additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). The NIH Director may rescind the certification of a host-vector system (see Section IV–C–1–b–(2)–(g), *Minor Actions*). If certification is rescinded, NIH will instruct investigators to transfer cloned DNA into a different system or use the clones at a higher level of physical containment level, unless NIH determines that the already constructed clones incorporate adequate biological containment. Certification of a host-vector system does not extend to modifications of either the host or vector component of that system. Such modified systems shall be independently certified by the NIH Director. If modifications are minor, it may only be necessary for the investigator to submit data showing that the modifications have either improved or not impaired the major phenotypic traits on which the containment of the system depends. Substantial modifications to a certified host-vector system requires submission of complete testing data.

Appendix I–II–B. Data To Be Submitted for Certification

Appendix I–II–B–1. Host-Vector 1 Systems Other than *Escherichia coli* K–12

The following types of data shall be submitted, modified as appropriate for the particular system under consideration: (i) A description of the organism and vector; the strain's natural habitat and growth requirements; its physiological properties, particularly those related to its reproduction, survival, and the mechanisms by which it exchanges genetic information; the range of organisms with which this organism normally exchanges genetic information and the type of information is exchanged; and any relevant information about its pathogenicity or toxicity; (ii) a description of the history of the particular strains and vectors to be used, including data on any mutations which render this organism less able to survive or transmit genetic information; and (iii) a general description of the range of experiments contemplated with emphasis on the need for developing such an Host-Vector 1 system.

Appendix I–II–B–2. Host-Vector 2 Systems

Investigators planning to request Host-Vector 2 systems certification may obtain instructions from NIH OSP concerning data to be submitted (see Appendices I–III–N and O, *Footnotes and References of Appendix I*). In general, the following types of data are required: (i) Description of construction steps with indication of source, properties, and manner of introduction of genetic traits; (ii) quantitative data on the stability of genetic traits that contribute to the containment of the system; (iii) data on the survival of the host-vector system under non-permissive laboratory conditions designed to represent the relevant natural environment; (iv) data on transmissibility of the vector and/or a cloned DNA fragment under both permissive and non-permissive conditions; (v) data on all other properties of the system which affect containment and utility, including information on yields of phage or plasmid molecules, ease of DNA isolation, and ease of transfection or transformation; and (vi) in some cases, the investigator may be asked to submit data on survival and vector transmissibility from experiments in which the host-vector is fed to laboratory animals or one or more human subjects. Such *in vivo* data may be required to confirm the validity of predicting *in vivo* survival on the basis of *in vitro* experiments. Data shall be submitted to the Office of Science Policy, National Institutes of Health, preferably by email to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*). Investigators are encouraged to publish their data on the construction, properties, and testing of proposed Host Vector 2 systems prior to consideration of the system by NIH. Specific instructions concerning the submission of data for proposed *Escherichia coli* K–12 Host-Vector 2 system (EK2) involving either plasmids or bacteriophage in *Escherichia coli* K–12, are available from the Office of Science Policy, National Institutes of Health, preferably by submitting a request for this information to: *NIHGuidelines@od.nih.gov;* additional contact information is also available here and on the OSP website (*www.osp.od.nih.gov*).

Appendix L, GENE THERAPY POLICY CONFERENCES (GTPCS), is proposed to be deleted in its entirety.

Appendix M, Points to Consider in the Design and Submission of Protocols for the Transfer of Recombinant or Synthetic Nucleic Acid Molecules into One or More Human Research Participants (Points to Consider), is proposed to be deleted in its entirety.

Dated: August 7, 2018.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2018–17760 Filed 8–16–18; 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 Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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; PAR–17–144: Limited Competition: National Primate Research Centers (P51).

Date: September 11–14, 2018.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Vintage Portland, 422 SW Broadway, Portland, OR 97205.

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: September 13–14, 2018.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Orlando at SeaWorld, 6677 Sea Harbor Drive, Orlando, FL 32821.

