

information collection requirements for mammography facilities, standards, and lay summaries for patients under part 900 (21 CFR part 900).

DATES: Submit written or electronic comments on the collection of information by January 6, 2004.

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: Peggy Robbins, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1223.

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 listed below.

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 Facilities, Standards, and Lay Summaries for Patients—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 § 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.

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

TABLE 1.—ESTIMATED ANNUAL RECORDING BURDEN¹

21 CFR Section	Number of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours	Total Capital Costs	Total Operating and Maintenance Costs
900.3	1	0.33	0.33	60	20		
900.3(b)(3)	1	0.33	0.33	60	20	\$50	
900.3(c)	5	0.33	1.67	15	25		
900.3(e)	1	0.1	0.1	1	0.1		
900.3(f)(2)	1	0.1	0.1	200	20		
900.4(c) and (d)	9,200	0.33	3,067	1	3,067		
900.4(e)	9,450	1	9,450	8	75,600		
900.4(f)	276	1	276	7	1,932		
900.4(h)	5	1	6,130	1	6,130		
900.4(i)(2)	1	0.33	0.33	1	0.33		