U.S. Food and Drug Administration
Mammography Quality Standards Act Requirements
21 CFR Part 900
OMB Control Number 0910-0309

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting approval from the Office of Management and Budget (OMB) for the extension of the information collection requirements contained in the final regulations for mammography facilities as amended. These requirements are implemented under 21 CFR Part 900. These regulations are necessary to implement the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) as amended by the Mammography Quality Standards Reauthorization Acts (MQSRA) of 1998 and 2004. The MQSA requires the establishment of a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation and certification bodies for mammography facilities, and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level.

Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer compliant mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

Title 21 CFR Part 900 Mammography, as amended, requires:

Notification of intent to become an AB - 21 CFR 900.3(b)(1) (Reporting)
Private, non-profit organizations or State agencies are required to inform FDA of their intent to become an AB.

Application for approval as an AB - 21 CFR 900.3(b)(3) (Reporting)
Private, non-profit organizations or State agencies are required to submit three copies of an application for approval as an AB. This requirement is subdivided into full and limited applications.

AB renewal of approval - 21 CFR 900.3(c) (Reporting)
An approved AB must apply for renewal of approval or notify FDA of its plans not to apply for renewal of approval at least nine months before the expiration date of a body's approval.

AB application deficiencies - 21 CFR 900.3(d)(2) (Reporting)
Applicants are required to rectify application deficiencies within a specified timeframe.

AB resubmission of denied applications - 21 CFR 900.3(d)(5) (Reporting)
Denied applications may be resubmitted.

Letter of intent to relinquish accreditation authority - 21 CFR 900.3(e) (Reporting)
An AB that decides to relinquish its accreditation authority before expiration of the body's term of approval shall submit a letter of such intent to FDA at least nine months before relinquishing such authority.

AB transfer of facility records - 21 CFR 900.3(f)(1) (Recordkeeping)
An AB that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall transfer facility records and other related information to a location approved by FDA.

Notification of facilities that AB relinquishes its accreditation - 21 CFR 900.3(f)(2) (Third-party disclosure (TPD))
An AB that does not apply for renewal of accreditation, is denied such approval by FDA, or relinquishes its accreditation authority shall notify all facilities accredited or seeking accreditation by the body that the body will no longer have accreditation authority.

Clinical images - 21 CFR 900.4(c) (TPD)
The AB shall review clinical images from each facility accredited by the body at least once every three years. This requirement is subdivided into AB and facility burdens.

Phantom images - 21 CFR 900.4(d) (TPD)
The AB shall review phantom images from each facility accredited by the body at least once every three years. This requirement is subdivided into AB and facility burdens.

Annual equipment evaluation and survey - 21 CFR 900.4(e) (TPD)
Every facility applying for accreditation is required to submit with its initial accreditation application a mammography equipment evaluation. All facilities must undergo an annual survey to assure continued compliance with accreditation standards and to provide continued oversight of facilities quality control programs as they relate to standards. Accreditation bodies must review these records annually. This requirement is subdivided into AB and facility burdens.

Summary report describing all facility assessments - 21 CFR 900.4(f) (Reporting)
The AB shall conduct onsite visits and random clinical image reviews of a sample of facilities to monitor and assess their compliance with standards established by the body

for accreditation. The AB shall submit annually to the FDA three copies of a summary report describing all facility assessments the body conducted under the provisions of this section for the year being reported.

Consumer complaints system, AB - 21 CFR 900.4(g) (Recordkeeping)
The AB is required to develop and administer a written and documented system, including timeframes, for collecting and resolving serious consumer complaints that could not be resolved at a facility.

AB reporting to FDA - 21 CFR 900.4(h) (Reporting)
The AB is required to submit to FDA the information required by 42 U.S.C. 263b(d) for each facility when the facility is initially accredited and at least annually when updated. The AB is required to notify FDA of applications containing information required by 42 U.S.C. 263b(c)(2) for provisional certificates and in 21 CFR 900.12(b)(2) for extension of provisional certificates. The AB is required to submit to FDA the name, identifying information, and other information for any facility for which the AB denies, suspends, or revokes accreditation. The AB is required to submit to FDA an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them. The AB is required to provide to FDA any other information relevant to 42 U.S.C. 263b and required by FDA about any facility accredited or undergoing accreditation by the body. This requirement is subdivided into AB and facility burdens.

AB financial records - 21 CFR 900.4(i)(2) (Reporting)
At FDA's request, accreditation bodies are required to submit financial records or other material to assist FDA in assessing the reasonableness of AB fees.

