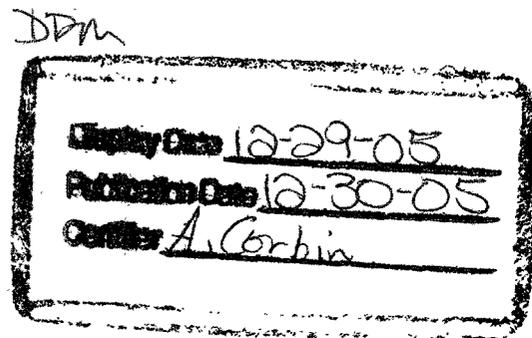


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D-0195]



Agency Information Collection Activities; Submission for Office of Management and Budget Review; Mammography Quality Standards Act Final Regulations; Modifications and Additions to Policy Guidance Help System #9

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 *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

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: 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 Final Regulations; Modifications and Additions to Policy Guidance Help System #9

The Mammography Quality Standards Act (MQSA) Final Regulations: Modifications and Additions to Policy Guidance Help System 9 provides guidance to mammography facilities and their personnel on a variety of issues involving the quality standards for mammography (§ 900.12 (21 CFR 900.12)). Use of the guidance results in new collections of information. Facilities are required to provide patients with lay summaries of the results of their mammography examinations (§ 900.12(c)(2)). This guidance document provides information on how to address a patient's refusal to receive a lay summary and recommends that the facility document why it was unable to meet this requirement. Additionally, the guidance addresses interpreting physician initial requirements (§ 900.12(a)(1)(i)(B)(2)), including recommendations on how to document the alternative to Board Certification for foreign-trained physicians.

The likely respondents are mammography facilities and their personnel who are subject to the MQSA quality standards requirements.

In the **Federal Register** of July 15, 2005 (70 FR 41043), FDA published a 60-day notice requesting comments on the information collection provisions. No comments were received.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

Activity	Number of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Reporting of refusal of lay summary	915	1	915	0.5	458

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

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN¹

Activity	Number of Record-keepers	Annual Frequency per Record	Total Annual Records	Hours Per Record	Total hours
Documentation of foreign-trained physicians' qualifications	92	1	92	8	736

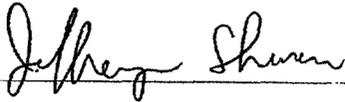
¹There are no capital costs or operating and maintenance costs associated with this collection of information

There are a total of 9,150 MQSA-certified facilities. Using past experience, FDA estimates that 10 percent of these facilities will receive patient requests that lay summary results not be sent. We also estimate that the facility will spend 0.5 hours per patient obtaining the patient's written request, filing that form in the patient's record and forwarding the summary to the patient's designee. With respect to foreign-trained physicians, past experience indicates

that this situation arises very infrequently. We estimate that only 1 percent of MQSA-certified facilities will have to maintain records documenting the qualifications of foreign-trained physicians.

Dated: DEC 22 2005

December 22, 2005.



Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

BILLING CODE 4160-01-S

