

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:****STORAGE:**

Paper records are kept in file folders. Magnetic tapes and disks are stored in libraries. Electronic records are stored in computers and attached equipment.

**RETRIEVABILITY:**

Records are filed and retrieved by Social Security Number or claim number.

**SAFEGUARDS:**

Records are stored in locked file cabinets or in secured rooms. Computer records are protected by a password system.

**RETENTION AND DISPOSAL:**

The Office of Human Resources Services disposes of the records as scheduled in the handbook, GSA Records Maintenance and Disposition system (OAD P 1820.2A).

**SYSTEM MANAGER AND ADDRESS:**

Chief, Employee Relations Branch, (CPSE), Office of Human Resources Services (CP), General Services Administration (CP), 18th and F Streets NW, Washington, DC 20405.

**NOTIFICATION PROCEDURES:**

Current employees should address requests to their supervisor or to the Human Resources Services officer. Former employees should address requests to the Human Resources Services officer.

**RECORD ACCESS PROCEDURES:**

Current employees should address requests to their supervisor or to the Human Resources Services officer. Former employees should address requests to the Human Resources Services officer. For the identification required, see 41 CFR part 105-64.

**PROCEDURE FOR CONTESTING THE CONTENT OF A RECORD:**

GSA rules for contesting the content and appealing an initial decision are in 41 CFR part 105-64.

**RECORD SOURCES:**

The employee and the personnel specialist who prepared a claim. [FR Doc. E7-167 Filed 1-9-07; 8:45 am]

**BILLING CODE 6820-34-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration**

[Docket No. 2006D-0515]

**Guidance for Industry and Food and Drug Administration Staff; Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays." This guidance document describes a means by which quality control material for cystic fibrosis nucleic acid assays may comply with the requirement of special controls for class II devices. It includes recommendations for validation of performance characteristics and recommendations for product labeling. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule to classify quality control material for cystic fibrosis nucleic acid assays into class II (special controls). This guidance document is being immediately implemented as the special control for quality control material for cystic fibrosis nucleic acid assays, but it remains subject to comment in accordance with the agency's good guidance practices (GGPs).

**DATES:** Submit written or electronic comments on this guidance at any time.

**ADDRESSES:** Submit written requests for single copies of the guidance document entitled "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays" 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 240-276-3151. 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:**

Zivana Tezak, Center for Devices and Radiological Health (HFZ-440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 240-276-0496 ext. 117.

**SUPPLEMENTARY INFORMATION:****I. Background**

Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule classifying quality control material for cystic fibrosis nucleic acid assays into class II (special controls) under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)). This guidance document will serve as the special control for quality control material for cystic fibrosis nucleic acid assays devices. Section 513(f)(2) of the act provides that any person who submits a premarket notification under section 510(k) of the act (21 U.S.C. 360(k)) for a device that has not previously been classified may, within 30 days after receiving an order classifying the device in class III under section 513(f)(1) of the act, request FDA to classify the device under the criteria set forth in section 513(a)(1) of the act. FDA shall, within 60 days of receiving such a request, classify the device by written order. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the **Federal Register** announcing such classification. Because of the time frames established by section 513(f)(2) of the act, FDA has determined, under § 10.115(g)(2) (21 CFR 10.115(g)(2)), that it is not feasible to allow for public participation before issuing this guidance as a final guidance document. Thus, FDA is issuing this guidance document as a level 1 guidance document that is immediately in effect. FDA will consider any comments that are received in response to this notice to determine whether to amend the guidance document.

**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 quality control material for cystic fibrosis nucleic acid assays. 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**

In order to receive "Class II Special Controls Guidance Document: Quality Control Material for Cystic Fibrosis Nucleic Acid Assays," you may either send an e-mail request to [dsmica@fda.hhs.gov](mailto:dsmica@fda.hhs.gov) to receive an electronic copy of the document, or send a fax request to 240-276-3151 to receive a hard copy. Please use the document number 1614 to identify the guidance you are requesting.

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. Paperwork Reduction Act of 1995**

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB Control No. 0910-0120; the collections of information in 21 CFR part 814 have been approved under OMB Control No 0910-0231; the collections of information in 21 CFR part 809 have been approved under OMB Control No. 0910-0485.

**V. Comments**

Interested persons may submit to the Division of Dockets Management (see

**ADDRESSES**) written or electronic comments regarding this document. Submit electronic comments to <http://www.fda.gov/dockets/ecomments>. Submit 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: December 29, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E7-120 Filed 1-9-07; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Office of the Secretary**

[Docket No. DHS-2006-0080]

**Notice of Meeting of National Infrastructure Advisory Council (NIAC)**

**AGENCY:** Directorate for Preparedness, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Infrastructure Advisory Council (NIAC) will meet in open session.

**DATES:** Tuesday, January 16, 2007, from 1:30 p.m. to 4:30 p.m.

**ADDRESSES:** National Press Club, 529 14th Street, NW., Washington, DC 20045.

You may submit comments, identified by DHS-2006-0080, by *one* of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.

- *E-mail:* [william.corcoran@associates.dhs.gov](mailto:william.corcoran@associates.dhs.gov). When submitting comments electronically, please include by DHS-2006-0080, in the subject line of the message.

- *Mail:* Jenny Menna, Department of Homeland Security, Directorate for Preparedness, Washington, DC 20528. To ensure proper handling, please reference by DHS-2006-0080, on your correspondence. This mailing address may be used for paper, disk or CD-ROM submissions.

- *Hand Delivery/Courier:* Jenny Menna, Department of Homeland

Security, Directorate for Preparedness, Washington, DC 20528. Contact Telephone Number 703-235-5316.

*Instructions:* All submissions received must include the words "Department of Homeland Security" and DHS-2006-0080, the docket number for this action. Comments received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** Jenny Menna, NIAC Designated Federal Officer, Department of Homeland Security, Washington, DC 20528; telephone 703-235-5316.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act (FACA), Pub. L. 92-463, as amended (5 U.S.C. App.). At this meeting, the NIAC will be briefed on the status of several Working Group activities in which the Council is currently engaged.

Due to a clerical error at DHS, this Notice was not published in the **Federal Register** in a timely fashion. However, because of scheduling concerns, it is impossible for DHS to reschedule the meeting; accordingly, this Notice is presented late pursuant to 41 CFR 102-3.150(b). In light of the late publication, DHS is making additional outreach efforts to notify stakeholders of this meeting.

This meeting is open to the public on a first-come, first-served basis. Please note that the meeting may close early if all business is finished.

A tentative agenda for the meeting is set forth below, but may be updated. Please consult the NIAC Web site, <http://www.dhs.gov/niac>, for the most current agenda. *Information on Services for Individuals with Disabilities:* For information on facilities or services for individuals with disabilities, or to request special assistance at the meeting, telephone the Designated Federal Officer as soon as possible.

Dated: January 5, 2007.

**Mary Kate Whalen,**

*Deputy Associate General Counsel for Regulatory Affairs.*

**DRAFT AGENDA OF JANUARY 16, 2007 MEETING**

I. Opening of Meeting .....	Jenny Menna, Designated Federal Officer, NIAC, Department of Homeland Security.
II. Roll Call of Members .....	Jenny Menna.