Former AB new application - 21 CFR 900.6(c)(1) (Reporting)
A former AB that has had its approval withdrawn may submit a new application for approval if the body can provide information to FDA to establish that the problems that were grounds for withdrawal of approval have been resolved.

Mammography facility certificate application - 21 CFR 900.11(b)(1) (TPD)
A facility must apply to an FDA-approved AB or to another entity as designated by FDA to qualify for a certificate for the lawful operation of a mammography facility.

Provisional mammography facility certificate application - 21 CFR 900.11(b)(2) (TPD)
New facilities beginning operation after October 1, 1994, are eligible to apply for provisional certificates.

Provisional mammography facility certificate extension application - 21 CFR 900.11(b)(3) (TPD)
A facility may apply for a 90-day extension to a provisional certificate.

Mammography facility certificate reinstatement application - 21 CFR 900.11(c) (TPD)

A previously certified facility that has allowed its certificate to expire, that has been refused a renewal of its certificate by FDA, or that has had its certificate revoked by FDA, may apply to have the certificate reinstated.

Documentation of interpreting physician initial requirements - 21 CFR 900.12(a)(1)(i)(B)(*2*) (Recordkeeping)
Facilities are required to document that their interpreting physicians meet all applicable initial requirements. Additional documentation may be needed for foreign-trained physicians, resulting in an increased recordkeeping burden.

Documentation of interpreting physician personnel requirements - 21 CFR 900.12(a)(4) (Recordkeeping)
Facilities are required to document that their interpreting physicians, radiologic technologists, and medical physicists meet all applicable personnel requirements.

Medical report of examination - 21 CFR 900.12(c)(1) (TPD)
Each facility shall ensure that the medical report of the examination contains specific identifying information and content.

Lay summary of examination - 21 CFR 900.12(c)(2) (TPD)
Each facility shall maintain a system to ensure that a lay summary of his or her examination is provided to each patient and that the medical report of the examination is provided to the referring physician or, in the absence of a referring physician, to the patient. These summaries and reports are to be provided within 30 days of the examination but in cases where the assessments are “suspicious” or “highly suggestive of malignancy”, they are to be provided as soon as possible. In cases where the patient does not want to receive a lay summary, the facility can satisfy the requirement through alternative means. The requirement is subdivided to address both scenarios.

Medical report of examination - 21 CFR 900.12(c)(3) (TPD)
Each facility shall maintain a system to ensure that the medical report of the examination is provided to the referring physician. These reports are to be provided within 30 days of the examination but in cases where the assessments are “suspicious” or “highly suggestive of malignancy”, they are to be provided as soon as possible.

Permanent medical record - 21 CFR 900.12(c)(4) (Recordkeeping)
Facilities are required to maintain mammography films and reports in a permanent medical record of the patient.

Procedures for cleaning equipment - 21 CFR 900.12(e)(13) (Recordkeeping)
Facilities shall establish and comply with a system specifying procedures to be followed by the facility for cleaning and disinfecting mammography equipment after contact with blood or other potentially infectious materials.

Audit program - 21 CFR 900.12(f) (Recordkeeping)
Each facility is required to establish and maintain a mammography medical outcomes audit program. As part of that program, an interpreting physician is required to review the audit data at least once every 12 months. This individual is required to identify issues and analyze results based on this audit.

Consumer complaints system, facility - 21 CFR 900.12(h)(2) (Recordkeeping)
Each facility is required to establish a written and documented system for collecting and documenting consumer complaints and to maintain a record of each serious complaint received by the facility for at least 3 years.

Report of unresolved serious complaints - 21 CFR 900.12(h)(4) (TPD)
Facilities must report unresolved serious complaints to their AB.

Information regarding compromised quality - 21 CFR 900.12(j)(1) (TPD)
If FDA believes that mammography quality at a facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information for review by the AB or other entity designated by FDA. This requirement is subdivided into AB and facility burdens.

Patient notification of serious risk - 21 CFR 900.12(j)(2) (TPD)
If FDA determines that any activity related to the provision of mammography at a facility may present a serious risk to human health such that patient notification is necessary, the facility shall notify patients or their designees, their physicians, or the public of action that may be taken to minimize the effects of the risk.

Reconsideration of accreditation - 21 CFR 900.15(c) (TPD)
A facility that has been denied accreditation by an AB may request reconsideration of that adverse decision by the AB.

