TABLE 1.—LIST OF SAFETY AND EFFECTIVENESS SUMMARIES FOR APPROVED PMAS MADE AVAILABLE FROM JANUARY 1, 2005, THROUGH MARCH 31, 2005—Continued

PMA No./Docket No.	Applicant	TRADE NAME	Approval Date
P040017/2005M–0110	Bayer Healthcare, LLC	ADVIA CENTAUR ANTI–HAV TOTAL ASSAY & ADVIA CENTAUR TOTAL QUALITY CONTROL MATERIALS	March 7, 2005
H030005/2005M–0132	CoAxia, Inc.	COAXIA NEUROFLO CATHETER	March 30, 2005

II. Electronic Access

Persons with access to the Internet may obtain the documents at *http://www.fda.gov/cdrh/pmapage.html*.

Dated: July 6, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–13901 Filed 7–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0195]

Draft Guidance for Industry and Food and Drug Administration Staff; The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9.'' The draft guidance document is intended to assist facilities and their personnel in meeting the Mammography Quality Standards Act (MQSA) final regulations.

DATES: Submit written or electronic comments on this draft guidance by October 13, 2005.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9'' to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label 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Submit written comments concerning this draft guidance and the information collection provisions to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061,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, 301–594–3332.

SUPPLEMENTARY INFORMATION:

I. Background

This draft guidance is intended to provide guidance to mammography facilities and their personnel. It represents the FDA's current thinking on various aspects of the final regulations implementing the MQSA (Public Law 102–539). Once finalized, this draft guidance document will add to and update material in the Policy Guidance Help System (PGHS) in order to address recurring inquiries to the Center for Devices and Radiological Health (CDRH) about these issues. The PGHS is a computerized system accessible through FDA's Web site that is intended to provide useful information to mammography facilities and their personnel on issues relating to MQSA. The guidance only addresses those portions of the PGHS that are being revised.

This draft guidance addresses the following issues:

1. Definitions of final interpretation and lossless and lossy digital compression;
2. Use of Small Field Digital Mammography image receptors;
3. Clarification relating to reestablishing processor operating levels;
4. Impact of the Health Insurance Portability and Accountability Act requirements on certain MQSA activities;
5. Retention of medical outcomes audit records;
6. Steps to take when patients do not wish to receive their lay summaries;
7. Combining medical reports;
8. The effect of film digitization and compression of Full Field Digital Mammography (FFDM) digital data on retention, transfer, and interpretation of mammographic images;
9. Clarification of continuing education requirements;
10. Use of foreign-trained physicians;
11. Use of the American Registry of Radiologic Technologists ARRT(M) certificate to meet certain radiologic technologist requirements;
12. Quality Control testing when using cushion pads on compression devices;
13. Medical physicist involvement in certain FFDM repairs;
14. Use of printers and monitors that were not specifically approved as part of an FFDM unit; and
15. Digitization of paper records and personnel documents.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on the issues described in the previous paragraphs. 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 #9'' 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 (1538) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

To receive ''The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9,'' you may either send a fax request to 301–443–8818 to receive a hard copy of the document, or send an e-mail request to *gwa@cdrh.fda.gov* to receive a hard copy or an electronic copy. Please use the document number 1538 to identify the guidance you are requesting.

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 Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance document contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). Under the PRA, Federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3 and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information in the following paragraphs.

With respect to the following collection of information, FDA invites comments on the following items: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9

Description: The Mammography Quality Standards Act Final Regulations: Modifications and Additions to Policy Guidance Help System #9 provides guidance to mammography facilities and their personnel on a variety of issues involving the quality standards for mammography (§900.12 (21 CFR 900.12)). Use of the guidance results in new collections of information. Facilities are required to provide patients with lay summaries of the results of their mammography examinations (§900.12(c)(2)). This guidance document provides information on how to address a patient's refusal to receive a lay summary and recommends that the facility document why it was unable to meet this requirement. Additionally, the guidance addresses interpreting physician initial requirements (§ 900.12(a)(1)(i)(B)(2)), including recommendations on how to document the alternative to Board Certification for foreign-trained physicians.

Respondents: The likely respondents are mammography facilities and their personnel who are subject to the MQSA quality standards requirements.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

Activity	No. of Respondents	Annual Frequency of Response	Total Annual Responses	Hours per Response	Total Hours
Reporting of refusal of lay summary	915	1	915	0.5	458

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

Activity	No. of Recordkeepers	Annual Frequency of Recordkeeping	Total Annual Records	Hours per Record	Total Hours
Documentation of foreign-trained physicians' qualifications	92	1	92	8	736

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

There are a total of 9,150 MQSA-certified facilities. Using past experience, FDA estimates that 10 percent of these facilities will receive patient requests that lay summary results not be sent. We also estimate that the facility will spend 0.5 hours per patient obtaining the patient's written request, filing that form in the patient's record and forwarding the summary to the patient's designee. With respect to foreign-trained physicians, past experience indicates that this situation arises very infrequently. We estimate that only 1 percent of MQSA-certified facilities will have to maintain records documenting the qualifications of foreign-trained physicians.

