

assist that office in processing your request, or fax your request to 301-443-8818. Submit written comments on the draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.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, 301-594-3332.

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

The draft guidance serves to clarify and update previously issued guidance on testing the AEC component of mammography units. Due to the use of increasingly sophisticated mammography units, previously issued guidance on this matter does not adequately address the issue. This draft guidance was developed with input from the National Mammography Quality Assurance Advisory Committee during a meeting held on August 26, 2002. Once finalized, this guidance will supersede the AEC guidance that currently appears in the July 18, 2002, version of the MQSA Policy Guidance Help System (<http://www.fda.gov/cdrh/mammography/robohelp/START.HTM>).

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on testing of the AEC component of mammography units. 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.

##### **II. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments>. Two hard copies of any mailed comments are to be submitted, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments are available for public examination in the

Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

##### **III. Electronic Access**

To receive "The Mammography Quality Standards Act Final Regulations Modifications and Additions to Policy Guidance Help System #6; Draft Guidance for Industry and FDA" by fax machine, 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 draft 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 Dockets Management Branch Internet site at <http://www.fda.gov/ohrms/dockets>.

Dated: February 3, 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 Cancer Institute; 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 Cancer Institute Special Emphasis Panel, Flexible System to Advance Innovative Research.

*Date:* March 19-21, 2003.

*Time:* 7 p.m. to 6 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Holiday Inn Select Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

*Contact Person:* Thomas M. Vollberg, PhD, Scientific Review Administrator, Special Review and Resources Branch, Division of Extramural Activities, National Cancer Institute, National Institute of Health, 6116 Executive Boulevard, Suite 703-7142, Rockville, MD 20852, 301/594-9582, [vollbert@mail.nih.gov](mailto:vollbert@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: February 11, 2003.

**LaVerne Y. Stringfield,**

*Director, Office of Federal Advisory Committee Policy.*

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