United States Food and Drug Administration

Mammography Standards Quality Act Requirements

OMB Control No. 0910-0309 -- EXTENSION

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection supports implementation of the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b). Applicable regulations are found in 21 CFR Part 900. Regulations in subpart A establish procedures whereby an entity can apply to become a Food and Drug Administration (FDA)-approved accreditation body (AB) to accredit facilities to be eligible to perform screening or diagnostic mammography services and establish requirements and standards for accreditation bodies; regulations in subpart B establish minimum national quality standards for mammography facilities to ensure safe, reliable, and accurate mammography. Finally, regulations in 21 CFR 900 subpart C establish procedures for a State to apply to become an FDA-approved certification agency to certify facilities within the State to perform mammography services. Subpart C regulations also establish requirements and standards for State certification agencies to ensure that all mammography facilities under their jurisdiction are adequately and consistently evaluated for compliance with quality standards at least as stringent as the national quality standards established by FDA. The regulations include reporting, recordkeeping, and disclosure provisions.

Respondents to the information collection are subject to inspection fees unless exempted. We have developed Form FDA 3422, entitled “Governmental Entity Declaration,” (rev. December 2022) to attest that a mammography facility qualifies as a "governmental entity" and is exempt from payment of inspection fees. We also use Form FDA 3422 to determine whether the facility provides services under the Breast and Cervical Cancer Mortality Prevention Act of 1990. We have established and maintain a website where information regarding the MQSA and FDA’s MQSA Program may be found, available at https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-mqsa-and-mqsa-program. We are requesting extension of OMB approval for the information collection provisions found in 21 CFR part 900 and associated Form FDA 3422, as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA uses the information to ensure that all United States mammography facilities are adequately and consistently evaluated for compliance with national quality standards for mammography. The 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. We use the information collection to ensure adherence to mandatory standards.

3. Use of Improved Information Technology and Burden Reduction

We estimate that 100% of respondents will use electronic means to fulfill the information collection. Accreditation bodies (ABs), as defined in the regulations, use the web-based Mammography Program Reporting and Information System (MPRIS) (available at https://mpris.fda.gov/MPRIS/) to submit data. Inspection findings are recorded electronically on the inspector's laptop and then uploaded into the system. Information is transmitted to State certification agencies electronically.

Associated fees are billed electronically on a monthly basis, as contracted by FDA, and intended to fulfill Government Paperwork Elimination Act (GPEA) requirements. Other efforts toward 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 remains voluntary. 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

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection imposes undue burden on small entities. We estimate that approximately 45% of respondents are small businesses. To assist respondents, we provide searchable resource information at https://www.fda.gov/radiation-emitting-products/mammography-quality-standards-act-and-program.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. 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

FDA published a 60-day notice for public comment in the Federal Register of December 9, 2025 (90 FR 57070). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR 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 collected is name, work address, work email address, work telephone number and occasionally work fax number. FDA 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 retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII 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.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

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 estimated number of respondents in the tables below are based on the number (8,931) of certified mammography facilities as of October 1, 2024. A text summary of the specific requirements of Title 21 CFR Part 900 Mammography, as amended, follows these tables.

12a. Annualized Hour Burden Estimate

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]
Part 900, MAMMOGRAPHY					
Subpart A, Accreditation					
Notification of intent to become an AB--900.3(b)(1)	0.33	1	0.33	1	1
Application for approval as an AB; full2--900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited3--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	0.1
Summary report describing all facility assessments--900.4(f)	338	1	338	7	2,366
AB reporting to FDA; facility4--900.4(h)	8,931	1	8,931	1	8,931
AB reporting to FDA; AB5--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
Total Subpart A					11,646
Subpart B, Quality and Standards Certification					
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
Total Subpart B					16
Subpart C, States as Certifiers					
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 (5 minutes)	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

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]
Total Subpart C	9	205	1,004	426	285
Inspection fee exemption--FDA Form 3422	355	1	355	0.25 (15 minutes)	89
Overall Total					12,036

