

and file servers and other types of data storage devices.

#### RETRIEVABILITY:

Records may be indexed by name or code number, but can be retrieved by manual or computer search of the case-tracking system using the name of the individual.

#### SAFEGUARDS:

##### 1. *Authorized users:*

Records in FDA's system are available to the Commissioner of Food and Drugs, FDA's System Managers, and to other appropriate FDA and HHS officials when there is a need to know in the performance of their duties. All authorized users are informed that the records are confidential and are not to be further disclosed.

##### 2. *Procedural safeguards:*

Access is strictly controlled by FDA's System Managers in compliance with the Privacy Act and this system notice. Access to the records is limited to ensure confidentiality. All questions and inquiries from any party should be addressed to FDA's Office of Good Clinical Practice.

##### 3. *Physical safeguards:*

All records (such as diskettes, computer listings, or documents) are kept in a secured area, locked rooms, and locked building. The facility has a 24-hour guard service, and access to the building is further controlled by an operational card key system. Access to the files, which are generally hard copy, are limited to a subset of persons with general access to the building. Access to individual offices is controlled by simplex locks. Records are kept in locked file cabinets in a room that is locked during non-working hours. Access to this room is restricted to specific personnel. Access to computer files is strictly limited through passwords and user-invisible encryption. Special measures commensurate with the sensitivity of the record are taken to prevent unauthorized copying or disclosure of the records.

#### RETENTION AND DISPOSAL:

The records are maintained in accordance with FDA's Records Control Schedule, applicable General Records Schedule (accessions), and disposition schedule approved by the National Archives and Records Administration (cases).

#### SYSTEM MANAGERS AND ADDRESSES:

Division of Inspections and Surveillance, Center for Biologics Evaluation and Research, Office of Compliance and Biologics Quality (refer

to <http://www.fda.gov> for address specifics).

Division of Bioresearch Monitoring, Center for Devices and Radiological Health, Office of Compliance (refer to <http://www.fda.gov> for address specifics).

Division of Scientific Investigations, Center for Drug Evaluation and Research, Office of Compliance (refer to <http://www.fda.gov> for address specifics).

Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (refer to <http://www.fda.gov> for address specifics).

Office of Enforcement, Office of Regulatory Affairs (refer to <http://www.fda.gov> for address specifics), and Regional Field Offices (refer to <http://www.fda.gov> for address specifics).

Center for Tobacco Products (refer to <http://www.fda.gov> for address specifics).

Division of Compliance, Center for Veterinary Medicine, Bioresearch Monitoring Program (refer to <http://www.fda.gov> for address specifics).

Office of Good Clinical Practice, Office of the Commissioner (refer to <http://www.fda.gov> for address specifics).

#### NOTIFICATION PROCEDURES:

In accordance with 21 CFR part 21 subpart D, an individual may submit a request to the FDA Privacy Act Coordinator, with a notarized signature, to confirm whether records exist about that individual. Requests should be directed to the FDA Privacy Act Coordinator (refer to <http://www.fda.gov> for the address specifics). Investigative records are exempt from this provision (see the following sentences: Records Exempted from Certain Provisions of the Act). In addition, some records may be exempt under 5 U.S.C. 552a(d)(5), if they are "compiled in reasonable anticipation of a civil action or proceeding." See also 21 CFR 21.41. Requests may be mailed to the FDA Privacy Act Coordinator (refer to <http://www.fda.gov> for the address specifics).

#### RECORD ACCESS PROCEDURES:

Same as notification procedures. Requesters should specify the record contents being sought. Access to record systems which have been granted an exemption from the Privacy Act access requirement may be made at the discretion of the system manager. If access is denied to requested records, an appeal may be made to the FDA Commissioner. A request can also be made for an accounting of disclosures that have been made of a record, if any.

#### CONTESTING RECORD PROCEDURES:

In accordance with 21 CFR 21.50, contact the FDA Privacy Act Coordinator (refer to <http://www.fda.gov>), and reasonably identify the record, specify the information being contested, the corrective action sought, and your reasons for requesting the correction, along with supporting information to show how the record is inaccurate, incomplete, untimely, or irrelevant. As stated previously, investigative records are exempt from this provision (see the following paragraphs of this document: Records Exempted from Certain Provisions of the Act). In addition, some records may be exempt under 5 U.S.C. 552a(d)(5) if they are "compiled in reasonable anticipation of a civil action or proceeding."

#### RECORD SOURCE CATEGORIES:

Individual on whom the record is maintained. Some material is obtained from third parties (e.g., a study sponsor, publication, or institutional review board), or is developed by FDA.

#### RECORDS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Investigatory records compiled for law enforcement purposes in this system are exempt from the notification, access, correction and amendment provisions of the Privacy Act (21 CFR 21.61).

Dated: January 4, 2012.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[USCG-2011-0975]

### National Maritime Security Advisory Committee; Meeting

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of Federal Advisory Committee Meeting.

**SUMMARY:** The National Maritime Security Advisory Committee (NMSAC) will meet on January 18-19, 2012 in Washington, DC to discuss various issues relating to national maritime security. This meeting will be open to the public.

