(21 U.S.C. 381(e)(2)) provides for the exportation of an unapproved device under certain circumstances if the exportation is not contrary to the public health and safety and it has the approval of the foreign country to which it is intended for export. Requesters communicate (either directly or through a business associate in the foreign country) with a representative of the foreign government to which they seek exportation, and written authorization must be obtained from the appropriate office within the foreign government approving the importation of the medical device. An alternative to obtaining written authorization from the foreign government is to accept a notarized certification from a responsible company official in the United States that the product is not in conflict with the foreign country's laws. This certification must include a statement acknowledging that the responsible company official making the certification is subject to the provisions of 18 U.S.C. 1001. This statutory provision makes it a criminal offense to knowingly and willingly make a false or fraudulent statement, or make or use a false document, in any manner within the jurisdiction of a department or Agency of the United States. The respondents to this collection of information are companies that seek to export medical devices. FDA's estimate of the reporting burden is based on the experience of FDA's medical device program personnel.

In the **Federal Register** of April 22, 2016 (81 FR 23720), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/Section of FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours	Total operating and maintenance costs
Foreign letter of approval—section 801(e)(2)	38	1	38	3	114	$9,500

[1] There are no capital costs associated with this collection of information.

Dated: August 15, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19807 Filed 8–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0134]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Quality Standards Act Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 19, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0309. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North,10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

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; regulations and standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. The intent of these regulations is 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.

The following sections of Title 21 of the Code of Federal Regulations (CFR) are not included in the burden tables because they are considered usual and customary practice and were part of the standard of care prior to the implementation of the regulations. Therefore, they resulted in no additional burden: 21 CFR 900.12(c)(1) and (3) and 900.3(f)(1). Section 900.24(c) was also 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 reporting burden.

We have rounded numbers in the ''Total Hours'' column in all three burden tables. (Where the number was a portion of 1 hour, it has been rounded to 1 hour. All other ''Total Hours'' have been rounded to the nearest whole number.)

We do not expect any respondents for § 900.3(c) because all four ABs are approved until April 2020.

In the **Federal Register** of June 8, 2016 (81 FR 36924), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity/21 CFR Section/Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours [1]	Total capital costs (in dollars)	Total operating and maintenance costs (in dollars)
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	10,000	
Application for approval as an AB; limited [3]—900.3(b)(3)	5	1	5	30	150		
AB renewal of approval—900.3(c)	0	1	0	15	1		
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		77,600
AB reporting to FDA; facility [4]—900.4(h)	8,654	1	8,654	1	8,654		4,327
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		208
Certification agency application deficiencies—900.21(c)(2)	0.1	1	0.1	30	3		
Certification electronic data transmission—900.22(h)	5	200	1000	0.083	83	30,000	
Changes to standards—900.22(i)	2	1	2	30	60		20
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—Form FDA 3422	700	1	700	0.25	175		
Total					11,777	40,000	82,155

[1] Total hours 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]	Total capital costs (in dollars)	Total operating and maintenance costs (in dollars)
AB transfer of facility records—900.3(f)(1)	0.1	1	0.1	0	1		

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 capital costs (in dollars)	Total operating and maintenance costs (in dollars)
Consumer complaints system; AB—900.4(g)	5	1	5	1	5		
Documentation of interpreting physician initial requirements—900.12(a)(1)(i)(B)(*2*)	87	1	87	8	696		
Documentation of interpreting physician personnel requirements—900.12(a)(4)	8,654	4	34,616	1	34,616		
Permanent medical record—900.12(c)(4)	8,654	1	8,654	1	8,654	28,000	
Procedures for cleaning equipment—900.12(e)(13)	8,654	52	450,008	0.083	37,351		
Audit program—900.12(f)	8,654	1	8,654	16	138,464		
Consumer complaints system; facility—900.12(h)(2)	8,654	2	17,308	1	17,308		
Certification agency conflict of interest—900.22(a)	5	1	5	1	5		
Processes for suspension and revocation of certificates—900.22(d)	5	1	5	1	5		
Processes for appeals—900.22(e)	5	1	5	1	5		
Processes for additional mammography review—900.22(f)	5	1	5	1	5		
Processes for patient notifications—900.22(g)	3	1	3	1	3		30
Evaluation of certification agency—900.23	5	1	5	20	100		
Appeals—900.25(b)	5	1	5	1	5		
Total					237,223	28,000	30