1 Numbers have been rounded.
2 One-time burden.
3 Refers to accreditation bodies applying to accredit specific full-field digital mammography 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]
Part 900, MAMMOGRAPHY					
Subpart A, Accreditation					
AB transfer of facility records--900.3(f)(1)	0.1	1	0.1	1	1
Consumer complaints system; AB--900.4(g)	5	1	5	1	5
Total Subpart A					6
Subpart B, Quality and Standards Certification					
Documentation of interpreting physician initial requirements--900.12(a)(1)(i)(B)(2)	89	1	89	8	712
Documentation of interpreting physician personnel requirements--900.12(a)(4)	8,931	4	35,724	1	35,724
Permanent medical record--900.12(c)(4)	8,931	1	8,931	1	8,931
Procedures for cleaning equipment--900.12(e)(13)	8,931	52	464,412	0.083 (5 minutes)	38,546
Audit program--900.12(f)	8,931	1	8,931	16	142,896
Consumer complaints system; facility--900.12(h)(2)	8,931	2	17,862	1	17,862
Total Subpart B					244,671
Subpart C, States as Certifiers					
Certification agency conflict of interest--900.22(a)	4	1	4	1	4
Processes for suspension and revocation of certificates--900.22(d)	4	1	4	1	4
Processes for appeals--900.22(e)	4	1	4	1	4
Processes for additional mammography review--900.22(f)	4	1	4	1	4
Processes for patient notifications--900.22(g)	3	1	3	1	3
Evaluation of certification agency--900.23	4	1	4	20	80
Appeals--900.25(b)	4	1	4	1	4
Total Subpart C					103

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]
Part 900, MAMMOGRAPHY					
Subpart A, Accreditation					
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)	2,955	1	2,955	1.44	4,255
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)	2,955	1	2,955	0.72 (43 minutes)	2,128
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)	8,931	1	8,931	1	8,931
Annual equipment evaluation and survey; AB[3]--900.4(e)	5	1	5	1,730	8,650
Total Subpart A					27,104
Subpart B, Quality Standards and Certification					
Provisional mammography facility certificate extension application--900.11(b)(3)	2	1	2	0.5 (30 minutes)	1
Mammography facility certificate reinstatement application--900.11(c)	288	1	288	5	1,440
Provision of personnel records to IPs--900.12(a)(4)	615	1	615	0.08 (5 minutes)	49
Transfer of personnel records by closing facilities--900.12(a)(4)	190	1	190	5	950
New assessment categories and breast density reporting in mammography report (one-time burden)--900.12(c)(1)(iv) to (vi)	8,931	1	8,931	23	205,413
Lay summary of examination--900.12(c)(2)	8,931	5,085	45,414,135	0.083 (5 minutes)	3,769,373
Breast density reporting in lay summary (one-time burden)--900.12(c)(2)	8,931	1	8,931	11	98,241

Lay summary of examination; patient refusal4--900.12(c)(2)	89	1	89	0.5 (30 minutes)	45
Transfer/provision of copies of mammograms and records upon patient's request--900.12(c)(4)(ii) and (iii)	8,931	520	4,644,120	0.08 (5 minutes)	371,530
Facility closure; notification and records access--900.12(c)(4)(v)	190	1	190	32	6,080
Report of unresolved serious complaints--900.12(h)(4)	20	1	20	1	20
Information regarding compromised quality; facility2--900.12(j)(1)	20	1	20	200	4,000
Information regarding compromised quality; AB3--900.12(j)(1)	20	1	20	320	6,400
Patient notification of serious risk--900.12(j)(2)	7	1	7	100	700
Reconsideration of accreditation--900.15(c)	5	1	5	2	10
Total Subpart B					4,464,252
Subpart C, States as Certifiers					
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 Subpart C					170
Total					4,491,526

[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.

As noted above, the estimated number of respondents in the tables are based on the number (8,931) of certified mammography facilities as of October 1, 2024. Title 21 CFR Part 900 Mammography, as amended, includes various reporting, recordkeeping, and third-party disclosure activities as described below.:

Notification of intent to become an AB - 21 CFR 900.3(b)(1) (Reporting)
An applicant (private, non-profit organizations or State agencies) must inform FDA of its intent to become an AB.

Application for approval as an AB - 21 CFR 900.3(b)(3) (Reporting)
Applicants must 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 must 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 must 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 must 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 and TPD)
Facilities must document that their interpreting physicians, radiologic technologists, and medical physicists meet all applicable personnel requirements. Facility personnel records must be available for review by the MQSA inspectors. Facilities must maintain records of personnel no longer employed by the facility for no less than 24 months and must provide copies of personnel records to current or former employees (when available) upon their request. Before a facility closes or ceases to provide mammography services, it must make arrangements for access by current and former personnel to their MQSA personnel records.

