U.S. Food and Drug Administration
Mammography Quality Standards Act Requirements; Mammography Facilities, Standards, and Lay Summaries for Patients
21 CFR Part 900
OMB Control No. 0910-0309
RIN 0910-AH04

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 revised information collection burden estimate associated with the proposed amendment of the requirements regarding mammography facilities. These requirements are implemented under 21 CFR Part 900.

FDA is proposing to update the mammography regulations that were issued under the Mammography Quality Standards Act of 1992 (MQSA) and the Federal Food, Drug, and Cosmetic Act (FD&C Act). We are proposing updates to modernize the regulations by incorporating current science and mammography best practices. These updates would improve the delivery of mammography services by: strengthening the communication of health care information; allowing for more informed decision making by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

The MQSA (Public Law 102-539) was enacted on October 27, 1992, and is codified at 42 U.S.C. 263b (section 354 of the PHS Act). Under the MQSA, all mammography facilities, except facilities of the Department of Veteran Affairs (VA), must be accredited by an approved accreditation body and certified by FDA (or an approved State certification agency) to provide mammography services (42 U.S.C. 263b(b)(1), (d)(1)(iv)). FDA is proposing these amendments to the mammography regulations (set forth in 21 CFR Part 900) under section 354 of the PHS Act (42 U.S.C. 263b), and sections 519, 537, and 704(e) of the FD&C Act (21 U.S.C. 360i, 360nn, and 374(e)).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.

The information collections are listed as follows:

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.

Proposed revisions:

FDA is proposing to amend its mammography reporting requirements to require that the mammography report provided to the healthcare provider and the lay summary report provided to the patient include basic mammography facility identification information and information concerning patient breast density. This action is intended to facilitate communication between mammography facilities, healthcare providers, and patients; facilitate the retrieval of mammography images; and help ensure that healthcare providers and patients obtain the necessary information from the mammography facility to enable a woman and her healthcare provider to make informed healthcare decisions. FDA also is proposing additional categories be added to the list of assessments that facilities are required to use in the mammography report. In addition, FDA is proposing to amend its requirements related to the transfer and provision of mammography records, the transfer and provision of personnel records upon request or facility closure, and FDA notification and mammographic records access upon facility closure.

A detailed description of the revisions related to the proposed rule is provided in section 12a of this document.

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.

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. 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.

Additionally, we are proposing updates to modernize the regulations by incorporating current science and mammography best practices. These updates would improve the delivery of mammography services by: strengthening the communication of health care information; allowing for more informed decisionmaking by patients and providers (by requiring facilities to provide them with additional health information); helping to ensure the availability of qualified mammography personnel; bolstering the medical outcomes audit to provide feedback to improve mammography interpretations; modernizing technological aspects of the standards; and adding additional tools to deal with noncompliant facilities.

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, 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 the MQSA, the information requested under MQSA is not duplicative.

5. Impact on Small Businesses or Other Small Entities

FDA has 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.

Proposed Rule:
As required by the Regulatory Flexibility Act, we analyzed regulatory options that would minimize any significant impact of the rule on small entities (see section III of the Preliminary Regulatory Impact Analysis (PRIA) for the "Mammography Quality Standards Act; Amendments to Part 900 Regulations" proposed rule). In the PRIA, we estimate that approximately 4,247 respondents are small businesses.

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 3-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 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

There are no special circumstances for this collection of information.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), FDA provided an opportunity for public comment on the information collection requirements of the proposed rule that published in the FEDERAL REGISTER of March 28, 2019 (84 FR 11669).

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

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.

CDRH's Privacy Officer is conducting a privacy review of this information collection and will submit a privacy impact assessment, if appropriate, to the FDA privacy office for review prior to finalization of the rulemaking.

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 3,938,123 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)	0	1	0	15	1

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]
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					11,777

[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

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]
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
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

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]
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.

