case if their State did not enter the SAC program. Because the benefits may actually increase, 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 assist mammography facilities seeking to improve the quality of their services or take enforcement actions against those relatively few facilities that present serious threats to the public health.

Based upon these considerations, FDA has determined that this proposed rule is consistent with the principles set forth in the Executive Order, the Regulatory Flexibility Act, and the Unfunded Mandates Act. The economic impact on the public as a whole or on the portion of 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, an insignificant 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 scenario leading to savings to the public as a whole and to the 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.

V. Executive Order 13132—Federalism

On August 4, 1999, the President issued Executive Order 13132, *Federalism*, in which he set forth certain principles to be followed by Executive departments and agencies in developing policies that affect the division of governmental responsibilities between the Federal Government and the States. For the reasons discussed below, and, to some extent described in more detail above, FDA believes that this proposed rule is consistent with the principles embodied in Executive Order 13132.

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 national standards, and, at the same time provides States that wish to become certification agencies with maximum flexibility in administering the program within their State.

Also, as previously noted, interested States have had several opportunities to participate in the development of this policy through NMQAAC, the SAC Working Group, as accreditation bodies, and through the SAC Demonstration Project. States will have an additional opportunity to participate by submitting comments on this proposed rule.

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 chose not to serve as certification agencies.

If a State becomes a SAC State, the facilities within its borders will no longer pay Federal inspection fees nor will federally appropriated funds be used 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 the statute, for the inspection-related functions that the agency has retained. A State that becomes a certification agency will determine how the responsibilities that it has assumed will be funded. The funding could come from State appropriations or from a State fee assessed under either State or MQSA authority or some combination of these two sources.

VI. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). A description of these provisions is given 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.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

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 that they certify will meet minimum national standards for mammography quality. The certifying agency also must provide such information as is needed by the 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.

TABLE 7.—PROPOSED 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 Capital Costs
900.21(b)	13	1.0	13	50	650	$130.00
900.21(c)(2)	13	1.0	13	25	475	$65.00
900.22(i)	2.0	0.1	0.2	5	2.0	$2.00
900.23	2.0	1.0	2.0	20	40.0	$20.00
900.24(a)	2.0	0.05	0.1	10	1.0	$2.00
900.24(b)	2.0	0.2	0.4	20	8.0	$4.00
900.24(b)(2)	2.0	0.05	0.1	20	2.0	$2.00
900.25(a)	2.0	0.25	0.5	5	2.5	$5.00
Total					1,410.5	$230.00

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 8.—PROPOSED REQUIREMENTS FOR STATES AS CERTIFIERS DURING INITIAL YEAR (ESTIMATED ANNUAL RECORDKEEPING BURDEN) [1]

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

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 9.—PROPOSED 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 Capital Costs
900.22(i)	15.0	0.1	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	10	7.5	$7.50
900.24(b)	15.0	0.2	3.0	20	60.0	$30.00
900.24(b)(2)	15.0	0.05	0.75	20	15.0	
900.25(a)	15.0	0.4	6.0	5	30.0	$60.00
Total					420.0	$262.50

[1] There are no operating and maintenance costs associated with this collection of information.

TABLE 10.—PROPOSED REQUIREMENTS FOR STATES AS CERTIFIERS DURING SECOND AND LATER YEARS (ESTIMATED ANNUAL RECORDKEEPING BURDEN) [1]

21 CFR Section	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Capital Costs
900.22(a)	15	1.0	15.0	1.0	15.0	$37.50
900.22(d) through (g)	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 operating and maintenance 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 on the State Governments that choose to become certification agencies and not upon 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 of the additional reporting and recordkeeping burden on the State Governments from these regulations is dependent upon 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, for purposes of estimation of the possible maximum

impact, it is assumed 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 new States added.

A further complication is that the regulations will lead to two types of reporting and recordkeeping burdens. The first is the initial, one time burden resulting from applying for and obtaining approval as a State certification agency. The second is the ongoing burden arising from FDA fulfilling its oversight responsibilities. Because of the different nature and timeframes of these burdens, it is not possible to follow the usual practice of stating the burden on a single set of tables. For this reason, two sets of tables are provided. The first provides estimates of the burden during the first year of the program. During this year, it is assumed that the 13 new States will apply for and obtain approval as certification agencies and so during that year they will bear the initial one time burden associated with applying for and receiving approval as a SAC State under proposed § 900.21. Iowa and Illinois, having already received approval during the Demonstration Project, will not have this burden. However, during the first year, they will have the ongoing burdens of the evaluation process (proposed § 900.23) and possibly that associated with obtaining FDA approval for changes in previously approved standards (proposed § 900.22(i)) and correcting deficiencies (proposed §§ 900.24 through 900.25). The 13 new States will not have been approved in time to have to face this ongoing burden during the first years. The second set of tables estimates the recordkeeping and reporting burden in succeeding years when all 15 States have only the ongoing burden.