This draft guidance also contains information collection provisions that have been approved by OMB in accordance with the PRA under existing regulations. The collections of information described in this guidance document for § 900.12 were previously approved under OMB control number 0910–0309 entitled ''Mammography Facilities, Standards, and Lay Summaries for Patients 21 CFR Part 900.''

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper 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: June 10, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–13974 Filed 7–14–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21802]

National Offshore Safety Advisory Committee; Vacancies

AGENCY: Coast Guard, DHS.

ACTION: Request for applications.

SUMMARY: The Coast Guard seeks applications for membership on the National Offshore Safety Advisory Committee (NOSAC). NOSAC provides advice and makes recommendations to the Coast Guard on matters affecting the offshore industry.

DATES: Application forms should reach the Coast Guard on or before September 30, 2005.

ADDRESSES: You may request an application form by writing to Commandant (G–MSO–2), U.S. Coast Guard, 2100 Second Street, SW., Washington, DC 20593–0001; by calling 202–267–1082; or by faxing 202–267–4570. A copy of the application form is also available from the Coast Guard's Advisory Committee Web page at: *http://www.uscg.mil/hq/g-m/advisory/index.htm.* Send your application in written form to the above street address. This notice is available on the Internet at *http://dms.dot.gov.*

FOR FURTHER INFORMATION CONTACT: Commander John M. Cushing, Executive Director of NOSAC, or James M. Magill, Assistant to the Executive Director, telephone 202–267–1082, fax 202–267–4570.

SUPPLEMENTARY INFORMATION: NOSAC is a Federal advisory committee established under the provisions of the Federal Advisory Committee Act (FACA), 5 U.S.C. App. 2 (Pub. L. 92–463, 86 Stat. 770, as amended). It consists of 15 regular members who have particular knowledge and experience regarding offshore technology, equipment, safety and training, as well as environmental expertise in the exploration or recovery of offshore mineral resources. It provides advice and makes recommendations to the Assistant Commandant for Marine Safety, Security and Environmental Protection regarding safety, security and rulemaking matters relating to the offshore mineral and energy industries. This advice assists the Coast Guard in developing policy and regulations and formulating the positions of the United States in advance of meetings of the International Maritime Organization.

NOSAC meets twice a year, with one of these meetings being held at Coast Guard Headquarters in Washington, DC. It may also meet for extraordinary purposes. Its subcommittees and working groups may meet to consider specific problems as required.

We will consider applications for seven positions. These positions will begin in January 2006. Applications should reach us by September 30, 2005, but we will consider applications received later if they arrive within a reasonable time before we make our recommendations to the Secretary of Homeland Security.

To be eligible, applicants should have experience in one of the following categories: (1) Offshore supply vessel services including geophysical services, (2) offshore operations, (3) construction of offshore facilities, (4) offshore production of petroleum, (5) offshore drilling, (6) general public interest associated with offshore activities, or (7) deepwater ports interests associated with offshore oil and gas storage. Please state on the application form which of the seven categories you are applying for. The term of office for categories (1) through (5) will be 3 years, and 4 years for categories (6) and (7). Each member will normally serve the above term, or until a replacement is appointed. Some members may serve consecutive terms. All members serve at their own expense and receive no salary, reimbursement of travel expenses, or other compensation from the Federal Government.

In support of the policy of the Coast Guard on gender and ethnic diversity, we encourage qualified women and members of minority groups to apply.

Dated: July 11, 2005.

Howard L. Hime,

Acting Director of Standards, Marine Safety, Security and Environmental Protection.

[FR Doc. 05–13956 Filed 7–14–05; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2005–21833]

Mark 11 Static Barrier Running Gear Entanglement System; Draft Programmatic Environmental Assessment

AGENCY: Coast Guard, DHS.

ACTION: Notice of availability and request for comments.

SUMMARY: The Coast Guard announces the availability of the Draft Programmatic Environmental Assessment (PEA) and Draft Finding of No Significant Impact (FONSI) for the Mark 11 Static Barrier Running Gear Entanglement System (RGES). The Coast Guard is proposing to establish and operate a Mark (MK) 11 Static Barrier RGES at various and currently unknown U.S. ports throughout the U.S. Maritime Domain, when necessary. The purpose of Proposed Action is to improve the Coast Guard's capabilities to intercept and interdict small boats and watercraft. The MK11 Static Barrier RGES would deliver an entanglement device which would foul the propellers of unauthorized vessels attempting to approach restricted areas. The MK 11 Static Barrier RGES would not duplicate existing protective measures, but would provide complimentary, non-redundant capabilities that would be able to close significant readiness gaps in our nation's strategic ports.

DATES: You are invited to request a copy of the Draft PEA and Draft FONSI and/or submit comments by August 26, 2005.

ADDRESSES: A copy of the Draft Programmatic Environmental Assessment (PEA) and/or the Draft Finding of No Significant Impact (FONSI) will be available in the public