

Dated: August 13, 2003.

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

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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.

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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;