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

(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: August 13, 2018.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2018–17785 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night; Availability of Document; Request for Comments; Notice of Peer-Review Meeting

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Toxicology Program (NTP) announces a meeting to peer review the Draft Report on Carcinogens Monograph on Night Shift Work and Light at Night. NTP has conducted a literature-based assessment to determine whether night shift work (*e.g.,* working at least three hours between 12 a.m. and 6 a.m.) and light at night are cancer hazards and should

be listed the Report on Carcinogens. The peer-review meeting will be held at the National Institute of Environmental Health Sciences (NIEHS) in Research Triangle Park, NC and is open to the public. Registration is requested for attendance at the meeting either in-person or by webcast and to present oral comments. Information about the meeting and registration is available at *https://ntp.niehs.nih.gov/go/36051.*

DATES:

Meeting: Scheduled for October 5, 2018, 8:30 a.m. to adjournment at approximately 5:00 p.m. Eastern Daylight Time (EDT). The preliminary agenda is available at *https://ntp.niehs.nih.gov/go/36051* and will be updated one week before the meeting.

Document Availability: The draft RoC monograph should be available by August 24, 2018, at *https://ntp.niehs.nih.gov/go/36051.*

Written Public Comment Submissions: Deadline is September 21, 2018.

Registration for Oral Comments: Deadline is September 21, 2018.

Registration To Attend Meeting In-Person or To View Webcast: Deadline is October 5, 2018.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709.

Meeting Web Page: The draft RoC monograph, preliminary agenda, registration, and other meeting materials will be available at *https://ntp.niehs.nih.gov/go/36051.*

Webcast: The URL for viewing the peer-review meeting webcast will be provided to registrants.

FOR FURTHER INFORMATION CONTACT: Kate Helmick, ICF, 2635 Meridian Parkway, Suite 200, Durham, NC, USA 27713. Phone: (919) 293–1673, Fax: (919) 293–1645, Email: *NTP-Meetings@icf.com.*

SUPPLEMENTARY INFORMATION:

Background: The invention of electric light transformed society, from one in which people's activities and sleep patterns were limited by the natural light: Dark cycle to a culture in which people now work, sleep, eat, and receive goods or services throughout the 24-hour day. Through lifestyle choices, home location, and work schedule, people are exposed to different patterns and types of light, including electric light at night (LAN), which may lead to cancer and other adverse health effects. These health effects may arise from misalignment of daily physiological and behavioral cycles (*i.e.,* circadian rhythms) with external stimuli or with each other (*i.e.,* circadian disruption). Circadian rhythms can include processes and behaviors like sleep-wake cycles, eating, and body temperature, among others.

NTP has conducted a literature-based assessment and applied the *Report on Carcinogens (RoC) listing criteria* to this assessment to determine whether night shift work (*e.g.,* working at least three hours between midnight and 6 a.m.) and light at night are cancer hazards. As circadian disruption is thought to be a key intermediate step, NTP has also reviewed the literature on this topic.

The monograph assesses the evidence from cancer studies in humans and experimental animals and mechanistic data and provides NTP's preliminary recommendation regarding whether night shift work and or light at night should be listed in the Report on Carcinogens, and if so, how the two exposure scenarios should be defined. The listing categories include *known or reasonably anticipated to be a human carcinogen.*

Meeting Attendance Registration: The meeting is open to the public with time set aside for oral public comment; in-person attendance at the NIEHS is limited by the space available (~100 attendees). Registration for in-person attendance is on a first-come, first-served basis. After the first 100 registrants, persons will be placed on a wait list and notified should an opening become available. Registration to attend the meeting in-person or view the webcast is by October 5, 2018, at *https://ntp.niehs.nih.gov/go/36051.* The URL for the webcast will be provided in the email confirming registration. Visitor and security information for those attending in person is available at *https://www.niehs.nih.gov/about/visiting/index.cfm.* Individuals with disabilities who need accommodation to view the webcast should contact Kate Helmick by phone: (919) 293–1673 or email: *NTP-Meetings@icf.com.* TTY users should contact the Federal TTY Relay Service at (800) 877–8339. Requests should be made at least five business days in advance of the event.