**DATES:** The Committee will meet on Wednesday, January 18, 2012 from 9 a.m. to 3 p.m. and Thursday, January 19, 2012 from 9 a.m. to 12 p.m. This

meeting may close early if all business is finished.

All written material and requests to make oral presentations should reach the Coast Guard on or before January 9, 2012.

**ADDRESSES:** The Committee will meet at the American Bureau of Shipping, 1400 Key Blvd., Suite 800, Arlington, VA 22209. Seating is very limited, members of the public wishing to attend should register with Mr. Ryan Owens, Alternate Designated Federal Official (ADFO) of NMSAC, telephone (202) 372-1108 or [ryan.f.owens@uscg.mil](mailto:ryan.f.owens@uscg.mil) no later than January 9, 2012. Additionally, this meeting will be broadcasted via a web enabled interactive online format and teleconference.

To participate via teleconference, dial (866) 717-0091, the pass code to join is 3038389#. Additionally, if you would like to participate in this meeting via the online web format, please log onto <https://connect.hsin.gov/r11254182> and follow the online instructions to register for this meeting.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the committee as listed in the "Agenda" section below. You may submit written comments no later than January 9, 2012, and identified by docket number [USCG-2011-0975] using one of the following methods:

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

- **Mail:** Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590-0001. We encourage use of electronic submissions because security screening may delay delivery of mail.

- **Fax:** (202) 493-2251.

- **Hand Delivery:** Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays. The telephone number is (202) 366-9329.

**Instructions:** All submissions received must include the words "Department of Homeland Security" and docket number [USCG-2011-0975]. All submissions received will be posted without alteration at [www.regulations.gov](http://www.regulations.gov), including any personal information provided. You may review a Privacy Act notice regarding our public dockets in

the January 17, 2008 issue of the **Federal Register** (73 FR 3316).

**Docket:** Any background information or presentations available prior to the meeting will be published in the docket. For access to the docket to read background documents or submissions received by the NMSAC, go to <http://www.regulations.gov>, insert "USCG-2011-0975" in the "Keyword" box, and then click "Search".

Public comment period will be held during the meetings on January 18, 2012, from 2 p.m. to 3 p.m., and January 19, 2012 from 11 a.m. to 12 p.m. Speakers are requested to limit their comments to 5 minutes. Please note that the public comment period will end following the last call for comments. Contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section below to register as a speaker.

**FOR FURTHER INFORMATION CONTACT:** Mr. Ryan Owens, ADFO of NMSAC, 2100 2nd Street SW., Stop 7581, Washington, DC 20593-7581; telephone (202) 372-1108 or email [ryan.f.owens@uscg.mil](mailto:ryan.f.owens@uscg.mil). If you have any questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone (202) 366-9826.

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. NMSAC operates under the authority of 46 U.S.C. 70112. NMSAC provides advice, consults with, and makes recommendations to the Secretary of Homeland Security, via the Commandant of the Coast Guard, on matters relating to national maritime security.

### Agenda of Meeting

#### Day 1

The agenda for the Committee meeting is as follows:

(1) Maritime Domain Awareness and Information Sharing. The Committee will hold a discussion and will be tasked with developing guidelines and recommendations for the Coast Guard in enhancing information sharing between the maritime industry and the Federal Government;

(2) Maritime Transportation Security Act/Chemical Facility Anti-Terrorism Standards Harmonization. The Committee will receive a brief and offer recommendations on the harmonization efforts of the Coast Guard and the Department of Homeland Security for these two regulatory programs;

(3) Transportation Worker Identification Credential. The TWIC working group will provide an update on the implementation of the TWIC

program from the industry perspective. The Transportation Security Administration will also provide an update on the development of TWIC readers;

(4) Public comment period.

#### Day 2

(1) Maritime Transportation Security Act (MTSA). The Committee will be briefed on upcoming regulatory actions associated with updates to MTSA;

(2) Global Supply Chain Security Initiative. Per the SAFE Port Act (Pub. L. 109-347) NMSAC continues to be consulted in regards to the Global Supply Chain Security Initiative. The Committee will receive an update on this initiative;

(3) Requirements for vessel guards while in port. NMSAC will review and provide comment on requirements for vessels to post or contract for guards while in US ports;

(4) Underwater Terrorism Preparedness Program. NMSAC will receive a brief on the Coast Guard Underwater Terrorism Preparedness Program;

(5) Public comment period.

Dated: December 29, 2011.

**P.F. Thomas,**

*Captain, U.S. Coast Guard, Acting Director of Prevention Policy.*

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**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2011-1032]

### Houston/Galveston Navigation Safety Advisory Committee; Vacancies

**AGENCY:** Coast Guard, DHS.

**ACTION:** Request for applications.

**SUMMARY:** The Coast Guard seeks applications for membership on the Houston/Galveston Navigation Safety Advisory Committee (HOGANSAC). This Committee provides advice and makes recommendations to the Coast Guard on matters relating to the safe transit of vessels and products through Galveston Bay, and to and from the Ports of Galveston, Houston, Texas City, and Galveston Bay.

**DATES:** Applicants must send a cover letter describing their interest, reasons for application, and qualifications, and should enclose a complete professional biography or resume to CDR Michael Zidik, the Alternate Designated Federal Officer (ADFO), on or before February 1, 2012.