

Dated: August 13, 2003.

Nancy E. Cheal,

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

[FR Doc. 03-21157 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day-03-109]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 for opportunity for public comment on proposed data collection projects, the Centers for Disease Control and Prevention (CDC) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the data collection plans and

instruments, call the CDC Reports Clearance Officer on (404) 498-1210.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Send comments to Anne O'Connor, CDC Assistant Reports Clearance Officer, 1600 Clifton Road, MS-D24, Atlanta, GA 30333. Written comments should be received within 60 days of this notice.

Proposed Project: An Evaluation Survey on the Use and Effectiveness of Internet SAMMEC—New—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Since 1987, the Centers for Disease Control and Prevention (CDC) has used

the Smoking-Attributable Mortality, Morbidity, and Economic Costs (SAMMEC) software to estimate the disease impact of smoking for the nation, states, and large populations. The Internet version of the SAMMEC software was released in 2002, and it contains two distinct computational programs, Adult SAMMEC and MCH SAMMEC, which can be used to estimate the adverse health outcomes and disease impact of smoking on adults and infants.

Since the release of Internet SAMMEC, more than 1230 tobacco control professionals in the State health departments and other tobacco control institutions in the country have used SAMMEC to generate the data they need for their projects. Some of them have provided comments and sent requests for assistance. The purpose of this survey is to evaluate the use and effectiveness of the SAMMEC software and identify ways to improve the system so that it will better meet the needs of the users in tobacco control and prevention.

There are no costs to the respondents except for their time in completing the questionnaire.

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)	Total burden (in hrs.)
Tobacco Control Professionals/Internet SAMMEC users	1000	1	15/60	250

Dated: August 13, 2003.

Nancy E. Cheal,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2003D-0025]

Guidance for Industry and FDA Staff on the Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "The Mammography Quality Standards

Act Final Regulations Modifications and Additions to Policy Guidance Help System #6." This document deals with testing of a mammography unit's Automatic Exposure Control (AEC) component and is intended to provide guidance to mammography facilities and their personnel. It represents FDA's current thinking on this aspect of the final regulations implementing the Mammography Quality Standards Act.

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies on a 3.5" diskette of the guidance document entitled "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6" to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels

to assist that office in processing your request, or fax your request to 301-443-8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Charles Finder, Center for Devices and Radiological Health (HFZ-240), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301-827-0009.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of February 19, 2003 (68 FR 8030), FDA published a document entitled "Medical Devices: Draft Guidance for Industry and FDA;

The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Availability" for public comment. Before the public comment period closed on May 20, 2003, 2 respondents submitted a total of 14 comments. In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its April 28, 2003, meeting and provided additional comments. In response to those comments, FDA has modified the guidance as follows by:

1. Further clarifying the term "equipment configuration,"
2. Adding different image receptor sizes as separate equipment configurations,
3. Not recommending that target-filter combinations be tested as separate equipment configurations, and
4. Emphasizing the need to minimize non-AEC component variability when conducting the AEC performance test.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on testing of a mammography unit's AEC component. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

To receive "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6" by FAX, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number 1435 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the guidance may also do so by using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information

on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>. A search capability for all CDRH guidance documents is available at <http://www.fda.gov/cdrh/guidance.html>. Guidance documents are also available on the Division of Dockets Management Internet site at <http://www.fda.gov/ohrms/dockets>.

IV. Comments

Interested persons may submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) at any time. 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. Comments received may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 4, 2003.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 03-21114 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center on Minority Health and Health Disparities; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the National Advisory Council on Minority Health and Health Disparities meeting.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant

applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council on Minority Health Disparities.

Date: September 16-17, 2003.

Open: September 16, 2003, 8:30 a.m. to 5:30 p.m.

Agenda: The agenda will include Opening Remarks, Administrative Matters, Director's Report, NCMHD, Presentations include The Role of the Advisory Council, Cancer Health Disparities Report, NIH Committee on Minority Health and Health Disparities Research Definitions and Application Methodology Status Report, Update on the Sullivan Commission, and other Council business.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Closed: September 17, 2003, 8:30 a.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814.

Contact Person: Lisa Evans, JD, Senior Advisor for Policy, National Center on Minority Health and Health Disparities, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, 301-402-1366, evansl@ncmhd.nih.gov.

Dated: August 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-21213 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel, Review of Supplement.

Date: September 30, 2003.