

IV. Submission of Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday. You can also view received comments on the Internet at <http://www.fda.gov/ohrms/dockets/dockets/dockets.htm>

Dated: July 28, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

National Mammography Quality Assurance Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: National Mammography Quality Assurance Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues.

Date and Time: The meeting will be held on September 26 and 27, 2005, from 9 a.m. to 6 p.m.

Location: Holiday Inn, Walker/Whetstone Rooms, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Charles Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-594-3332, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512397. Please call the Information Line for up-to-date information on this meeting.

Agenda: The committee will discuss the following issues:

(1) Regulatory and nonregulatory mechanisms to enhance mammography quality while reducing the regulatory and inspection burden on facilities;

(2) Recommendations made by the Institute of Medicine regarding the current Mammography Quality Standards Act (MQSA) program, interventional mammography, and nonmammographic breast imaging procedures; and

(3) All relevant guidance documents issued since the last meeting.

The committee will also receive updates on recently approved alternative standards, voluntary stereotactic accreditation programs, and the radiological health program. MQSA regulations and guidance documents are available to the public on the Internet at <http://www.fda.gov/cdrh/mammography>.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by September 5, 2005. Oral presentations from the public will be scheduled between approximately 9:30 a.m. and 10:30 a.m. on both days. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before September 5, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shirley Meeks at 240-276-0450, ext. 105, at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: July 27, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05-15373 Filed 8-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Indian Health Service Loan Repayment Program

SUMMARY: The Department of Health and Human Services, as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Indian Health Service (IHS) is providing a 60-day advance opportunity for public comment on a proposed extension of current information collection activity to be submitted to the Office of Management and Budget for review.

Proposed Collection: Title: 0917-0014, "Indian Health Service Loan Repayment Program." *Type of Information Collection Request:* Extension, without revision, of currently approved information collection, 0917-0014, "Indian Health Service Loan Repayment Program." *Form Number:* None. *Forms:* The IHS Loan Repayment Program Information Booklet contains the instructions and the application formats. *Need and Use of Information Collection:* The IHS Loan Repayment Program (LRP) identifies health professionals with pre-existing financial obligations for education expenses that meet program criteria and who are qualified and willing to serve at, often remote, IHS health care facilities. Under the program, eligible health professionals sign a contract under which the IHS agrees to repay part or all of their indebtedness for professional training education. In exchange, the health professionals agree to serve for a specified period of time in IHS health care facilities. Eligible health professionals that wish to apply must submit an application to participate in the program. The application requests personal, demographic and educational training information, including information on the educational loans of

the individual for which repayment is being requested (i.e., date, amount, account number, purpose of each loan, interest rate, the current balance, etc.). The data collected is needed and used to evaluate applicant eligibility; rank

and prioritize applicants by speciality; assign applicants to IHS health care facilities; determine payment amounts and schedules for paying the lending institutions; and to provide data and statistics for program management

review and analysis. *Affected Public:* Individuals and households. *Type of Respondents:* Individuals. The table below provides the estimated burden hours for this information collection:

ESTIMATED BURDEN HOURS

Data collection instrument	Estimated number of respondents	Responses per respondent	Average burden hour per response *	Total annual burden hrs.
Section I	425	1	0.25 (15 mins)	106.25
Section II	425	1	0.50 (30 mins)	212.5
Section III	425	4	0.25 (15 mins)	425
Contract	425	1	0.334 (20 mins)	141.95
Affidavit	425	1	0.167 (10 mins)	70.97
Lender Certificate	1700	1	0.25 (15 mins)	425.0

* For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the agency processes the information collected in a useful and timely fashion; (c) the accuracy of public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether the methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collected; and (f) ways to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Send Comments and Requests For Further Information: Send your written comments and requests for more information on the proposed collection or requests to obtain a copy of the data collection instrument(s) and instructions to: Mrs. Chris Rouleau, IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852-1601, call non-toll free (301) 443-5938, send via facsimile to (301) 443-2316, or send your e-mail requests, comments, and return address to: crouleau@hqe.ihs.gov.

Comment Due Date: Your comments regarding this information collection are best assured of having their full effect if received within 60-days of the date of this publication.

Dated: July 28, 2005.

Charles W. Grim,
Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 05-15279 Filed 8-2-05; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Request for Public Comment: 60-Day Proposed Information Collection: Final Rule To Implement Title V of the Tribal Self-Governance Amendments of 2000

SUMMARY: The Department of Health and Human Services (DHHS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) (44 U.S.C. 3506(c)(2)(A)). This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Indian Health Service (IHS) is providing a 60-day advance opportunity for public comment on a proposed extension of current information collection activity to be submitted to the Office of Management and Budget for review.

Proposed Collection: Title: 0917-0026, "Final Rule to Implement Title V of the Tribal Self-Governance Amendments of 2000". *Type of*

Information Collection Request: Extension, without revision, of currently approved information collection, 0917-0026, "Final Rule to Implement Title V of the Tribal Self-Governance Amendments of 2000". *Form Number:* None. *Forms:* None. *Need and Use of Information Collection:* The "Tribal Self-Governance Amendments of 2000", Pub. L. 106-206 (the act), repeals Title III of the Indian Self-Determination Act, Pub. L. 93-638, as amended, (ISDA) and enacts Title V that established a permanent Self-Governance program within DHHS. Thus, Indian and Alaska Native Tribes are now able to compact for the operation, control, and redesign of various IHS activities on a permanent basis. The final rule has been negotiated among representatives of Self-Governance and non-Self-Governance Tribes and the DHHS. The final rule included provision governing how DHHS/IHS carries out its responsibility to Indian Tribes under the Act and how Indian Tribes carry out their responsibilities under the Act. As required by section 517(b) of the Act, the Department has developed this final rule with active Tribal participation of Indian Tribes, inter-Tribal consortia, Tribal organizations and individual Tribal members, using the guidance of the Negotiated Rulemaking Act, 5 U.S.C. 561 *et seq.* Health status reporting requirements will be negotiated on an individual Tribal basis and included in individual compacts of funding agreements. Response to the data collection continues to be voluntary; however, submission of the data is essential to participation in the Tribal Self-Governance process. Self-Governance Tribes have the option of participating in a voluntary national uniform data collection effort with the IHS. The department is seeking