TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
801(e)(2)	25	1	25	2.5	62.5

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimates are based on the experience of FDA's medical device program personnel.

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8026 Filed 9–21–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0381]

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) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the 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 the estimated reporting and recordkeeping burden associated with the Mammography Quality Standards Act requirements.

DATES: Submit written or electronic comments on the collection of information by November 21, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Denver Presley, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1472.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3520), 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.

The Mammography Quality Standards Act Requirements—21 CFR Part 900 (OMB Control Number 0910–0309)—Extension

The Mammography Quality Standards Act 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. This requires undergoing a review of their clinical images and providing the accreditation body 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 compliant 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 estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency perResponse	Total Annual Records	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(b)(1)	0.33	1	0.33	1	0.33		
900.3(b)(3) full[1]	0.33	1	0.33	320	106	$10,000	

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

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency perResponse	Total Annual Records	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.3(b)(3) limited[2]	5	1	5	30	150		
900.3(d)(2)	0.1	1	0.1	30	3		
900.3(d)(5)	0.1	1	0.1	30	3		
900.3(e)	0.1	1	0.1	1	0.1		
900.3(f)(2)	0.1	1	0.1	200	20		$36
900.4(c) facility[3]	2,947	1	2,947	10.54	4,538		
900.4(c) AB[4]	6	1	6	378	2,268		$117,867
900.4(d) facility[3]	2,947	1	2,947	0.77	2,947		
900.4(d) AB[4]	6	1	6	189	1,134		
900.4(e) facility[3]	8,840	1	8,840	1	8,840		$8,840
900.4(e) AB[4]	6	1	6	1,473	8,838		
900.4(f)	336	1	336	7	2,352		$77,840
900.4(h) facility[3]	8,840	1	8,840	1	8,840		$3,536
900.4(h) AB[4]	6	1	6	10	60		
900.4(i)(2)	1	1	1	16	16		
900.6(c)(1)	0.1	1	0.1	60	6		
900.11(b)(3)	5	1	5	0.5	2.5		
900.11(c)	270	1	270	5	1,350		
900.12(c)(2)	8,840	4,072	36,000,000	0.083	3,000,000		$14,400,000[5]
900.12(c)(2) patient refusal[5]	89	1	89	0.5	44.5		
900.12(h)(4)	5	1	5	1	5		
900.12(j)(1) facility[3]	25	1	25	200	5,000		$250
900.12(j)(1) AB[4]	25	1	25	1,000	25,000		$750
900.12(j)(2)	3	1	3	100	300		$3,604
900.15(c)	5	1	5	2	10		
900.15(d)(3)(ii)	1	1	1	2	2		
900.18(c)	2	1	2	2	4		
900.18(e)	2	1	2	1	2		
900.21(b)	1	1	320	320	2	$30,000	$71
900.21(c)(2)	0.33	1	0.33	30	10		
900.22(h)	6	200	1,200	0.083	100		
900.22(i)	2	1	2	30	60		
900.23	6	1	6	20	120		
900.24(a)	0.3	1	0.3	200	60		$26
900.24(a)(2)	0.15	1	0.15	100	15		$13

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

21 CFR Section/ FDA Form	No. of Respondents	Annual Frequency perResponse	Total Annual Records	Hours per Response	Total Hours	Total Capital Costs	Total Operating & Maintenance Costs
900.24(b)	1.2	1	1.2	30	36		
900.24(b)(1)	0.3	1	0.3	200	60		$26
900.24(b)(3)	0.15	1	0.15	100	15		$13
900.25(a)	0.2	1	0.2	16	3.2		
FDA Form 3422	700	1	700	0.25	175		
Total					3,072,138	$40,000	$14,612,872

[1] Refers to entities that are applying for the first time.
[2] Refers to accreditation bodies applying to accredit specific Full Field Digital Mammography units.
[3] Refers to the facility component of the burden for this requirement.
[4] Refers to the accreditation body 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.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

CFR Section	Number of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record-keeper	Total Hours	Total Capital Costs	Total Oper-ating & Maintenance Costs
900.4(g)	6	1	6	1	6		
900.12(a)(1)(i)(B)(2)	89	1	89	8	712		
900.12(a)(4)	8,840	4	35,360	1	35,360		
900.12(c)(4)	8,840	1	8,840	1	8,840	$25,000	
900.12(e)(13)	8,840	52	459,680	0.083	38,154		
900.12(f)	8,840	1	8,840	16	141,440		
900.12(h)(2)	8,840	2	17,680	1	17,680		
900.22(a)	6	1	6	1	6		
900.22(d)	6	1	6	1	6		
900.22(e)	6	1	6	1	6		
900.22(f)	3	1	3	1	3		
900.22(g)	6	1	6	1	6		$60
900.25(b)	6	1	6	1	6		
Total					242,225	$25,000	$60

This request for OMB approval now serves to consolidate previously approved information collection, OMB Control Number 0910–0580 into 0910–0309. The hourly burden as well as the associated operating costs were increased to better represent the actual burden and costs on facilities and accreditation bodies.

The following regulations were not included in the above burden tables because they were 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 reporting or recordkeeping burden: 21 CFR 900.12(c)(1), 900.12(c)(3), and 900.3(f)(1).

The following regulations were not included in the previously mentioned burden tables because they were not considered applicable during the information collection period or their burdens were reported under other regulatory requirements. Therefore, they resulted in no additional reporting or recordkeeping burden: 21 CFR 900.3(c), 900.11(b)(1), 900.11(b)(2), and 900.24(c).

Dated: September 15, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 06–8027 Filed 9–21–06; 8:45 am]

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