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 provide each patient a summary of the mammography report written in lay terms within 30 calendar days of the mammographic examination which shall, at a minimum, include the name of the patient; the name, address, and telephone number of the facility performing the mammographic examination; and an assessment of breast density as described in paragraphs (c)(2)(iii) and (iv) of this section. If the assessment of the mammography report is "Suspicious" or "Highly Suggestive of Malignancy," the facility shall provide the patient a summary of the mammography report written in lay language within 7 calendar days of the final interpretation of the mammograms.

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 must maintain mammography films and reports in a permanent medical record of the patient.

Provision/transfer of medical record copies - 21 CFR 900.12(c)(4)(ii) and (iii) (TPD)
Facilities shall upon request by, or on behalf of, the patient, permanently or temporarily transfer, or provide copies of, the original mammograms and copies of the patient's reports to a medical institution, a physician or healthcare provider of the patient, or to the patient directly.

Facility closure – 21 CFR 900.12(c)(4)(v)
Before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records.

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.

12b. Annualized Cost Burden Estimate

Table 3. – Annualized Burden Costs[1]

Type of Respondent	Total Burden Hours	Hourly Wage Rate[1]	Total Respondent Costs (rounded)
Receptionists and Information Clerks	2,136,884	$38.35	$81,949,501
Medical Records Specialists	2,136,884	$26.91	$57,503,548
Radiologic Technologists	213,688	$38.35	$8,194,935
Total			$147,677,984

[1] Wage rate assumes a 40-hour work week and is rounded to the nearest dollar and has been doubled to account for benefits and overhead.

We therefore estimate an annualized cost burden of $TBD.

We assume the activities identified in Question-12a will be completed by Radiologic Technologists (occupation code 29-2034) (approximately 10% of tasks); Receptionists and Information Clerks (occupation code 43-4171) (approximately 45% of tasks); and Medical Records Specialists (occupation code 29-2072) (approximately 45% of tasks). To estimate costs to respondents, we used mean wage rates from the U.S. Department of Labor's Bureau of Labor Statistics National Occupational Employment and Wage Estimates (available at http://www.bls.gov/oes/current/oes_nat.htm) (May 2024). We doubled these figures to account for benefits and overhead, and calculated the costs as followed.

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or Capital Costs

A. Capital Costs - $47,376,047; as follows:

21 CFR 900.3(b)(3)	$10,776
21 CFR 900.21(b)	$32,327
21 CFR 900.12(c)(4)	$30,171
21 CFR 900.12(c)(2)	$6,961,357

21 CFR 900.12(c)(1)(v) to (vi) $37,802,154
21 CFR 900.12; quality standards $2,539,262

The capital costs associated with 21 CFR 900.3(b)(3) and 21 CFR 900.21(b) are those one-time costs 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 required storage space for records due to the 10-year retention period. The capital cost associated with 21 CFR 900.12(c)(2) is a one-time cost to add breast density reporting to the lay summary reporting as required by the recent rulemaking. The capital cost associated with 21 CFR 900.12(c)(1)(v) to (vi) is a one-time cost to add new assessment categories and breast density reporting to the mammography report. There is also an estimated total annual capital cost for recordkeeping of $2,539,262 associated with the quality standards at 21 CFR 900.12, which increased by $42,810 due to an increase in the number of respondents.

B. Total Operating & Maintenance Cost

Cumulative operating and maintenance costs associated with these requirements are $26,229,903. This is the average cost we believe facilities incur to report and maintain records under the following mammography regulations, respectively:

21 CFR Section	Type of Record or Report	Operating and Maintenance Cost
900.3(f)(2)	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.	$54
900.4(c)	The AB shall review clinical images from each facility accredited by the body at least once every three years.	$248,670
900.4(e)	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.	$9,325
900.4(f)	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.	$83,618
900.4(h)	The AB is required to notify FDA of applications for provisional certificates and for extension of provisional certificates. The AB is also required to submit the name, identifying information, and other information for any facility for which the AB denies, suspends, or revokes accreditation. The AB must submit an annual report summarizing all serious complaints received during the previous calendar year, their resolution status, and any actions taken in response to them.	$4,663
900.12(a)(4)	Facilities must document that their interpreting physicians, radiologic technologists, and medical physicists meet all applicable personnel requirements.	$7,000,000