Reconsideration of accreditation following appeal - 21 CFR 900.15(d)(3)(ii) (Reporting)
A facility that has been denied accreditation following appeal to the AB may request reconsideration of that adverse decision by FDA.

Application for alternative standard - 21 CFR 900.18(c) (Reporting)
Mammography facilities, accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography may apply for approval of an alternative standard or for an amendment or extension of the alternative standard by submitting an application to FDA.

Alternative standard amendment - 21 CFR 900.18(e) (Reporting)
An application for amending or extending approval of an alternative standard must provide an explanation supported by data of how such an amendment or extension would assure equal or greater quality of production, processing, or interpretation of mammograms than the original standard.

Certification agency application - 21 CFR 900.21(b) (Reporting)
An applicant seeking FDA approval as a certification agency must submit an application to FDA.

Certification agency application deficiencies - 21 CFR 900.21(c)(2) (Reporting)
If FDA notifies the applicant of any deficiencies in the application, the applicant must correct the deficiencies or FDA may deny the application.

Certification agency conflict of interest - 21 CFR 900.22(a) (Recordkeeping)
A certification agency must establish and implement measures that FDA has approved to reduce the possibility of conflict of interest or facility bias on the part of individuals acting on the certification agency's behalf.

Processes for suspension and revocation of certificates - 21 CFR 900.22(d) (Recordkeeping)
A certification agency must establish processes for the suspension and revocation of certificates and other enforcement actions, appeals, additional mammography review from accreditation bodies, and patient notification.

Processes for appeals - 21 CFR 900.22(e) (Recordkeeping)
A certification agency must establish processes for appeals of inspection findings, enforcement actions, and adverse certification decisions.

Processes for additional mammography review - 21 CFR 900.22(f) (Recordkeeping)
A certification agency must establish processes for additional mammography review from accreditation bodies.

Processes for patient notifications - 21 CFR 900.22(g) (Recordkeeping)
A certification agency must establish processes for patient notification.

Certification electronic data transmission - 21 CFR 900.22(h) (Reporting)
A certification agency shall ensure timely and accurate electronic transmission of inspection and certification data to FDA.

Changes to standards - 21 CFR 900.22(i) (Reporting)
A certification agency shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted.

Evaluation of certification agency - 21 CFR 900.23 (Recordkeeping)
FDA will perform an annual evaluation of each certification agency. The certification agency must correct any major deficiencies noted by FDA or FDA may withdraw approval of the certification agency.

Notification of requirement to correct major deficiencies - 21 CFR 900.24(a) (TPD)
A certification agency that is required to correct major deficiencies shall notify all facilities certified or seeking certification by it within a time period and in a manner approved by FDA.

Notification of loss of approval; major deficiencies - 21 CFR 900.24(a)(2) (TPD)
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 time frame and in a manner approved by FDA.

Certification agency minor deficiencies - 21 CFR 900.24(b) (Reporting)
If FDA notifies a certification agency that there are certain minor deficiencies in its program, the certification agency must correct those deficiencies or FDA may withdraw its approval.

Notification of probationary status - 21 CFR 900.24(b)(1) (TPD)
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 and in a manner approved by FDA.

Notification of loss of approval; minor deficiencies - 21 CFR 900.24(b)(3) (TPD)
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 time frame and in a manner approved by FDA.

Certification agency transfer of records to FDA - 21 CFR 900.24(c)
A certification agency that has had its approval withdrawn must transfer facility records and other related information as directed by FDA. Section 900.24(c) is not included in the burden tables because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, there wouldn't be an additional burden.

Appeal of adverse action taken by FDA - 21 CFR 900.25(a) (Reporting)
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 21 CFR Part 16.

Appeals - 21 CFR 900.25(b) (TPD)

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.

Inspection fee exemption - Form FDA 3422 (Reporting)
Under the MQSA, all certified mammography facilities except governmental entities, as determined by FDA, are subject to payment of inspection fees. The information provided by this form is used by FDA to determine if the facility is operated by any Federal department, State, district, territory, possession, federally recognized Indian tribe, city, county, town, village, municipal corporation or similar political organization or subpart thereof. Collection of information from this form will also allow FDA to determine if the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990.

2. Purpose and Use of the Information Collection

The most likely respondents to this information collection will be accreditation bodies, State certification agencies, and mammography facilities seeking certification. The likely respondents are from the private sector (business, for-profit and non-profit) and State, local or tribal governments.