Proposed revisions:

In its proposed rule "Mammography Quality Standards Act; Amendments to Part 900 Regulations" (84 FR 11669), FDA is proposing to amend its mammography reporting requirements to require that the mammography report provided to the health care provider and the lay summary report provided to the patient include basic mammography facility identification information and information concerning patient breast density. This action is intended to facilitate communication between mammography facilities, healthcare providers, and patients; facilitate the retrieval of mammography images; and help ensure that health care providers and patients obtain the necessary information from the mammography facility to enable a woman and her health care provider to make informed health care decisions. FDA also is proposing additional categories be added to the list of assessments that facilities are required to use in the mammography report. In addition, FDA is proposing to amend its requirements related to the transfer and provision of mammography records, the transfer and provision of personnel records upon request or facility closure, and FDA notification and mammographic records access upon facility closure.

The proposed amendments to Part 900, if finalized, will necessitate revisions to this ICR. We request approval to add the following ICs to the annual third-party disclosure burden:

Proposed revisions--Estimated Annual Third-Party Disclosure Burden[1]

Activity/21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Provision of personnel records -- 900.12(a)(4)	608	1	608	0.08 (5 minutes)	49
Transfer of personnel records by closing facilities—900.12(a)(4)	87	1	87	5	435
New assessment categories and breast density reporting in mammography report (one-time burden)—900.12(c)(1)(iv)-(c)(1)(vi)	8,691	1	8,691	23	199,893
Breast density reporting in lay summary (one-time burden)—900.12(c)(2)	8,691	1	8,691	11	95,601
Transfer/provision of copies of mammograms and records upon patient's request—900.12(c)(4)(ii) and (c)(4)(iii)	8,691	1,508	13,106,028	0.08 (5 minutes)	1,048,482
Facility closure; notification and records access—900.12(c)(4)(v)	87	1	87	32	2,784
Patient notification of significant risk (by State certification agency)--900.12(j)(2)	5	1	5	100	500
Total					1,347,744

[1] Columns may not sum due to rounding.

Personnel records—900.12(a)(4): Under § 900.12(a)(4), facilities are required to maintain records of training and experience regarding personnel who work or have worked at the facility as interpreting physicians, radiologic technologists, or medical physicists. Facilities must maintain records of personnel no longer employed by the facility at least until the next annual inspection and until FDA has determined that the facility is in compliance with the MQSA personnel requirements. FDA is not proposing any changes to these requirements. The information collection (recordkeeping) burden for this provision is currently approved under this ICR.

Also, under proposed § 900.12(a)(4), facilities would have to provide copies of personnel records to current or former interpreting personnel (physician, radiological technologist and medical physicist) upon their reasonable request. We estimate that there are, on average, 7 interpreting personnel per facility (approximately 61,082 total). We estimate that 1 percent of these personnel (611 personnel annually) would request the records and that it would take approximately 5 minutes to provide the copies for each request.

Additionally, under proposed § 900.12(a)(4), before a facility closes or ceases to provide mammography services, it would have to make arrangements for personnel to access their MQSA personnel records. This access may be provided by the permanent transfer of these records to the personnel or the transfer of the records to a facility or other entity that would provide access to these records. We estimate that annually 1 percent of the total facilities would close or cease to provide mammography services and that it would

take each of the facilities approximately 5 hours to transfer the records.

Medical records and mammography reports—900.12(c)(1) through (c)(4): Section 900.12(c)(1), Contents and terminology, sets forth the requirement for facilities to prepare a written report of the results of each mammographic examination performed under its certificate. Section 900.12(c)(1) requires that the report include patient identifying information, date of examination, facility name and location, the final assessment of findings (or classification as to why no final assessment can be made), name of the interpreting physician, and recommendations to the health care provider.

This proposed rule would include two additional final assessment categories and an additional classification in the mammography report, and would also require an assessment of breast density in the report (proposed § 900.12(c)(1)(iv) through (c)(1)(vi)). We estimate a one-time burden for facilities to update their existing mammography reports with these new categories. Based on the Eastern Research Group (ERG), Inc.'s report, we believe this would take 23 hours per facility (Ref. 31).

