

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 In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its April 28, 2003, meeting and provided additional comments.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.*

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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](mailto:evansl@ncmhd.nih.gov).

Dated: August 12, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

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**BILLING CODE 4140-01-M**

## 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.