This information collection is necessary to assure safe, accurate, and reliable mammography on a nationwide basis. Information collected from mammography facilities has been used to ensure that the personnel, equipment, and quality systems have met and continue to meet the regulations under MQSA and will be used by patients to manage their health care properly.

Certain provisions of the MQSA require that accreditation of mammography facilities by private, nonprofit organizations or State agencies and certification of mammography facilities by State agencies be approved by FDA according to standards established by FDA. FDA has used data from the current accreditation and certification process to ensure that the requirements of the final rule are met. The information collected for accreditation and certification bodies of mammography facilities has been and will continue to be used by FDA to ensure that private, nonprofit organizations or State agencies have met the standards established by FDA for accreditation bodies to accredit and State certification agencies to certify facilities that provide mammography services.

3. Use of Improved Information Technology and Burden Reduction

FDA estimates that 95% of the respondents will use electronic means to fulfill the agency's requirement or request. A particularly significant use of information technology in the MQSA program to reduce the reporting and recordkeeping burden is that the accreditation bodies and State certification agencies provide the required information to FDA almost entirely by electronic means. Most information currently is processed through the program's electronic Mammography Program Reporting and Information System (MPRIS). Presently, accreditation bodies send information electronically through

the use of web pages whereby data is updated. Inspection findings are reported electronically on the inspector's laptop and then uploaded into the system. Information is transmitted to State certification agencies electronically. Compliance Officers and Regional Radiological Health Representatives (RRHR) modify non-compliance information found in the inspections. Billing files are created monthly and then sent electronically to an FDA contractor who then produces the bills. The MPRIS system is essentially paperless at this point, and currently meets Government Paperwork Elimination Act (GPEA) requirements.

Other examples of reducing burden through technology include FDA's permitting physician's electronic signatures on medical reports and its acceptance of electronic recordkeeping in such areas as the medical audit, quality control, and patient reports. The use of electronic forms of reporting and recordkeeping submissions to FDA continues to remain voluntary at this point.

Any information generated for the patient's use may be communicated to the patient in any appropriate format.

4. Efforts to Identify Duplication and Use of Similar Information

The MQSA was enacted to establish uniform national quality standards for all mammography facilities. Under the previous regulatory system, no national comprehensive mammography quality standards existed. The American College of Radiology (ACR) is the principal professional organization of physicians trained in radiology and medical radiation physics in the United States. In 1987, the ACR began the voluntary Mammography Accreditation Program (MAP), the purpose of which was to provide assurance of quality to patients seeking services at ACR-accredited facilities. Today, ACR is performing their accreditation program under FDA authority.

While some of the information previously included in the MAP was the same as now required by FDA under this information collection, only those facilities that had voluntarily sought accreditation previous to October 1, 1994 (less than a quarter of the total) had provided this information to the ACR. Hence, the information being collected under the MQSA was not previously available for all facilities on a nationwide basis. FDA found no other information sources that were available. Because there is no similar information available to assure that mammography facilities are complying with the requirements of MQSA, the information requested under MQSA is not duplicative.

5. Impact on Small Businesses or Other Small Entities

The number of respondents that are small businesses is 8,679. FDA does not believe that the collection of information will adversely affect small businesses or other small entities. Because smaller facilities by definition have fewer employees and lower volumes of mammography examinations than large facilities, these facilities will have a lesser amount of burden. Thus, the amount of burden will be proportional to the volume of

examinations at the mammography facility. Hence, facilities of all sizes will experience an equal burden in relative terms (i.e., small facilities will not be affected any more or less than large facilities).

FDA has also attempted to minimize the information collection burden on small entities by developing a small entity compliance guide. This guide was issued under section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996. Subsequently, as additional questions arose with respect to complying with the regulations, FDA provided further guidance in answer to these questions. To date, twenty-one major guidance documents have been made available, one of which concentrated specifically on recordkeeping questions. In accordance with Good Guidance Practices, these documents were made available electronically to the public. As each document was issued, the information in it was incorporated into an electronic file called the Policy Help Guidance System. This file is available to the public on the FDA's mammography Web Site http://www.fda.gov/Radiation-EmittingProducts/MammographyQualityStandardsActandProgram/default.htm, along with an incorporated search engine. Members of the public may consult the guidance on the Web site or download it and the search engine to their own computer for more convenient use. This guidance, like the previously published compliance guide, is intended to help small entities comply with the final regulations.

