exposed to at least 10 times the NIOSH REL.

To effectively prevent silicosis, not only must control measures be improved, but workers must be persuaded to protect themselves and employers must be motivated to provide workers with proper engineering controls and training. Previous research has too often focused on the behaviors and attitudes of workers and not on employers. Since employers have a tremendous influence on the health of workers and since their motivations may differ from workers', it is important to focus on them as well. Well-designed and theory-driven communication interventions have the capacity to promote protective health behaviors. To develop messages that will have the greatest success at motivating workers to protect themselves and employers to protect their workers from silicosis, information on workers' and employers' beliefs, attitudes, and behaviors regarding silicosis must be determined. A recently completed pilot-study indicated a need to motivate employers to provide appropriate engineering controls and respiratory protection and a need to persuade workers to protect themselves.

The goal of this project is to develop a health communication intervention program targeting both masonry contractors and workers that will increase the use of engineering controls (specifically, wet-sawing) and respiratory protection. The aforementioned pilot study will serve as a foundation upon which the intervention will be developed. The effectiveness of the intervention will be evaluated using a pre-post test questionnaire.

The study results will provide a basis for intervention programs that masonry contractors can use to educate their workers regarding risk of exposure to silica dust on masonry work sites. The methodology could be applied to other construction procedures such as jack hammering, sand blasting, and similar dust producing procedures to produce similar intervention programs. Eventually we would hope, silica exposures among construction workers would decrease significantly. The total cost to respondents is $0.00.

Respondents	No. of respondents	No. of responses/respondent	Average burden/response (in hrs.)	Total burden (in hrs.)
Workers	200	2	0.33	132
Contractors	20	2	0.33	13.2
Total				145.2

Charles W. Gollmar,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention (CDC).

[FR Doc. 98–33035 Filed 12–11–98; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–0453]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Medical Devices: Third-Party Review Program Under U.S./EC MRA

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 (the PRA).

DATES: Submit written comments on the collection of information by January 13, 1999.

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: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. 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 section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Medical Devices: Third-Party Review Program Under U.S./EC MRA (OMB Control Number 0910–0378—Extension)

The third-party program under the United States/European Community Mutual Recognition Agreement (U.S./EC MRA) is intended to implement that part of U.S./EC MRA that covers the exchange of quality system evaluation reports for all medical devices and premarket evaluation reports for selected low-to-moderate risk devices. Under MRA, firms may apply to become designated as a U.S. Conformity Assessment Body (CAB). Firms who are designated will be qualified to conduct quality system evaluations for all classes of devices and product-type examinations and verifications for selected devices based on EC requirements under the voluntary third-party program authorized by MRA. Firms designated as EC CAB's could, in turn, conduct quality system evaluations for all classes of devices and premarket 510(k) evaluations for selected devices based on FDA requirements. Under the voluntary third-party program, reports of these evaluations would be submitted by EC CAB's to FDA. EC CAB's would also be required to maintain copies of their evaluation reports.

In the **Federal Register** of August 4, 1998 (63 FR 41573), the agency requested comments on the proposed collection of information. The agency received two comments.

One comment questioned why FDA chose 12 as the number of U.S. CAB's, when Europe already has 20. The agency's estimate is based on discussions with the National Institute of Science and Technology of the U.S. Department of Commerce and officials of other standards organizations as well as firms who have expressed interest directly to FDA. FDA still believes that 12 is the appropriate number.

The other comment questioned why FDA did not include all eligible class I and class II devices in the program. FDA did not include in the program three class I devices that are regulated by the Center for Biologics Evaluation and Research (CBER), because FDA determined that it would not be cost effective to train CBER employees in the program for only three devices. FDA included in the program the 97 class II devices for which guidance and/or

recognized standards exist and which represent 60 percent of the 510(k)s we receive each year. If the program is successful, FDA will add additional devices, as appropriate.

FDA estimates the burden of this collection as follows:

TABLE 1.—Estimated Annual Reporting Burden[1]

Item	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Requests for designation as U.S. CAB	12	1	12	24	288
Premarket reports by EC CAB's	20	5	100	40	4,000
Quality system reports by EC CAB's	20	5	100	32	3,200
Total					7,488

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

TABLE 2.—Estimated Annual Recordkeeping Burden[1]

Item	No. of Recordkeepers	Annual Frequency per Recordkeeping	Total Annual Records	Hours per Recordkeeper	Total Hours
Records of evaluation of premarket submissions by EC CAB's	20	5	100	10	1,000
Records of evaluation of quality systems	20	5	100	10	1,000
Total					2,000

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

The burdens are explained as follows:

I. Reporting

A. Requests for Designation as U.S. CAB

Under this program, U.S. firms may apply for designation as a U.S. CAB. Such designation will enable that firm to perform third-party evaluations of U.S. products for export to EC. Likewise, European firms may apply to be designated as EC CAB's, which will enable them to perform third-party evaluations of products to be exported to the United States. The application for nomination as an EC CAB does not represent an information collection burden subject to the PRA because the designation procedure is an internal process which is required by, and administered by, European authorities. Only the application for designation as a U.S. CAB represents a paperwork burden under the PRA. The agency anticipates, based on discussions with the National Institute of Science and Technology of the U.S. Department of Commerce and officials of other standards organizations, as well as firms who have expressed interest directly to FDA, that approximately 12 applications for designation as U.S. CAB's will be received.

B. Premarket Reports

Under this program, EC CAB's will be able to perform third-party evaluations for certain products produced in Europe for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluation for approximately 100 medical device products annually. The agency further estimates, based on dialogue with EC officials, that 20 firms will be designated to act as EC CAB's.

C. Quality System Reports

Under this program, EC CAB's will be able to perform third-party evaluations of the quality systems established by manufacturers of European products produced for export to the United States. EC CAB's would be required to submit reports of their evaluations to FDA. Based upon information gathered during the negotiation of U.S./EC MRA, the agency anticipates that European manufacturers will request third-party evaluations for approximately 100 medical device products annually. The agency estimates that 20 EC CAB's will perform these evaluations.

II. Recordkeeping

As stated previously, firms designated as EC CAB's will be able to perform third-party evaluations of quality systems and premarket submissions for certain products produced for export to the United States. Such evaluation will be conducted consistent with FDA's regulatory requirements, and FDA will require the reviewers to keep, in their records, a copy of the report that they submit to FDA for each evaluation. The agency anticipates that 100 premarket reports and 100 quality system reports will be generated and required to be maintained by EC CAB's annually. Thus, the agency estimates that 100 records of evaluations of quality systems and premarket submissions will be retained by the designated EC CAB's. Based on experience with the Third-Party Review Pilot Program, which was announced in the **Federal Register** of April 3, 1996 (61 FR 14789), the agency anticipates that each recordkeeper will require no more than 2 hours of recordkeeping per review. The agency is estimating five reviews per respondent and a total of 10 hours per recordkeeper.

Dated: December 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98N–1063]

Announcement of a New Format for Export Certificates

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a new format for export certificates. The new format features the use of several security measures in the paper used to print export certificates to deter falsification of or tampering with FDA-