With respect to the ongoing burden, based upon the agency's experience with accreditation bodies, which must meet a similar requirement, it was estimated that a SAC State would seek approval for a change in previously approved standards once every 10 years. The annual frequency for reporting under proposed § 900.22(i) thus would be 0.1. Each SAC State will be evaluated annually so the annual frequency for reporting under proposed § 900.23 will be one. It was estimated that each State will have to respond to major deficiencies under proposed § 900.24(a) only once every 20 years and minor deficiencies under proposed § 900.24(b) only once every 5 years. The annual frequencies for reporting under those requirements were thus 0.05 and 0.2 respectively. In the cases where there are minor deficiencies, it was assumed that the State will in most cases make the necessary corrections, but once every 20 years (in other words, once out of every four times it has minor deficiencies), the State would face possible withdrawal of approval under proposed § 900.24(b)(2), so an annual of frequency of response of 0.05 was used there as well. Finally, it was assumed that once every 4 years (an annual frequency of 0.25) each SAC State would seek an informal hearing under proposed § 900.25(a) in responding to some adverse action against it.

The estimated recordkeeping burden was related to the maintenance of standard operating procedures (SOP's) in several areas. It was assumed that each State would spend an hour per year maintaining each SOP.

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 1,416.5 hours during the first year after the regulations were effective and an estimated additional burden of 465.0 hours in each succeeding year. Again, it should be remembered that the actual burden is dependent upon how many States voluntarily choose to enter the SAC program. These estimates are based up 15 States becoming SAC States. They would be reduced or increased if fewer 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 this proposed rule to OMB for review. Interested persons are requested to send comments regarding information collection by May 1, 2000 to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy A. Taylor, Desk Officer for FDA.

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, it is proposed that 21 CFR parts 16 and 900 be amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR part 16 is revised 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 adding in numerical order 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 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 by adding paragraphs (zz) and (aaa) to read as follows:

§ 900.2 Definitions.

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

* * * * *

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

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

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

Subpart C—States as Certifiers

Sec.
900.20 Scope.
900.21 Application for approval as a certification agency.
900.22 Standards for certification agencies.
900.23 Evaluation.
900.24 Withdrawal of approval.
900.25 Hearings and appeals.

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 an FDA-approved certification agency to certify facilities 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 national quality standards established by FDA.

§ 900.21 Application for approval as a certification agency.

(a) *Eligibility*. State agencies capable of meeting the requirements of this subpart may apply for approval as certification agencies.

(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) 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 their equivalence to FDA standards under § 900.12;

(iii) Detailed description of the applicant's review and decision making 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 fully certified mammography facilities will be inspected according to statutory requirements and procedures and policies for notifying facilities of inspection deficiencies;

(L) Policies and procedures for enforcement of 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; and

(O) 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 substantially the same as the quality standards published under subpart B of this part.

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

(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 the MQSA.

§ 900.22 Standards for certification agencies.

The certification agency shall accept the following responsibilities in order to ensure safe and accurate 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) of this section 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 equivalent to those of MQSA and this part 900.

(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 accreditation or certification decisions.

(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.

(g) *Patient notification*. There shall be processes for the certification agency to conduct, or cause to be conducted, patient notifications should the State 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

[1] SAC means States as certifiers.

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 standards that FDA has previously accepted under § 900.21 or this section.

§ 900.23 Evaluation.

FDA shall evaluate annually the performance of each certification agency. Such an evaluation shall include the use of performance indicators that address the adequacy of program performance in certification, inspection, and enforcement activities as well as 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 initiatives. The evaluation also shall include a review of any changes made 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 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 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, 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.

(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 its 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 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) 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

(2) 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: December 15, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 00–7653 Filed 3–29–00; 8:45 am]

BILLING CODE 4160–01–F

POSTAL SERVICE

39 CFR Part 111

Amendments to Proposed Domestic Mail Manual Changes for Sacking and Palletizing Periodicals Nonletters and Standard Mail (A) Flats, for Traying First-Class Flats, and for Labeling Pallets

AGENCY: Postal Service.

ACTION: Proposed Rule; Amendment.

SUMMARY: This rule sets forth amendments to the proposed rule published in the **Federal Register** issue of February 29, 2000 (65 FR 10735). The Postal Service has determined to add a 5-digit scheme carrier routes sack and a 5-digit scheme carrier routes pallet to the proposed presort rules published in the aforementioned **Federal Register**.

Dates: Comments to this proposed rule amendment and to the proposed rule published February 29, 2000 (65 FR 10735) must be received on or before April 14, 2000.

ADDRESSES: Mail or deliver written comments to the Manager, Mail Preparation and Standards, USPS Headquarters, 475 L'Enfant Plaza SW, Room 6800, Washington, DC 20260–2413. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday at the Postal Service Library, 475 L'Enfant Plaza SW, Room 11-N, Washington DC.

FOR FURTHER INFORMATION CONTACT: Lynn Martin, (202) 268–6351, or Linda Kingsley, (202) 268–2252.

SUPPLEMENTARY INFORMATION: On February 29, 2000, the Postal Service published a proposed rule in the **Federal Register** (65 FR 10735). This proposed rule set forth, along with other proposed Domestic Mail Manual (DMM) changes, the addition of new DMM section M720. This proposed DMM M720, if adopted, will allow mailers to place carrier route, 5-digit automation rate, and 5-digit Presorted rate packages of Periodicals and Standard Mail (A) in the same 5-digit container. The new 5-digit containers are named ''merged 5-digit'' and if scheme sortation is opted