U.S. FOOD & DRUG ADMINISTRATION

MAMMOGRAPHY QUALITY STANDARDS

OMB Control No. 0910-0309 – Revision

RIN 0910-AH04

SUPPORTING STATEMENT: **Part A – Justification:**

1. Circumstances Making the Collection of Information Necessary

Regulations in 21 CFR Part 900 implement the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b). We are updating the regulations and the associated information collection provisions to incorporate current science and mammography best practices. Among other revisions, the regulations now 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. FDA also added categories to the list of assessments that facilities are required to use in the mammography report. In addition, FDA amended 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. Respondents continue to use **Form FDA 3422** entitled, "*Governmental Entity Declaration*" to attest that a mammography facility qualifies as a "governmental entity" and is exempt from payment of inspection fees.

We therefore request OMB approval for the information collection provisions established by the final rule.

2. Purpose and Use of the Information Collection

The revisions are intended to improve the delivery of mammography services by strengthening communication of healthcare 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 action is also 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 patient and their healthcare provider to make informed healthcare decisions.

3. Use of Improved Information Technology and Burden Reduction

We estimate 100% of the 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) 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. 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 Final Regulatory Impact Analysis (FRIA) for the "Mammography Quality Standards Act" rulemaking). We estimate that approximately 4,003 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

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). We received several comments related to the proposed rule. Descriptions of the comments and our responses are provided in section V of the final rule of March 10, 2023 (88 FR 15126). Comments and responses related to the provisions that underlie the information collection are described in the

following sections: V.A, regarding general comments; V.D, regarding retention and release of personnel records; V.E, regarding digital accessories; V.F, regarding facility identification information in mammography report and lay summary; V.G, regarding final and incomplete assessments and lay summaries; V.H, regarding deadlines for mammography reports; V.I, regarding breast density notification--general support for density notification; V.J, regarding breast density notification language; V.K, regarding breast density notification and the role of the referring healthcare provider; V.L, regarding format for image interpretation, retention, transfer, and release of copies; V.M, regarding deadlines for image transfer and the release of copies; V.N, regarding facility closure and mammography record retention; V.O, regarding mammography medical outcomes audit; V.P, regarding patient and referring provider notification; V.Q, regarding revocation of certification; V.X, regarding federalism and the relationship between Federal and State breast density reporting requirements; and V.Y, regarding timeframe for implementation of this rule. No changes were made to the estimated burden as a result of the comments.

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

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII submitted using FDA Form 3422 (Governmental Entity Declaration) is name, work address, telephone number, and employee identification number (EIN). We have 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 Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. FDA also minimized the PII to be collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under 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.

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1 – Estimated Annual Recordkeeping

21 CFR 900; Revised Regulations	No. of Recordkeepers	Records per Record keeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours	Capital Costs
900.12; quality standards	8,781	1	8,781	16	140,496	$2,496,452

Table 2 – Estimated Annual Disclosures

21 CFR 900; Revised Regulations	No. of Respondents	Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours	Capital Costs
Provision of personnel records to IPs--900.12(a)(4)	615	1	615	0.08 (5 mins)	49	
Transfer of personnel records by closing facilities--900.12(a)(4)	88	1	88	5	440	
New assessment categories and breast density reporting in mammography report (one-time burden)--900.12(c)(1)(iv) to (vi)	8,781	1	8,781	23	201,963	37,166,396
Breast density reporting in lay summary (one-time burden)--900.12(c)(2)	8,781	1	8,781	11	96,591	6,844,077
Transfer/provision of copies of mammograms and records upon patient's request--900.12(c)(4)(ii) and (iii)	8,781	1,135	9,966,435	0.08 (5 mins)	797,315	
Facility closure; notification and records access--900.12(c)(4)(v)	88	1	88	32	2,816	
Patient notification of significant risk (by State certification agency)--900.12(j)(2)	5	1	5	100	500	
Total			0		1,099,674	44,010,473

The estimated number of respondents (8,781) is based on the number of certified mammography facilities as of July 1, 2022. A discussion of the revisions and amendments to the regulations are found in the preamble of the final rule; amended regulations are identified in the List of Subjects.

12b. Annualized Cost Burden Estimate

Consistent with our Final Regulatory Impact Analysis (FRIA) and as published in the final rule, we estimate respondent costs for the information collection to be $ 5,919,014.

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

We estimate capital costs associated with the final rule to be $46,506, 925 annually, as discussed more fully in our FRIA.

14. Annualized Cost to the Federal Government

The currently approved costs of administering the information collection, $11,811,450, include this rulemaking.

15. Explanation for Program Changes or Adjustments

The information collection reflects program changes resulting from agency rulemaking. To account for the changing regulatory provisions we have increased our estimated annual number of responses by 9,984,794, our estimated annual number of hours by 1,099,674, and have accounted for respondent costs of $5,919,014 attributable to implementation of the new requirements.

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

The OMB expiration date will be displayed as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.