Under the proposed rule, if the final assessment is "Suspicious" or "Highly suggestive of malignancy," the facility would have to provide the report to the health care provider, or if the referring health care provider is unavailable, to a responsible designee (proposed 900.12(c)(3)(ii)) within a specified timeframe; the current regulation states that facilities must make reasonable attempts to provide the report in such situations "as soon as possible." The provision of the report to the health care provider was not included in the currently approved information collection burden, OMB control number 0910-0309, because it was considered usual and customary practice and was part of the standard of care prior to the implementation of the regulations (see 5 CFR 1320.3(b)(2)). Provision of the mammography report to health care providers continues to be part of the standard of care and remains the usual and customary business practice. Therefore, these changes would not result in additional burden.

Under § 900.12(c)(2), Communication of mammography results to the patients, within 30 days of the mammographic examination, each facility shall provide each patient a summary of the mammography report written in lay terms. Under the proposed rule, if the final assessment is "Suspicious" or "Highly suggestive of malignancy," the facility would have to provide the patient a summary of the mammography report within a specified timeframe (proposed 900.12(c)(2)); the current regulation states that facilities must make reasonable attempts to provide the report in such situations "as soon as possible." Under the proposed rule, this summary would need to include the name of the patient and name, address, and telephone number of the facility. We estimate that the proposed requirements for the lay summary to include this information would not result in a change to the currently approved information collection burden for § 900.12(c)(2).

Proposed § 900.12(c)(2) also would require facilities to provide an assessment of breast density in the lay summary. We estimate a one-time burden for facilities to update their existing lay summary reports with the breast density assessments. Based on the ERG report, we believe this would take 11 hours per facility (Ref. 31).

Also, under § 900.12(c)(2)(ii), each facility that accepts patients who do not have a health care provider shall maintain a system for referring such patients to a health care provider when clinically indicated. The proposed rule would also require that the system provide referrals when "mammographically" indicated. We estimate this proposed addition would not result in a change to the currently approved information collection burden.

The proposed requirements in § 900.12(c)(2)(iii) and (c)(2)(iv) to provide an explanation of the breast density assessment identified in (c)(1)(vi), are not considered to be "collections of information" because the language is originally supplied by the Federal government for the purpose of disclosure to members of the public (5 CFR 1320.3(c)(2)).

Under proposed § 900.12(c)(4)(i), facilities that perform mammograms must maintain mammographic records. The proposed rule would require that facilities implement policies and procedures to minimize the possibility of record loss, and would require that records be maintained in the modality in which they were produced. We estimate these proposed additions would not result in a change to the currently approved information collection burden.

Under § 900.12(c)(4)(ii), facilities shall, upon request by or on behalf of the patient, transfer or release the mammograms and copies of the patient's reports to a medical institution, a physician or health care provider of the patient, or to the patient directly. Under proposed § 900.12(c)(4)(ii) and (c)(4)(iii), facilities would need to transfer original mammograms (and copies of associated reports) or provide copies of mammograms (and copies of associated reports) within a specified period of time. Copies of mammograms would need to be in the same modality in which they were produced. Moreover, for digital mammograms or digital breast tomosynthesis, the facility would have to be able to provide the recipient with original digital images electronically if the examination is being transferred for final interpretation. While the burden of maintaining records under (c)(4) is included in the currently approved burden estimate, the currently approved burden estimate does not include the third-party disclosure burden of transferring the records. We estimate that approximately one third of patients would request transfer or release of the records (this equals an average of approximately 1,505 requests per facility) and it would take approximately 5 minutes per request.

Under proposed section 900.12(c)(4)(v), before a facility closes or ceases to provide mammography services, it would have to make arrangements for access by patients and health care providers to their mammographic records. Additionally, the facility would have to notify its accreditation body and certification agency in writing of the arrangements it has made and must make reasonable efforts to notify all affected patients. We estimate that 1 percent of facilities would close on an annual basis and that it would take each facility approximately 32 hours to provide notification and access to the records.

