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Certifier	Jen Windsor

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 99N-1502]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Quality Mammography Standards; Lay Summaries for Patients**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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.

**Quality Mammography Standards; Lay Summaries for Patients**

The Mammography Quality Standards Act (Public Law 102-539) (the MQSA) was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required

that, to lawfully provide mammography services after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, shall be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). To become accredited and certified, a facility had to meet national quality standards to be established by the Secretary. The authority to establish these standards, to approve accreditation bodies, and to certify facilities was delegated by the Secretary to FDA. Facilities were initially accredited and certified if they met the standards contained within the interim rules issued by FDA in the **Federal Register** of December 21, 1993 (58 FR 67558 and 67565), and amended by another interim rule published in the **Federal Register** on September 30, 1994 (59 FR 49808). More comprehensive standards were proposed by FDA in the **Federal Register** of April 3, 1996 (61 FR 14856, 61 FR 14870, 61 FR 14884, 61 FR 14898, and 61 FR 14908). After some revision in response to the approximately 8,000 comments received on the proposed rule, a final rule amending part 900 (21 CFR part 900) was published in the **Federal Register** of October 28, 1997 (62 FR 55852) (hereinafter referred to as the October 1997 final rule). The effective date of most of the new standards contained within the final rule was April 28, 1999, but a few will not become effective until October 28, 2002.

On October 9, 1998, the Mammography Quality Standards Reauthorization Act (MQSRA) (Public Law 105-248) became law. The basic purpose of the MQSRA was to extend the authorities established by the MQSA until September 30, 2002. However, the MQSRA also contained a requirement that was significantly different from the corresponding requirement in the October 1997 final rule. Although this MQSRA requirement became effective on April 28, 1999, FDA decided to amend the final rule to incorporate the change. The purpose of this amendment is to provide to the mammography facilities the convenience of being able to find all of the quality standards within a single document instead of having to consult both the October 1997 final rule and the MQSRA and to avoid confusion as to the applicable reporting requirement.

This regulation merely implements a statutory information collection requirement; there is no additional burden attributable to the regulation. This rule would conform the requirements of this section with the requirement of section 6 of Public Law 105-248 which states that: “(IV) whether or not such a physician is available or there is no such physician, a summary of the written report shall be sent directly to the patient in terms easily understood by a lay person.” To produce the required lay summary, the mammography facilities will review the medical report of each patient’s examination and collect from it the necessary information.

Section 900.12(c)(2) requires that each mammography facility shall send each patient a summary of the mammography report written in lay terms within 30 days of the mammographic examination. If assessments are “Suspicious” or “Highly suggestive of malignancy,” § 900.12(c)(2) requires that the facility shall make reasonable attempts to ensure that the results are communicated to the patient as soon as possible.

In the **Federal Register** of June 17, 1999, FDA published a direct final rule (64 FR 32404) and a companion proposed rule (64 FR 32443). FDA invited interested persons to comment on the direct final rule and companion proposed rule by August 31, 1999. FDA received no comments

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
900.12(c)(2)	9,800	4,080	39,984,000	5 minutes	3,332,000

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA estimates that there are 9,800 facilities performing mammography in the United States. FDA also estimates that these 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 would be 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. Thus, the estimated burden is 3,332,000 (39,984,000 x 1/12 hour).

Dated: October 12, 1999



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William K. Hubbard  
Senior Associate Commissioner for Policy, Planning  
and Legislation

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*Jen Windsor*