There are situations where the facilities are required to submit information of interest to both the accreditation bodies and FDA or the State certification agency. From the beginning of the program, FDA has required only a single submission of this information. Typically, the information is sent to the AB, which then, as discussed above, transmits it electronically to FDA. This reduces the burden that would rise if the facility was required to submit the information directly both to FDA and the AB.

Further, in the interest of maintaining flexibility while improving the overall quality of mammography, FDA has provided an avenue through which an effective alternative standard may be implemented. The Agency has created a mechanism for mammography facilities and accreditation bodies, State governments that are not accreditation bodies, and manufacturers and assemblers of equipment used for mammography to request permission to meet an alternative standard rather than an existing quality standard. The request must be supported by such evidence as required by the Agency to render a determination that the suggested alternative is at least as effective as the FDA-mandated standard in helping to achieve high quality mammography.

6. Consequences of Collecting the Information Less Frequently

Depending on the specific requirement, respondents will respond to the data collection on an occasional, daily, weekly, quarterly, semiannual, annual, and every three year basis. Less frequent information collection may result in an unacceptable quality of mammography being provided by many facilities. With less frequent information collection, the accreditation bodies, State certification agencies, and FDA would not be able to assure that facilities are adequately meeting the quality standards. FDA believes

that the reporting and recordkeeping frequency in the final rule is the minimum necessary to assure safe, accurate, and reliable mammography on a nationwide basis.

There are no legal obstacles to the collection of this information.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with 5 CFR 1320.5(d).

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), on May 1, 2019, (84 FR 18548), FDA published a 60-day notice for public comment in the Federal Register. We received one comment that expressed general concern regarding the cost and quality of mammography equipment. However, the comment did not refer to any particular provision of the regulations or the information collection burden estimate. We note that in the Federal Register of March 28, 2019 (84 FR 11669), FDA published a proposed rule to update the Mammography Regulations. As part of the proposed rule, FDA prepared a Preliminary Economic Analysis of Impacts. Comments received on the proposed rule are currently being considered.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) annually. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. It is charged with advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC also discusses and comments on all guidances before they are made final. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also meets or holds teleconferences several times a year with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. The Agency has also long enjoyed a good relationship with the Conference of State Radiation Program Directors (CRCPD), which is the professional organization of the State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

9. Explanation of any Payment of Gift to Respondents

No payment or gifts shall be provided to respondents under this regulation.

10. Assurance of Confidentiality Provided to Respondents

This ICR (extension) collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via FDA Form 3422 (Governmental Entity Declaration) is name, work address, telephone number, and employee identification number (EIN).

FDA further determined that although PII is collected the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, FDA does not use name or any other personal identifier to routinely retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

In preparing this Supporting Statement, FDA staff consulted with the FDA Privacy Office to ensure appropriate handling of information collected. FDA minimized the PII to be collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information. Mammography facility information submitted to FDA under 21 CFR Part 900 are releasable under the FOIA as set forth in 21 CFR Part 20.

Mammography reports and patient lay summaries issued under 21 CFR 900(c)(2) and (c)(3) will only be available to the patient or concerned health officials.

11. Justification for Sensitive Questions

This information collection does not include questions pertaining to sexual behavior, attitude, religious beliefs, or any other matters that are commonly considered private or sensitive in nature.

12. Estimate of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

The total estimated annual reporting and recordkeeping burden for meeting the regulations is 3,938,137 and is documented in the tables below.

Table 1.--Estimated Annual Reporting Burden					
Activity/ 21 CFR Section/ FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours[1]
Notification of intent to become an AB--900.3(b)(1)	0.33	1	0.33	1	1
Application for approval as an AB; full[2]--900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited[3]--900.3(b)(3)	5	1	5	30	150
AB renewal of approval--900.3(c)	1	1	1	15	15
AB application deficiencies--900.3(d)(2)	0.1	1	0.1	30	3
AB resubmission of denied applications--900.3(d)(5)	0.1	1	0.1	30	3
Letter of intent to relinquish accreditation authority--900.3(e)	0.1	1	0.1	1	1
Summary report describing all facility assessments--900.4(f)	330	1	330	7	2,310
AB reporting to FDA; facility[4]--900.4(h)	8,654	1	8,654	1	8,654
AB reporting to FDA; AB[5]--900.4(h)	5	1	5	10	50
AB financial records--900.4(i)(2)	1	1	1	16	16
Former AB new application--900.6(c)(1)	0.1	1	0.1	60	6
Reconsideration of accreditation following appeal--900.15(d)(3)(ii)	1	1	1	2	2
Application for alternative standard--900.18(c)	2	1	2	2	4
Alternative standard amendment--900.18(e)	10	1	10	1	10
Certification agency application--900.21(b)	0.33	1	0.33	320	106
Certification agency application deficiencies--900.21(c)(2)	0.1	1	0.1	30	3
Certification electronic data transmission--900.22(h)	5	200	1000	0.083	83
Changes to standards--900.22(i)	2	1	2	30	60
Certification agency minor deficiencies--900.24(b)	1	1	1	30	30
Appeal of adverse action taken by FDA--900.25(a)	0.2	1	0.2	16	3
Inspection fee exemption--FDA Form 3422	700	1	700	0.25	175
Total					11,791

