



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2025-N-4942]

#### Agency Information Collection Activities; Proposed Collection; Comment Request;

#### Mammography Standards Quality Act Requirements

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with the Mammography Quality Standards Act.

**DATES:** Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

#### *Electronic Submissions*

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### *Written/Paper Submissions*

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

*Instructions:* All submissions received must include the Docket No. FDA-2025-N-4942 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Standards Quality Act Requirements." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted

as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at:

<https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

**FOR FURTHER INFORMATION CONTACT:** Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, [PRAStaff@fda.hhs.gov](mailto:PRAStaff@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

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

#### Mammography Quality Standards Act Requirements--21 CFR Part 900

##### OMB Control Number 0910-0309 -- Extension

The Mammography Quality Standards Act (Pub. L. 102-539) requires the establishment of a Federal certification and inspection program for mammography facilities; standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. Implementing regulations are found in part 900 ([21 CFR part 900](#)). The regulations are intended to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step

in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint 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.

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

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

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

FDA estimates the burden of this collection of information as follows:

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
<b>Part 900, MAMMOGRAPHY</b>					
<b>Subpart A, Accreditation</b>					
Notification of intent to become an AB--900.3(b)(1)	0.33	1	0.33	1	0.33
Application for approval as an AB; full <sup>2</sup> --900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited <sup>3</sup> --900.3(b)(3)	5	1	5	30	150
AB renewal of approval--900.3(c)	1	1	1	15	15
AB application deficiencies--900.3(d)(2)	0.1	1	0.1	30	3
AB resubmission of denied applications--900.3(d)(5)	0.1	1	0.1	30	3
Letter of intent to relinquish accreditation authority--900.3(e)	0.1	1	0.1	1	1
Summary report describing all facility assessments--900.4(f)	338	1	338	7	2,366
AB reporting to FDA; facility <sup>4</sup> --900.4(h)	8,931	1	8,931	1	8,931
AB reporting to FDA; AB <sup>5</sup> --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
<b>Total Subpart A</b>					<b>11,648</b>
<b>Subpart B, Quality and Standards Certification</b>					
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
<b>Total Subpart B</b>					<b>16</b>
<b>Subpart C, States as Certifiers</b>					
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
<b>Total Subpart C</b>					<b>285</b>
Inspection fee exemption--FDA Form 3422	355	1	355	0.25 (15 minutes)	89
<b>Total</b>					<b>12,0381,692</b>

<sup>1</sup> Total hours have been rounded.

<sup>2</sup> Refers to the facility component of the burden for this requirement.

<sup>3</sup> Refers to the AB component of the burden for this requirement.

<sup>4</sup> Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

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 <sup>1</sup>
<b>Part 900, MAMMOGRAPHY</b>					
<b>Subpart A, Accreditation</b>					
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
<b>Total Subpart A</b>					<b>6</b>
<b>Subpart B, Quality and Standards Certification</b>					
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
<b>Total Subpart B</b>					<b>244,671</b>
<b>Subpart C, States as Certifiers</b>					
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
<b>Total Subpart C</b>					<b>103</b>
<b>Total</b>					<b>244,774</b>

<sup>1</sup> 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 <sup>1</sup>
<b>Part 900, MAMMOGRAPHY</b>					
<b>Subpart A, Accreditation</b>					
Notification of facilities that AB relinquishes its accreditation--900.3(f)(2)	0.1	1	0.1	200	20

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 <sup>1</sup>
Clinical images; facility <sup>2</sup> --900.4(c), 900.11(b)(1), and 900.11(b)(2)	2,955	1	2,955	1.44	4,255
Clinical images; AB <sup>3</sup> --900.4(c)	5	1	5	416	2,080
Phantom images; facility <sup>2</sup> --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 <sup>3</sup> --900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility <sup>2</sup> --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 <sup>3</sup> --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 refusal <sup>4</sup> --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; facility <sup>2</sup> --900.12(j)(1)	20	1	20	200	4,000
Information regarding compromised quality; AB <sup>3</sup> --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					

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 <sup>1</sup>
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

<sup>1</sup> Total hours have been rounded.

<sup>2</sup> Refers to the facility component of the burden for this requirement.

<sup>3</sup> Refers to the AB component of the burden for this requirement.

<sup>4</sup> Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Our estimated burden for the information collection reflects an overall decrease of 4,225,729 hours and a corresponding decrease of 321,202 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.

**Lowell M. Zeta,**

*Acting, Deputy Commissioner for Policy, Legislation, and International Affairs.*