

**ADDRESSES:** Submit written comments 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>.

**FOR FURTHER INFORMATION CONTACT:** Kelly Williams-Randolph, Center for Food Safety and Applied Nutrition (HFS-810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2506, FAX: 301-436-2639, or e-mail: [Kelly.Williams@cfpsan.fda.gov](mailto:Kelly.Williams@cfpsan.fda.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In the *Federal Register* of October 20, 2004, FDA published a notice announcing a public meeting on November 15, 2004, and soliciting comments on FDA's premarket notification program for NDIs with an opportunity for public comment for 45 days. FDA requested comments from industry, consumers, and other interested members of the public concerning the content and format requirements for NDI notifications made under section 413(a)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 350b(a)(2)). FDA held this meeting to give the public an opportunity to provide information and views on topics outlined in the notice. The agency intends to consider all comments received in the meeting and sent to the docket in determining whether any future action is necessary or appropriate.

The agency has received a request from a number of trade associations for an extension of the comment period to and including February 1, 2005. The request set forth several reasons in support of allowing additional time to submit comments. First, according to the request, the 45-day comment period did not allow sufficient time for interested parties to adequately address the large number of detailed and specific questions put forth by FDA and the significant impact on industry, especially small businesses, of the issues raised in the notice. The request noted that the questions (many of which contained subparts) will require extended industry discussion to ensure broad input from member firms and to organize the information obtained from

their member companies. Second, the request noted that the original December 3, 2004, deadline for submitting comments did not provide interested parties enough time to consider the transcript of the November 15, 2004, meeting in developing their comments. The request explained that an extension until February 1, 2005, would allow industry to submit more focused and detailed comments without significantly delaying the agency's consideration of the issues set forth in the meeting notice.

FDA has considered the request and is reopening the comment period for the October 20, 2004, notice until February 1, 2005. The agency agrees that reopening the comment period will allow adequate time for interested persons to submit comments without significantly delaying the agency's consideration of the issues set forth in the October 20, 2004, notice.

**II. Request for Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the issues raised in the October 20, 2004, notice. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 17, 2004.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. 04-28135 Filed 12-23-04; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HOMELAND SECURITY**

**Directorate of Information Analysis and Infrastructure Protection (IAIP)**

**[DHS-2004-0032]**

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

**AGENCY:** Directorate of Information Analysis and Infrastructure Protection, DHS.

**ACTION:** Notice of meeting.

**SUMMARY:** The National Infrastructure Advisory Council (NIAC) will meet on Tuesday, January 11, 2005, from 1 p.m. to 4 p.m. at the Hamilton Crowne Plaza in Washington, DC. The meeting will be open to the public. Limited seating will be available. Reservations are not accepted.

The NIAC advises the President of the United States on the security of critical infrastructures which include banking and finance, transportation, energy, manufacturing, and emergency government services. At this meeting, the NIAC will be briefed on the status of several Working Group activities that the Council undertook at its last meeting.

**DATES:** The NIAC will meet Tuesday, January 11, 2005, from 1 p.m. to 4 p.m.

**ADDRESSES:** The NIAC will meet at the Hamilton Crowne Plaza, 14th and K Street, NW., Washington, DC. You may submit comments, identified by DHS Docket DHS-2004-0032 by one of the following methods:

- EPA Federal Partner EDOCKET Web Site: <http://www.epa.gov/feddocket>. Follow the instructions for submitting comments on the Web site.
- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments.
- Mail/Hand Delivery/Courier: Department of Homeland Security, Attn: Ms. Nancy J. Wong, Infrastructure Coordination Division, Directorate of Information Analysis and Infrastructure Protection/703-235-5352, Anacostia Navel Annex, 245 Murray Lane, SW., Building 410, Washington, DC 20528, 7:30 a.m. to 4 p.m.

Instructions: All submissions received must include the DHS-2004-0032. All comments received will be posted without change to <http://www.epa.gov/feddocket>, including any personal information provided.

**FOR FURTHER INFORMATION CONTACT:** Nancy J. Wong, NIAC Designated Federal Official, telephone 703-235-5352.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act, 5 U.S.C. App. 2.

**AGENDA OF COMMITTEE MEETING ON JANUARY 11, 2005**

I. Opening of Meeting .....	Nancy J. Wong, U.S. Department of Homeland Security (DHS)/Designated Federal Officer, NIAC.
II. Roll Call of Members .....	Nancy J. Wong.
III. Opening Remarks and Introductions.	NIAC Chairman, Erle A. Nye, Chairman of the Board, TXU Corporation.
	NIAC Vice Chairman, John T. Chambers, Chairman and CEO, Cisco Systems, Inc.