[1] Total hours have been rounded.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating and maintenance costs (in dollars)
Notification of facilities that AB relinquishes its accreditation—900.3(f)(2)	0.1	1	0.1	200	20	50
Clinical images; facility [3]—900.4(c), 900.11(b)(1) and (2)	2,885	1	2,885	1.44	4,154	
Clinical images; AB [4]—900.4(c)	5	1	5	416	2,080	230,773
Phantom images; facility [3]—900.4(d), 900.11(b)(1) and (2)	2,885	1	2,885	0.72	2,077	
Phantom images; AB [4]—900.4(d)	5	1	5	208	1,040	
Annual equipment evaluation and survey; facility [3]—900.4(e), 900.11(b)(1) and (2)	8,654	1	8,654	1	8,654	8,654
Annual equipment evaluation and survey; AB [4]—900.4(e)	5	1	5	1,730	8,650	
Provisional mammography facility certificate extension application—900.11(b)(3)	0	1	0	0.5	1	

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR Section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]	Total operating and maintenance costs (in dollars)
Mammography facility certificate reinstatement application—900.11(c)	312	1	312	5	1,560	24,000,000
Lay summary of examination—900.12(c)(2)	8,654	5,085	44,055,590	0.083	3,652,464	.....
Lay summary of examination; patient refusal [5]—900.12(c)(2)	87	1	87	0.5	44	.....
Report of unresolved serious complaints—900.12(h)(4)	20	1	20	1	20	.....
Information regarding compromised quality; facility [3]—900.12(j)(1)	20	1	20	200	4,000	300
Information regarding compromised quality; AB [4]—900.12(j)(1)	20	1	20	320	6,400	600
Patient notification of serious risk—900.12(j)(2)	5	1	5	100	500	19,375
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	68
Notification of loss of approval; major deficiencies—900.24(a)(2)	0.15	1	0.15	100	15	25.50
Notification of probationary status—900.24(b)(1)	0.3	1	0.3	200	60	51
Notification of loss of approval; minor deficiencies—900.24(b)(3)	0.15	1	0.15	100	15	25.50
Total	.....	.....	.....	.....	3,691,842	24,259,921

[1] There are no capital costs associated with this collection of information.
[2] Total hours have been rounded.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the AB component of the burden for this requirement.
[5] Refers to the situation where a patient specifically does not want to receive the lay summary of her exam.

Dated: August 15, 2016.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2016–19808 Filed 8–18–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Service Administration

Advisory Committee on Interdisciplinary, Community-Based Linkages; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Public Law 92–463), notice is hereby given of the following meeting:

Name: Advisory Committee on Interdisciplinary, Community-Based Linkages (ACICBL)

Dates and Times: September 19, 2016

Place: Webinar/Conference Call

Status: The meeting will be open to the public.

Purpose: The ACICBL provides advice and recommendations to the Secretary of the Department of Health and Human Services (Secretary) concerning policy, program development, and other matters of significance related to interdisciplinary, community-based training grant programs authorized under sections 750—759, Title VII, Part D of the Public Health Service Act, as amended by the Affordable Care Act. The Advisory Committee focuses on the targeted program areas and/or disciplines for Area Health Education Centers, geriatrics, allied health, chiropractic, podiatric medicine, social work, graduate psychology, and rural health.

The purpose of the ACICBL meeting is to continue discussions on the ACICBL 16th report which is focused on enhancing community-based clinical training.

Agenda: The ACICBL agenda will be available 2 days prior to the meeting on the HRSA Web site at *http://www.hrsa.gov/advisorycommittees/bhpradvisory/acicbl/index.html.*

SUPPLEMENTARY INFORMATION: Requests to make oral comments or provide written comments to the ACICBL should be sent to Dr. Joan Weiss, Designated Federal Official, using the address and phone number below. Individuals who plan to participate on the conference call and webinar should notify Dr. Weiss at least 3 days prior to the meeting, using the address and phone number below. Members of the public will have the opportunity to provide comments. Interested parties should refer to the meeting subject as the HRSA Advisory Committee on Interdisciplinary, Community-Based Linkages.

- The conference call-in number is 1–800–619–2521. The passcode is: 9271697.
- The webinar link is *https://hrsa.connectsolutions.com/acicbl.*

Contact: Anyone requesting information regarding the ACICBL should contact Dr. Joan Weiss, in one of three ways: (1) Send a request to the following address: Dr. Joan Weiss, Designated Federal Official, Bureau of Health Workforce, Health Resources and Services Administration, Room 15N39, 5600 Fishers Lane, Rockville, Maryland 20857; (2) call (301) 443–0430; or (3) send an email to *jweiss@hrsa.gov.*

Jason E. Bennett,

Director, Division of the Executive Secretariat.

[FR Doc. 2016–19814 Filed 8–18–16; 8:45 am]

BILLING CODE 4165–15–P