

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00N-1373]

DMB

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Certifier	<i>S. N. Reese</i>

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Reporting and Recordkeeping Requirements for Mammography Facilities

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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

DATES: Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Peggy Schlosburg, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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.

oc00199

Reporting and Recordkeeping Requirements for Mammography Facilities—21 CFR Part 900 (OMB Control Number 0910-0309)—Extension

Public Law 102-539, the Mammography Quality Standards Act of 1992 (MQSA) (42 U.S.C. 263b) as amended by the Mammography Quality Standards Reauthorization Act (MQSRA) of 1998 (Public Law 105-248) establishes the authority for a Federal certification and inspection program for mammography facilities; regulations and standards for accreditation bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. MQSRA extended the life of the MQSA program for 4 years from its original expiration date of 1998 until 2002, and also modified some of the provisions. The most significant modification from a report and recordkeeping viewpoint under 21 CFR 900.12(c)(2) was that mammography facilities were required to send a lay summary of each examination to the patient.

FDA, under this regulation, collects information from accreditation bodies and mammography facilities by requiring each accreditation body to submit an application for approval and to establish a quality assurance program. On the basis of accreditation, facilities are certified by FDA and must prominently display their certificate. FDA uses the information to ensure that private, nonprofit organizations or State agencies meet the standards established by FDA for accreditation bodies to accredit facilities that provide mammography services. Information collected from mammography facilities has also been used to ensure that the personnel, equipment, and quality systems has and continues to meet the regulations under MQSA and will be used by patients to manage their health care properly. The intent of these regulations is to assure safe, reliable, and accurate mammography on a nationwide level. The most likely respondents to this information collection will be accreditation bodies and mammography facilities seeking certification.

In the **Federal Register** of July 17, 2000 (65 FR 44061), the agency requested comments 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

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs:
900.3	6	1	6				
900.3(b)(3)	10	1	10	60	360		
900.3(c)	4	0.14	0.56	60	600	\$50	
900.3(e)	1	0.2	0.2	15	8.4		
900.3(f)(2)	1	0.2	0.2	1	0.2		
900.4(c)	834	1	834	1	0.2		
900.4(e)	10,000	1	10,000	1	834		
900.4(f)	1,000	1	1,000	8	80,000		
900.4(h)	6	1	6	14.5	14,500		
900.4(i)(2)	1	1	1	6	4,500		
900.6(c)(1)	1	1	1	1	1		
900.11(b)(2)	25	1	25	1	1		
900.11(b)(3)	5	1	5	2	50		
900.11(c)	10,000	0.0050	50	0.5	2.5		
900.12(c)(2)	9,800	4,080	39,984,000	20	1,000		\$1,000
900.12(j)(1)	10	1	10	5 minutes	3,332,000		
900.15(d)(3)(ii)	10,000	0.0020	20	1	10		
900.18(c)	10,000	0.0005	6	2	40		\$100
900.18(e)	10	0.1000	1	2	12		\$60
Total				1	3,434,010	\$50,	\$1,170

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

21 CFR Section	No. of Record-keepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours	Total Operating and Maintenance Costs
900.3(f)(1)	10	130	1,300	200	2,000	
900.4(g)	10,000	1	10,000	1	10,000	
900.11(b)(1)	1,000	1	1,000	1	1,000	
900.12(c)(4)	10,000	1	10,000	1	10,000	
900.12(e)(13)	6,000	52	312,000	0.125	39,000	
900.12(f)	10,000	1	10,000	1	10,000	
900.12(h)	10,000	2	20,000	0.5	10,000	\$20,000
Total					82,000	\$20,000

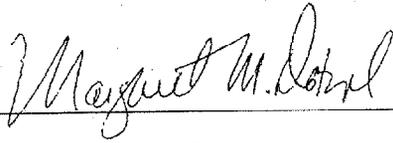
¹There are no capital costs associated with this collection of information.

All costs of implementing requirements for certification of mammography facilities will be borne by accreditation bodies; the incremental costs that accreditation bodies will face are not expected to be significant. The collection's burden is based upon the estimated number of summaries received by FDA, which in turn is based on the estimated number of examinations expected to be performed in a given year. If mammography examinations increase in number in subsequent years, which is expected for at least the foreseeable future, the annual burden and costs to meet this requirement will increase.

Included in the burden estimate is the FDA estimate for mammography lay summaries, which is the practice of notifying the patient in layman's terms of the results of the patient's mammography examination. FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that those facilities perform a total of 40 million mammography examinations in a year. In 90 percent of these cases, the notification to the patient can be established by a brief standardized letter to the patient. FDA estimates that preparing and sending this letter will take approximately 5 minutes. In the 10 percent of the cases in which there is a finding of "Suspicious" or "Highly suggestive of malignancy," the facility

is required to make reasonable attempts to ensure that the results are communicated to the patients as soon as possible. FDA believes that this requirement can be met by a 5-minute call from the health professional to the patient.

Dated: October 19, 2000



Margaret M. Dotzel
Associate Commissioner for Policy

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