900.12(c)(2)	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.	$25,861,265
900.12(c)(4)(v)	Before a facility closes or ceases to provide mammography services, it must make arrangements for access by patients and healthcare providers to their mammographic records.	$7,000,000
900.12(j)(1)	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.	$970
900.12(j)(2)	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.	$20,878
900.21(b)	An applicant seeking FDA approval as a certification agency must submit an application to FDA.	$224
900.22(g)	A certification agency must establish processes for patient notification.	$32
900.22(i)	A certification agency shall obtain FDA authorization for any changes it proposes to make in any standards that FDA has previously accepted.	$22
900.24(a)	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.	$73
900.24(a)(2)	A certification agency that has lost its approval shall notify facilities certified or seeking certification by it as well as the appropriate accreditation bodies with jurisdiction in the State that its approval has been withdrawn.	$27
900.24(b)(1)	If FDA places a certification agency on probationary status, the certification agency shall notify all facilities certified or seeking certification by it of its probationary status within a time and in a manner approved by FDA.	$55
900.24(b)(3)	If FDA determines that a certification agency that has been placed on probationary status is not implementing corrective actions satisfactorily or within the established schedule, FDA may withdraw approval of the certification agency. The certification agency shall notify all facilities certified or seeking certification by it, as well as	$27

	the appropriate accreditation bodies with jurisdiction in the State, of its loss of FDA approval.	

14. Annualized Cost to the Federal Government

We currently allocate 42 full time equivalent (FTE) employees to implement the accreditation, quality standards, and certification provisions of the MQSA. This amounts to a total of $15,215,424 based on a cost of $362,272 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 provided by agency economists for FY 2024.

15. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 4,224,764 hours and a corresponding decrease of 320,858 responses. We attribute this adjustment due to the number of certified mammography facilities. The estimated number of respondents in the tables are based on the number (8,931) of certified mammography facilities as of October 1, 2024. Title 21 CFR Part 900 Mammography, as amended, includes various reporting, recordkeeping, and third-party disclosure activities. In addition, there was a decrease in state certifiers from 5 to 4 - Illinois, Iowa, South Carolina, and Texas.

ROCIS reflects a decrease in burden. The amount shown may not match the actual decrease because the numbers in the previous submission were miscalculated in both the burden table and ROCIS. This submission corrects those errors.

Table 1.--Estimated Annual Reporting Burden

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Notification of intent to become an AB--900.3(b)(1)	1	1	0	Estimate Revision
Application for approval as an AB; full2--900.3(b)(3)	106	106	0	Estimate Revision
Application for approval as an AB; limited3--900.3(b)(3)	150	150	0	Estimate Revision
AB renewal of approval--900.3(c)	15	15	0	Estimate Revision
AB application deficiencies--900.3(d)(2)	3	3	0	Estimate Revision
AB resubmission of denied applications--900.3(d)(5)	3	3	0	Estimate Revision
Letter of intent to relinquish accreditation authority--900.3(e)	1	1	0	Estimate Revision

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Summary report describing all facility assessments--900.4(f)	2,310	2,366	+ 56	Estimate Revision
AB reporting to FDA; facility4--900.4(h)	8,654	8,931	+ 277	Estimate Revision
AB reporting to FDA; AB5--900.4(h)	50	50	0	Estimate Revision
AB financial records--900.4(i)(2)	16	16	0	Estimate Revision
Former AB new application--900.6(c)(1)	6	6	0	Estimate Revision
Reconsideration of accreditation following appeal--900.15(d)(3)(ii)	2	2	0	Estimate Revision
Application for alternative standard--900.18(c)	4	4	0	Estimate Revision
Alternative standard amendment--900.18(e)	10	10	0	Estimate Revision
Certification agency application--900.21(b)	106	106	0	Estimate Revision
Certification agency application deficiencies--900.21(c)(2)	3	3	0	Estimate Revision
Certification electronic data transmission--900.22(h)	83	83	0	Estimate Revision
Changes to standards--900.22(i)	60	60	0	Estimate Revision
Certification agency minor deficiencies--900.24(b)	30	30	0	Estimate Revision
Appeal of adverse action taken by FDA--900.25(a)	3	3	0	Estimate Revision
Inspection fee exemption--FDA Form 3422	175	89	- 86	Estimate Revision

Table 2.--Estimated Annual Recordkeeping Burden

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
AB transfer of facility records--900.3(f)(1)	1	1	0	Estimate Revision
Consumer complaints system; AB--900.4(g)	5	5	0	Estimate Revision
Documentation of interpreting physician initial requirements--900.12(a)(1)(i)(B)(2)	696	712	+ 16	Estimate Revision

