TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR part 25; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
CFSAN	51	1	51	8	408
Subtotal			30,326		236,784
Total			30,423		325,404

[1] There are no capital, or operational and maintenance costs associated with the information collection.

CDER:

Under §§ 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i) (21 CFR 312.23(a)(7)(iv)(e), 314.50(d)(1)(iii), and 314.94(a)(9)(i)), each investigational new drug application (IND), new drug application (NDA), and abbreviated new drug application (ANDA) must contain a claim for CE under § 25.30 or § 25.31, or an EA under § 25.40.

CDRH:

Under § 814.20(b)(11) (21 CFR 814.20(b)(11)), premarket approvals (PMAs) (original PMAs and supplements) must contain a claim for CE under § 25.30 or § 25.34 or an EA under § 25.40.

CBER:

Under 21 CFR 601.2(a), biologic license applications (BLAs) as well as INDs (§ 312.23), NDAs (§ 314.50), ANDAs (§ 314.94), and PMAs (§ 814.20) must contain either a claim of CE under § 25.30 or § 25.32 or an EA under § 25.40.

CVM:

Under 21 CFR 514.1(b)(14), new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs); 21 CFR 514.8(a)(1) supplemental NADAs and ANADAs; 21 CFR 511.1(b)(10) investigational new animal drug applications and generic investigational new animal drug applications, and 21 CFR 571.1(c) food additive petitions must contain a claim for CE under § 25.30 or § 25.32 or an EA under § 25.40.

CTP:

Under sections 905, 910, and 911 of the FD&C Act (21 U.S.C. 387e, 387j, and 387k), product applications and supplements, premarket tobacco applications (PMTAs), substantial equivalences (SEs), exemption from SEs, and modified risk tobacco product applications must contain a claim for a CE or an EA. Upon evaluation, we have concluded that the majority of the EA burden for tobacco products is accounted for in other information collections currently approved by OMB. The burden we attribute to SEs is currently approved in OMB control number 0910–0673; the burden we attribute to PMTAs is currently approved in OMB control number 0910–0768; and the burden we attribute to SE exemptions is currently approved in OMB control number 0910–0684.

CFSAN:

The estimates for respondents and numbers of responses are based on the annualized numbers of petitions and notifications qualifying for CEs listed under § 25.32(i) and (q) that the Agency has received in the past 3 years. To avoid counting the burden attributed to § 25.32(o) as zero, we have estimated the burden for this claim of CE at one respondent making one submission a year for a total of one annual submission. The burden for submitting a claim of CE is captured under § 25.15(a) and (d).

As a result of revising the information collection to include submissions made to CFSAN, it reflects an increase in burden of 108 responses and 10,668 hours annually.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17154 Filed 8–9–22; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 October 11, 2022.

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 October 11, 2022. 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–2013–N–0134 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Mammography Quality Standards 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 Sanford, 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.*

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.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR section/FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]
Notification of intent to become an AB—900.3(b)(1)	0.33	1	0.33	1	1
Application for approval as an AB; full [2]—900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited [3]—900.3(b)(3).	5	1	5	30	150
AB renewal of approval—900.3(c)	1	1	1	15	15
AB application deficiencies—900.3(d)(2)	0.1	1	0.1	30	3
AB resubmission of denied applications—900.3(d)(5)	0.1	1	0.1	30	3
Letter of intent to relinquish accreditation authority—900.3(e).	0.1	1	0.1	1	1
Summary report describing all facility assessments—900.4(f).	330	1	330	7	2,310
AB reporting to FDA; facility [4]—900.4(h)	8,718	1	8,718	1	8,718
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	1,000	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
Inspection fee exemption—FDA Form 3422	419	1	419	0.25 (15 minutes)	105
Total					11,785

[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	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]
AB transfer of facility records—900.3(f)(1)	0.1	1	0.1	0	1
Consumer complaints system; AB—900.4(g)	5	1	5	1	5
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(2).	87	1	87	8	696
Documentation of interpreting physician personnel requirements—900.12(a)(4).	8,718	4	34,872	1	34,872
Permanent medical record—900.12(c)(4)	8,718	1	8,718	1	8,718
Procedures for cleaning equipment—900.12(e)(13)	8,718	52	453,336	0.083 (5 minutes)	37,627
Audit program—900.12(f)	8,718	1	8,718	16	139,488
Consumer complaints system; facility—900.12(h)(2)	8,718	2	17,436	1	17,436
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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN—Continued

Activity/21 CFR section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours [1]
Total					238,971

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN

Activity/21 CFR section	Number of respondents	Number 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 (43 minutes)	2,077
Phantom images; AB [3]—900.4(d)	5	1	5	208	1,040
Annual equipment evaluation and survey; facility [2]—900.4(e), 900.11(b)(1), and 900.11(b)(2).	8,718	1	8,718	1	8,718
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 (30 minutes)	1
Mammography facility certificate reinstatement application—900.11(c).	281	1	281	5	1,405
Lay summary of examination—900.12(c)(2)	8,718	5,085	44,331,030	0.083 (5 minutes)	3,679,475
Lay summary of examination; patient refusal [4]—900.12(c)(2).	87	1	87	0.5 (30 minutes)	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					3,718,764

[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.

Respondents use the Mammography Program Reporting and Information System to submit information. Our estimated burden for the information collection reflects an overall increase of 28,664 hours and a corresponding increase of 9,137,449 responses/records. We attribute this adjustment to an increase in the number of submissions we received over the last few years. We do not include burden for §§ 900.12(c)(1) and (3), 900.3(f)(1), and 900.24(c) 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, we assume no additional reporting burden.

Dated: August 4, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–17151 Filed 8–9–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Nursing Research; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Nursing Research.

The meeting will be open to the public as indicated below, with attendance limited to space available.