

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN <sup>1</sup>

Reporting activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Information for Determination of the Date of First Licensure .....	10	1	10	150	1,500

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

As indicated in table 1 of this document, FDA estimates that it will receive a total of approximately 10 requests annually for determination of the date of first licensure of a 351(a) product under 351(k)(7) of the PHS Act. The average burden per response (hours) is based on FDA experience with similar information collection requirements.

#### IV. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>, <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm>, or <http://www.regulations.gov>.

Dated: July 29, 2014.

**Leslie Kux,**

*Assistant Commissioner for Policy.*

[FR Doc. 2014–18169 Filed 8–4–14; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute on Aging Special Emphasis Panel; Aging Lung Disease.

*Date:* September 4, 2014.

*Time:* 2:00 p.m. to 6:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* ISIS S. MIKHAIL, MPH, DRPH, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, [MIKHAIL@mail.nih.gov](mailto:MIKHAIL@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: July 30, 2014.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014–18420 Filed 8–4–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Center For Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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:* Center for Scientific Review Special Emphasis Panel; Fellowship: Host Genome and Oral Microbiome.

*Date:* August 12, 2014.

*Time:* 4:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Anshumali Chaudhari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4124, MSC 7802, Bethesda, MD 20892, (301) 435–1210, [chaudhaa@csr.nih.gov](mailto:chaudhaa@csr.nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations, imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS).

Dated: July 30, 2014.

**David Clary,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014–18419 Filed 8–4–14; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), 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 Institute on Aging Special Emphasis Panel, Research and Education on Aging and Technology.

*Date:* September 2, 2014.

*Time:* 3:30 p.m. to 7:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

*Contact Person:* Kimberly Firth, Ph.D., National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Suite 2C212, Bethesda, MD 20892, 301–402–7702, [firthkm@mail.nih.gov](mailto:firthkm@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: July 30, 2014.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2014-18418 Filed 8-4-14; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

[Docket No. USCG-2013-0240]

#### Change-1 to the Marine Safety Manual, Volume III

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of availability.

**SUMMARY:** The Coast Guard announces the availability of Change-1 to the Marine Safety Manual (MSM), Volume III, Marine Industry Personnel, and the corresponding Commandant Change Notice that highlights the changes made to that manual. MSM Volume III provides information and interpretations on international conventions and U.S. statutory and regulatory issues relating to marine industry personnel. Change-1 is presented in a new format to facilitate future revisions by creating three distinct parts; Part A: Mariner Credentialing (Chapters 1-17), Part B: Vessel Manning (legacy Chapters 20-26, now Chapters 1-7), and Part C: Shipment and Service (legacy Chapters 18-19, now Chapters 1-2). The Commandant Change Notice discusses the substantive changes to Part B, Chapters 1 through 7. This Change includes revisions to Part C, Chapters 1 and 2, to account for revised regulations, updated forms, and reformatting. Part A will be reviewed and revised as part of a separate initiative.

**DATES:** Unless specifically stated otherwise, Change-1 to Marine Safety Manual, Volume III, Marine Industry Personnel, COMDTINST M16000.8B is effective as of August 5, 2014. Documents discussed in this notice should be available in the online docket within three business days of today's publication. This change has been incorporated into the electronic copy of the manual available on the Internet at [http://www.uscg.mil/directives/listing\\_cim.asp?id=16000-16999](http://www.uscg.mil/directives/listing_cim.asp?id=16000-16999). There will be no hardcopy distribution of this change.

**ADDRESSES:** To view the documents mentioned in this notice, go to <http://www.regulations.gov> and use "USCG-2013-0240" as your search term. Locate this notice in the search results, and use the filters on the left side of the page to locate specific documents by type. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. We have an agreement with the Department of Transportation to use the Docket Management Facility.

**FOR FURTHER INFORMATION CONTACT:** For information about this document, call or email Lieutenant Corydon Heard, Office of Commercial Vessel Compliance (CG-CVC), U.S. Coast Guard; telephone 202-372-1208, email [Corydon.F.Heard@uscg.mil](mailto:Corydon.F.Heard@uscg.mil). For information about viewing material in the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202-366-9826, toll free 1-800-647-5527.

**SUPPLEMENTARY INFORMATION:**

#### Background and Purpose

The Marine Safety Manual, Volume III, Marine Industry Personnel, COMDTINST M16000.8B, provides information and interpretations on international conventions and U.S. statutory and regulatory issues relating to marine industry personnel. The last revisions were released on May 27, 1999. The primary reasons for these changes are to incorporate the 2010 amendments to the International Convention on Standards of Training, Certification and Watchkeeping for Seafarers, 1978, as amended (STCW Convention), update the provisions for vessel manning, revise the discussion on the impact of multiple international standards, to clarify the applicability of tonnage measurement systems to U.S. flag vessels, and to include changes resulting from the consolidation of merchant mariner qualification credentials. The Coast Guard published two notices in the **Federal Register** announcing the availability of the changes to Part B (legacy chapters 20-26) and requested public comments (See 78 FR 48696 and 79 FR 14714) as well as input from the Merchant Marine Personnel Advisory Committee.

#### Background and Purpose

Specifically, the substantive changes announced in the initial notice (August 9, 2013) included: (1) Updated provisions for vessel manning, including guidance for the issuing of safe manning documents; (2) clarified roles, responsibilities, and facilitation of

communications with the appropriate offices at Coast Guard Headquarters in alignment with current Coast Guard organization; and (3) revised discussion on the impact of multiple international standards, including the Officer's Competency Certificates Convention (OCCC) 1936, the International Convention for Safety of Life at Sea (SOLAS), the Global Maritime Distress and Safety System (GMDSS), and the Principles of Minimum Safe Manning (IMO Resolution A.1047(27)). Additionally, the initial draft clarified the applicability of tonnage measurement systems to U.S. flag vessels, and included changes resulting from the consolidation of merchant mariner qualification credentials, including the removal of references to the operated uninspected towing vessel endorsement.

The primary reasons for the supplemental notice (March 17, 2014) were to announce the incorporation of the 2010 amendments to the STCW Convention and to address the 15 public comments received from the initial solicitation as well as input from the Merchant Marine Personnel Advisory Committee.

We received 12 public comment responses to the March 17, 2014 supplemental **Federal Register** notice. These comment responses contained a total of approximately 29 specific recommendations, suggestions, and other comments. We have created a comment matrix that provides a summary of each comment and the corresponding Coast Guard response, as well as internal Coast Guard comments. A copy of this comment matrix is available for viewing in the public docket for this notice. For more detailed information, please consult the actual public comment letters, which are available in the docket. You may access the docket going to <http://www.regulations.gov>, using "USCG-2013-0240" as your search term, and following the instructions in the **ADDRESSES** section above.

The basic ideas and principles encompassed in the initial and supplemental drafts remain. Some commenters raised concerns and objections over several proposed revisions to the MSM. In response to these comments, the Coast Guard has made some additional revisions. The Coast Guard notes, however, that the MSM (and any revisions made to the MSM) reflect current law and regulation and are intended to provide guidance and information to marine industry personnel. A brief discussion of the comments is included below. For a more in-depth discussion of the