[1] Total hours have been rounded.
[2] One time burden.
[3] Refers to accreditation bodies applying to accredit specific full-field digital mammography (FFDM) units.
[4] Refers to the facility component of the burden for this requirement.
[5] Refers to the AB component of the burden for this requirement.

Table 2.--Estimated Annual Recordkeeping Burden					
Activity/21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours[1]
AB transfer of facility records--900.3(f)(1)	0.1	1	0.1	0	1
Consumer complaints system; AB--900.4(g)	5	1	5	1	5
Documentation of interpreting physician initial requirements--900.12(a)(1)(i)(B)(*2*)	87	1	87	8	696
Documentation of interpreting physician personnel requirements--900.12(a)(4)	8,654	4	34,616	1	34,616
Permanent medical record--900.12(c)(4)	8,654	1	8,654	1	8,654
Procedures for cleaning equipment--900.12(e)(13)	8,654	52	450,008	0.083	37,351
Audit program--900.12(f)	8,654	1	8,654	16	138,464
Consumer complaints system; facility--900.12(h)(2)	8,654	2	17,308	1	17,308
Certification agency conflict of interest--900.22(a)	5	1	5	1	5
Processes for suspension and revocation of certificates--900.22(d)	5	1	5	1	5
Processes for appeals--900.22(e)	5	1	5	1	5
Processes for additional mammography review--900.22(f)	5	1	5	1	5
Processes for patient notifications--900.22(g)	3	1	3	1	3
Evaluation of certification agency--900.23	5	1	5	20	100
Appeals—900.25(b)	5	1	5	1	5
Total					237,223
[1] Total hours have been rounded.					

Table 3.--Estimated Annual Third-Party Disclosure Burden					
Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Notification of facilities that AB relinquishes its accreditation--900.3(f)(2)	0.1	1	0.1	200	20
Clinical images; facility[2]--900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	1.44	4,154
Clinical images; AB[3]--900.4(c)	5	1	5	416	2,080

Table 3.--Estimated Annual Third-Party Disclosure Burden					
Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours[1]
Phantom images; facility[2]--900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,885	1	2,885	0.72	2,077
Phantom images; AB[3]--900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility[2]--900.4(e), 900.11(b)(1), and 900.11(b)(2)	8,654	1	8,654	1	8,654
Annual equipment evaluation and survey; AB[3]--900.4(e)	5	1	5	1,730	8,650
Provisional mammography facility certificate extension application--900.11(b)(3)	0	1	0	0.5	1
Mammography facility certificate reinstatement application--900.11(c)	312	1	312	5	1,560
Lay summary of examination--900.12(c)(2)	8,654	5,085	44,055,590	0.083	3,652,464
Lay summary of examination; patient refusal[4]--900.12(c)(2)	87	1	87	0.5	44
Report of unresolved serious complaints--900.12(h)(4)	20	1	20	1	20
Information regarding compromised quality; facility[2]--900.12(j)(1)	20	1	20	200	4,000
Information regarding compromised quality; AB[3]--900.12(j)(1)	20	1	20	320	6,400
Patient notification of serious risk--900.12(j)(2)	5	1	5	100	500
Reconsideration of accreditation--900.15(c)	5	1	5	2	10
Notification of requirement to correct major deficiencies--900.24(a)	0.4	1	0.4	200	80
Notification of loss of approval; major deficiencies--900.24(a)(2)	0.15	1	0.15	100	15
Notification of probationary status--900.24(b)(1)	0.3	1	0.3	200	60
Notification of loss of approval; minor deficiencies--900.24(b)(3)	0.15	1	0.15	100	15
Total					3,691,842

[1] Total hours have been rounded.
[2] Refers to the facility component of the burden for this requirement.
[3] Refers to the AB component of the burden for this requirement.
[4] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

The following regulations were not included in the above burden tables because they were considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional hour burden: 21 CFR 900.12(c)(1), 900.12(c)(3), and 900.3(f)(1). Section 900.24(c) was also not included in the previously mentioned burden tables because if a certifying State had its approval withdrawn, FDA would take over certifying authority for the affected facilities. Because FDA already has all the certifying State's electronic records, there wouldn't be an additional reporting burden.