## AGENDA OF COMMITTEE MEETING ON JANUARY 11, 2005—Continued

	The Honorable Tom Ridge, Secretary, Department of Homeland Security (Invited). Lt. Gen. Frank Libutti, Under Secretary for Information Analysis and Infrastructure Protection (IAIP), DHS (Invited). Robert P. Liscouski, Assistant Secretary for Infrastructure Protection, DHS (Invited). Frances Fragos Townsend, Special Assistant to the President for Critical Infrastructure. NIAC Chairman Erle A. Nye.
IV. Introduction and Welcome of New NIAC Members.	
V. Ethics Briefing .....	Robert Coyle, DHS Office of Government Ethics.
VI. Approval of October Minutes ....	NIAC Chairman Erle A. Nye.
VII. Briefing of the New DHS Sector Partnership Model.	Mr. R. James Caverly, Director, Infrastructure Coordination Division, DHS.
VIII. Status Reports on Current Initiatives.	NIAC Chairman Erle A. Nye Presiding.
A. Intelligence Process and Work Products Regarding Critical Infrastructures.	NIAC Vice Chairman John T. Chambers, Chairman & CEO, Cisco Systems, Inc. and Chief Gilbert Gallegos, Police Chief, City of Albuquerque, New Mexico, NIAC Member.
B. Risk Management Approaches Protection.	Thomas E. Noonan, Chairman, President to & CEO, Internet Security Systems, Inc., NIAC Member; Martha Marsh, President & CEO, Stanford Hospital and Clinics, NIAC Member.
C. Assuring Adequate National Intellectual Capital to Secure Cyber-Based Critical Infrastructures.	Alfred R. Berkeley III, e-Xchange Advantage Corp., NIAC Member and Dr. Linwood Rose, President, James Madison University, NIAC Member.
IX. Reports Related to Past NIAC Recommendations.	NIAC Chairman Erle A. Nye Presiding.
A. Summary of NIAC Recommendations by Subject Area.	Nancy J. Wong, U.S. Department of Homeland Security (DHS)/Designated Federal Official, NIAC.
X. Presentation/Discussion of DHS/DOJ Cyber Security Survey.	Presentation by Patrick J. Morrissey, Deputy Director, Law Enforcement and Intelligence, National Cyber Security Division (NCSD), Department of Homeland Security.
XI. New Business .....	NIAC Chairman Erle A. Nye, NIAC Members.
XII. Adjournment .....	NIAC Chairman Erle A. Nye.

**Procedural**

These meetings are open to the public. Please note that the meetings may close early if all business is finished.

**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 Official as soon as possible.

Dated: December 13, 2004.

**Nancy J. Wong,**

*Designated Federal Official for NIAC.*

[FR Doc. 04-28206 Filed 12-23-04; 8:45 am]

**BILLING CODE 4410-10-P**

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard**

[USCG-2004-19946]

**Random Drug Testing Rate for Covered Crewmembers**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of minimum random drug testing rate.

**SUMMARY:** The Coast Guard has set the calendar year 2005 minimum random

drug testing rate at 50 percent of covered crewmembers. An evaluation of the 2003 Management Information System (MIS) data collection forms submitted by marine employers determined that random drug testing on covered crewmembers for the calendar year 2003 resulted in positive test results 2.07 percent of the time. Based on this percentage, we will maintain the minimum random drug testing rate at 50 percent of covered crewmembers for the calendar year 2005.

**DATES:** The minimum random drug testing rate is effective January 1, 2005 through December 31, 2005. You must submit your 2004 MIS reports no later than March 15, 2005.

**ADDRESSES:** The annual MIS report may be submitted in writing to Commandant (G-MOA), U.S. Coast Guard Headquarters, 2100 Second Street SW., Room 2404, Washington, DC 20593-0001 or by electronic submission to the following Internet address: <http://www.uscg.mil/hq/g-m/moa/dapip.htm>.

**FOR FURTHER INFORMATION CONTACT:** For questions about this notice, please contact Mr. Robert C. Schoening, Drug and Alcohol Program Manager, Office of Investigations and Analysis (G-MOA), U.S. Coast Guard Headquarters, telephone (202) 267-0684. If you have questions on viewing the docket, call Andrea M. Jenkins, Program Manager, Dockets Operations, Department of

Transportation, telephone (202) 366-0271.

**SUPPLEMENTARY INFORMATION:** Under 46 CFR 16.230, the Coast Guard requires marine employers to establish random drug testing programs for covered crewmembers on inspected and uninspected vessels. All marine employers are required to collect and maintain a record of drug testing program data for each calendar year, January 1 through December 31. You must submit this data by 15 March of the following year to the Coast Guard in an annual MIS report.

You may either submit your own MIS report or have a consortium or other employer representative submit the data in a consolidated MIS report. The chemical drug testing data is essential to analyze our current approach for deterring and detecting illegal drug abuse in the maritime industry.

Since 2003 MIS data indicates that the positive random testing rate is greater than one percent industry-wide (2.07 percent), the Coast Guard announces that the minimum random drug testing rate is set at 50 percent of covered employees for the period of January 1, 2005, through December 31, 2005, in accordance with 46 CFR 16.230(e).

Each year we will publish a notice reporting the results of the previous calendar year's MIS data, and the minimum annual percentage rate for