

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 In addition, the National Mammography Quality Assurance Advisory Committee reviewed the draft guidance during its April 28, 2003, meeting and provided additional comments.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

BILLING CODE 4160-01-S

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.

Time: 2 p.m. to 5 p.m.

Agenda: To review and evaluate grant applications.

Place: NIEHS/National Institutes of Health, Building 4401, East Campus, 79 T.W. Alexander Drive, Research Triangle Park, NC 27709, (Telephone Conference Call).

Contact Person: Sally Eckert-Tilotta, Phd, National Inst. of Environmental Health Sciences, Office of Program Operations, Scientific Review Branch, P.O. Box 12233, MD EC-30, Research Triangle Park, NC 27709, 919/541-1446, eckertt1@niehs.nih.gov.

(Catalogue of Federal Domestic Assistance program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-21214 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine; 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 Library of Medicine Special Emphasis Panel IADL.

Date: September 24, 2003.

Time: 1 p.m. to 3 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20817, (Telephone Conference Call).

Contact Person: Merlyn Rodrigues, MD, PhD, Medical Officer/SRA, National Library

of Medicine, Extramural Programs, 6705 Rockledge Drive, Suite 301, Bethesda, MD 20894.

(Catalogue of Federal Domestic Assistance Program Nos. 93.879, Medical Library Assistance, National Institutes of Health, HHS)

Dated: August 8, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-21211 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Notice of Meeting

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

The meeting will be open to the public, 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.

Name of Committee: Recombinant DNA Advisory Committee.

Date: September 17-18, 2003.

Time: 8 a.m. to 6 p.m.

Agenda: Protocol review, data management, a review and discussion of the RAC informed Consent Working Group (ICWG) draft Guidance Document, and a presentation by Dr. Shawn Burgess, Head of the Developmental Genomics Section, Genome Technology Branch, NHGRI, NIH, on "Integration Sites of Retroviral Vectors in the Human Genome."

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

Contact Person: Stephen M. Rose, Ph.D., Executive Secretary, Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Room 750, Bethesda, MD 20892, 301-496-9838, sr8j@nih.gov.

Information is also available on the Institute's/Center's home page: <http://www4.od.nih.gov/oba/>, where an agenda and any additional information for the meeting will be posted when available.

OMB's "Mandatory Information Requirements for Federal Assistance Program Announcements" (45 FR 39592, June 11, 1980) requires a statement concerning the official government programs contained in the Catalog of Federal Domestic Assistance. Normally NIH lists in its announcements the number and title of affected individual programs for the guidance of the public. Because the guidance in this notice covers virtually every NIH and Federal research program in which DNA recombinant

molecule techniques could be used, it has been determined not to be cost effective or in the public interest to attempt to list these programs. Such a list would likely require several additional pages. In addition, NIH could not be certain that every Federal program would be included as many Federal agencies, as well as private organizations, both national and international, have elected to follow the NIH Guidelines. In lieu of the individual program listing, NIH invites readers to direct questions to the information address above about whether individual programs listed in the Catalog of Federal Domestic Assistance are affected.

(Catalogue of Federal Domestic Assistance Program Nos. 93.14, Intramural Research Training Award; 93.22, Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds; 93.232, Loan Repayment Program for Research Generally; 93.39, Academic Research Enhancement Award; 93.936, NIH Acquired Immunodeficiency Syndrome Research Loan Repayment Program; 93.187, Undergraduate Scholarship Program for Individuals from Disadvantaged Backgrounds, National Institutes of Health, HHS)

Dated: 12, 2003.

LaVerne Y. Stringfield,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. 03-21215 Filed 8-18-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Radiological Emergency Preparedness: Planning and Preparing for a Fast-Breaking Event

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, Department of Homeland Security.

ACTION: Notice with request for comments.

SUMMARY: Pursuant to completion of the Radiological Emergency Preparedness (REP) Program exercise evaluation criteria, the Federal Emergency Management Agency (FEMA) is proposing a means to evaluate the capability of Offsite Response Organizations (ORO) to respond to a fast-breaking event at a commercial nuclear power plant.

DATES: FEMA must receive comments on or before October 20, 2003.

ADDRESSES: You may submit your comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, Room 840, 500 C Street, SW., Washington, DC 20472, or send them by e-mail to