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Documentation of interpreting physician personnel requirements--900.12(a)(4)	34,616	35,724	+ 1,108	Estimate Revision
Permanent medical record--900.12(c)(4)	8,654	8,931	+ 277	Estimate Revision
Procedures for cleaning equipment--900.12(e)(13)	37,351	38,546	+ 1,195	Estimate Revision
Audit program--900.12(f)	138,464	142,896	+4,432	Estimate Revision
Consumer complaints system; facility--900.12(h)(2)	17,308	17,862	+ 554	Estimate Revision
Certification agency conflict of interest--900.22(a)	5	4	- 1	Estimate Revision
Processes for suspension and revocation of certificates--900.22(d)	5	4	- 1	Estimate Revision
Processes for appeals--900.22(e)	5	4	- 1	Estimate Revision
Processes for additional mammography review--900.22(f)	5	4	- 1	Estimate Revision
Processes for patient notifications--900.22(g)	3	3	0	Estimate Revision
Evaluation of certification agency--900.23	100	80	- 20	Estimate Revision
Appeals--900.25(b)	5	4	- 1	Estimate Revision

Table 3.--Estimated Annual Third-Party Disclosure Burden

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Notification of facilities that AB relinquishes its accreditation--900.3(f)(2)	20	20	0	Estimate Revision
Clinical images; facility[2]--900.4(c), 900.11(b)(1), and 900.11(b)(2)	4,154	4,255	+ 101	Estimate Revision
Clinical images; AB[3]--900.4(c)	2,080	2,080	0	Estimate Revision
Phantom images; facility[2]--900.4(d), 900.11(b)(1), and 900.11(b)(2)	2,077	2,128	+ 51	Estimate Revision
Phantom images; AB[3]--900.4(d)	1,040	1,040	0	Estimate Revision

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Annual equipment evaluation and survey; facility[2]--900.4(e), 900.11(b)(1), and 900.11(b)(2)	8,654	8,931	+ 277	Estimate Revision
Annual equipment evaluation and survey; AB[3]--900.4(e)	8,650	8,650	0	Estimate Revision
Provisional mammography facility certificate extension application--900.11(b)(3)	1	1	0	Estimate Revision
Mammography facility certificate reinstatement application--900.11(c)	1,560	1,440	- 120	Estimate Revision
Provision of personnel records to IPs--900.12(a)(4)	49	49	0	Estimate Revision
Transfer of personnel records by closing facilities--900.12(a)(4)	440	950	+ 510	Estimate Revision
New assessment categories and breast density reporting in mammography report (one-time burden)--900.12(c)(1)(iv) to (vi)	201,963	205,413	+ 3,450	Estimate Revision
Lay summary of examination--900.12(c)(2)	3,652,464	3,769,373	+ 116,909	Estimate Revision
Breast density reporting in lay summary (one-time burden)--900.12(c)(2)	96,591	98,241	+ 1,650	Estimate Revision
Lay summary of examination; patient refusal4--900.12(c)(2)	44	45	+ 1	Estimate Revision
Transfer/provision of copies of mammograms and records upon patient's request--900.12(c)(4)(ii) and (iii)	797,315	371,530	- 425,785	Estimate Revision
Facility closure; notification and records access--900.12(c)(4)(v)	2,816	6,080	+ 3,264	Estimate Revision
Report of unresolved serious complaints--900.12(h)(4)	20	20	0	Estimate Revision
Information regarding compromised quality; facility2--900.12(j)(1)	4,000	4,000	0	Estimate Revision
Information regarding compromised quality; AB3--900.12(j)(1)	6,400	6,400	0	Estimate Revision
Patient notification of serious risk--900.12(j)(2)	500	700	+ 200	Estimate Revision
Reconsideration of accreditation--900.15(c)	10	10	0	Estimate Revision

Activity/CFR Section	Previous Approved Annual Burden Hours	Requested Annual Burden Hours	Difference (Hours) (+/-)	Rationale for Change (Estimate Revision/Programmatic)
Notification of requirement to correct major deficiencies--900.24(a)	80	80	0	Estimate Revision
Notification of loss of approval; major deficiencies--900.24(a)(2)	15	15	0	Estimate Revision
Notification of probationary status--900.24(b)(1)	60	60	0	Estimate Revision
Notification of loss of approval; minor deficiencies--900.24(b)(3)	15	15	0	Estimate Revision

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date and inform respondents of its significance in accordance with PRA requirements.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.