Quality assurance-mammography medical outcomes audit—900.12(f): Section 900.12(f)(1) requires each facility to establish a system to collect and review outcome data for all

mammographic examinations performed, including follow-up on the disposition of all positive mammograms and correlation of pathology results with the interpreting physician's mammography report. The proposed rule would clarify that positive predictive value, cancer detection rate, and recall rate would have to be collected during this audit. We estimate that the proposed clarifications would not result in a change to the currently approved information collection burden.

Additional mammography review and patient and referring physician notification—900.12(j): Under section 900.12(j)(1), if FDA believes that mammographic quality at a facility has been compromised and may present a significant risk to human health, the facility must provide clinical images and other relevant information for review by the accreditation body or other entity designated by FDA. Under the proposed rule, the State certification agency may request and then review such information. We estimate these proposed revisions would not result in a change to the currently approved information collection burden.

Under section 900.12(j)(2), when FDA has determined that the quality of mammography performed by the facility poses a serious risk to human health, a facility may be required to notify all patients who received mammograms at the facility or those patients who are determined to be at risk due to the quality of their mammography, and their referring physicians of the deficiencies and resulting potential harm, appropriate remedial measures, and other relevant information. Under the proposed rule, facilities would need to notify referring non-physician health care providers (along with referring physicians). We estimate this proposed revision would not result in a change to the currently approved information collection burden. Also under the proposed rule, State certification agencies (along with FDA) would have the authority to notify patients and their providers if a facility is unable or unwilling to do so. We estimate that the burden to State certification agencies would be similar to the approved burden estimate for facilities; approximately 5 notifications per year will take 100 hours per notification.

12b. Annualized Cost Burden Estimate

The total hour cost estimate for the annual reporting and recordkeeping burden is estimated to be $96098,313,661. 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	2,381,373	$14.25	$33,934,565
Medical records and Health Information Technicians	2,381,373	$20.59	$49,032,470
Radiologic Technologists	529,194	$29.00	$15,346,626

Total	$98,313,661

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 $68,000.

21 CFR 900.3(b)(3)	$10,000
21 CFR 900.21(b)	$30,000
21 CFR 900.12(c)(4)	$28,000

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 $24,342,107. This is the cost that facilities bear to report and maintain records under the mammography regulations

21 CFR 900.3(f)(2)	$50
21 CFR 900.4(c)	$230,773
21 CFR 900.4(e)	$8,654
21 CFR 900.4(f)	$77,600
21 CFR 900.4(h)	$4,327
21 CFR 900.12(c)(2)	$24,000,000
21 CFR 900.12(j)(1)	$900
21 CFR 900.12(j)(2)	$19,375
21 CFR 900.21(b)	$208
21 CFR 900.22(g)	$30
21 CFR 900.22(i)	$20
21 CFR 900.24(a)	$68
21 CFR 900.24(a)(2)	$25.50
21 CFR 900.24(b)(1)	$51
21 CFR 900.24(b)(3)	$25.50

Proposed rule:
The proposed rule contains five provisions with nonzero estimated costs or cost savings affecting mammography facilities. Modifying mammography report forms by adding additional categories for the final and incomplete assessment and adding breast density information would make the largest contribution to the estimated one-time costs of this proposed rule. We note that our cost estimate assumes that current forms are not in

alignment with the proposed rule and that modification would require not only a change in the form, but also a change in procedure with associated costs for training, discussion, and coordination among staff within mammography facilities. Due to uncertainty about baseline practices regarding different provisions of the proposed rule, and the cost of implementing changes in mammography report forms, we requested comment on our estimates of cost.

In the PRIA for the proposed rule, we estimate one-time costs of $4,328-$6,903 per entity (depending on size) and annual costs of $387-$675 per entity (depending on size). We estimate the total one-time cost of learning about/reading the rule to be $1,015,978.

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

In its proposed rule "Mammography Quality Standards Act; Amendments to Part 900 Regulations" (84 FR 11669) FDA is proposing to amend its mammography reporting requirements. The proposed revisions to the third-party disclosure burden described in section 12a of this ICR, would result in an increase of 1,347,744 hours to the estimated burden.

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.