12b. Annualized Cost Burden Estimate

The total hour cost estimate for the annual reporting and recordkeeping burden is estimated to be $73,213,227. This estimate is based on data from the U.S. Department of Labor's Bureau of Labor Statistics "May 2017 National Occupational Employment and Wage Estimates United States" (http://www.bls.gov/oes/current/oes_nat.htm). We estimate that the burden will be performed by Radiologic Technologists (occupation code 29-2034) (approximately 10%), Receptionists and Information Clerks (occupation code 43-4171) (approximately 45%), and Medical Records and Health Information Technicians (occupation code 29-2071) (approximately 45%).

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs (rounded)
Receptionists and Information Clerks	1,773,385	$14.25	$25,270,736
Medical records and Health Information Technicians	1,773,385	$20.59	$36,513,997
Radiologic Technologists	394,086	$29.00	$11,428,494
Total			$73,213,227

13. Estimate of the Other Total Annual Cost to Respondents and/or Recordkeepers/Capital Costs

A. Total Capital Cost

The total capital cost associated with these regulations is $73,274.

21 CFR 900.3(b)(3)	$10,776
21 CFR 900.21(b)	$32,327
21 CFR 900.12(c)(4)	$30,171

The capital costs associated with 21 CFR 900.3(b)(3) and 21 CFR 900.21(b) are those that entities wishing to become new accreditation bodies or certifying agencies would incur in order to establish the basic infrastructure needed to perform the functions of accreditation bodies or certifying agencies. The capital cost associated with 21 CFR 900.12(c)(4) is related to the added storage space for the records due to the 10-year retention period.

B. Total Operating & Maintenance Cost

The total operating and maintenance cost associated with these requirements is $26,229,903. This is the cost that facilities bear to report and maintain records under the mammography regulations.

21 CFR 900.3(f)(2)	$54
21 CFR 900.4(c)	$248,670
21 CFR 900.4(e)	$9,325
21 CFR 900.4(f)	$83,618
21 CFR 900.4(h)	$4,663
21 CFR 900.12(c)(2)	$25,861,265
21 CFR 900.12(j)(1)	$970
21 CFR 900.12(j)(2)	$20,878
21 CFR 900.21(b)	$224
21 CFR 900.22(g)	$32
21 CFR 900.22(i)	$22
21 CFR 900.24(a)	$73
21 CFR 900.24(a)(2)	$27
21 CFR 900.24(b)(1)	$55
21 CFR 900.24(b)(3)	$27

14. Annualized cost to the Federal Government

FDA is currently using 42 FTE's to implement the accreditation, quality standards, and certification provisions of the MQSA. This amounts to a total of $11,352,810 based on a cost of $270,305 per position (which is the agency's projected average cost of an FTE including benefits*).

*Based on the Food and Drug Administration fully loaded FTE cost model (domestic) for FY 2018, as provided by agency economists.

15. Explanation for Program Changes or Adjustments

There are no program changes. The hour burden has been adjusted to account for a slight increase in the number of respondents for § 900.3(c) "AB renewal of approval." This resulted in a 14-hour increase to the burden estimate.

Additionally, we updated the capital costs and operating and maintenance costs by adjusting them for inflation since the last update to those estimates.* This adjustment resulted in a $1,893,071 increase to the estimated capital and operating and maintenance costs ($24,410,106 previously; $26,303,177 current extension request).

* Using the Bureau of Labor and Statistics CPI Inflation Calculator (https://www.bls.gov/data/inflation_calculator.htm). Updates were calculated from July 2013 (date of submission to OMB of the last update to the "Estimate of the Other Total

Annual Cost to Respondents and/or Recordkeepers/Capital Costs" section of the burden estimate) to January 2019. The estimates are rounded to the nearest dollar.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish the results of this information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exception to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.