Public Comment Registration: NTP invites written and oral public comments on the draft RoC monograph that address scientific/technical issues. Guidelines for public comments are available at *https://ntp.niehs.nih.gov/ntp/about_ntp/guidelines_public_comments_508.pdf.*

The deadline for submission of written comments is September 21, 2018. Written public comments should be submitted through the meeting website. Persons submitting written comments should include name, affiliation, mailing address, phone, email, and sponsoring organization (if any). Written comments received in response to this notice will be posted on the NTP website and the submitter will be identified by name, affiliation, and sponsoring organization (if any). Comments that address scientific/technical issues will be forwarded to the peer-review panel and NTP staff prior to the meeting.

The agenda allows for one oral public comment period (up to 12 commenters, up to 5 min per speaker). Registration to provide oral comments is September 21, 2018, at *https://ntp.niehs.nih.gov/go/36051.* Registration is on a first-come, first-served basis. Each organization is allowed one time slot. Oral comments may be presented in person at NIEHS or by teleconference line. The access number for the teleconference line will be provided to registrants by email prior to the meeting. Commenters will be notified after September 21, 2018, the deadline to register for oral public comments, about the actual time allotted per speaker.

If possible, oral public commenters should send a copy of their slides and/or statement or talking points to Kate Helmick by email: *NTP-Meetings@icf.com* by September 21, 2018.

Meeting Materials: The draft RoC monograph and preliminary agenda will be available on the NTP website at *https://ntp.niehs.nih.gov/go/36051.* The draft RoC monograph should be available by August 24, 2018. Additional information will be posted when available or may be requested in hardcopy, contact Kate Helmick by phone: (919) 293–1673 or email: *NTP-Meetings@icf.com.* The preliminary meeting agenda will be available on the meeting web page and will be updated one week before the meeting. Individuals are encouraged to access the meeting web page to stay abreast of the most current information regarding the meeting.

Following the meeting, a report of the peer review will be prepared and made available on the NTP website.

Background Information on the RoC: Published biennially, each edition of the RoC is cumulative and consists of substances newly reviewed in addition to those listed in previous editions. For each listed substance, the RoC contains a substance profile, which provides information on cancer studies that support the listing—including those in humans and animals and studies on possible mechanisms of action, information about potential sources of exposure to humans, and current Federal regulations to limit exposures. The 14th RoC, the latest edition, was published on November 3, 2016

(available at *https://ntp.niehs.nih.gov/go/roc14*).

Background Information on NTP Peer-Review Panels: NTP panels are technical, scientific advisory bodies established on an ''as needed'' basis to provide independent scientific peer review and advise NTP on agents of public health concern, new/revised toxicological test methods, or other issues. These panels help ensure transparent, unbiased, and scientifically rigorous input to the program for its use in making credible decisions about human hazard, setting research and testing priorities, and providing information to regulatory agencies about alternative methods for toxicity screening. NTP welcomes nominations of scientific experts for upcoming panels. Scientists interested in serving on an NTP panel should provide their current curriculum vitae to Kate Helmick by email: *NTP-Meetings@icf.com.* The authority for NTP panels is provided by 42 U.S.C. 217a; section 222 of the Public Health Service Act, as amended. The panel is governed by the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: August 8, 2018.

Brian R. Berridge,

Associate Director, National Toxicology Program.

[FR Doc. 2018–17782 Filed 8–16–18; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2018–0565]

Lifejacket Approval Harmonization

AGENCY: Coast Guard, DHS.

ACTION: Notice and request for comments.

SUMMARY: The Coast Guard announces that it is harmonizing personal flotation device (PFD) standards between the United States and Canada by accepting a new standard for approval of PFDs. Specific elements of the new standard are contained in a policy letter and deregulatory savings analysis, on which we are requesting public comment, and are intended to promote the Coast Guard's maritime safety and stewardship missions.

DATES: Comments must be submitted to the online docket via *http://www.regulations.gov,* or reach the Docket Management Facility, on or before October 16, 2018.

ADDRESSES: You may submit comments identified by docket number USCG–2018–0565 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See the ''Public Participation and Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Jacqueline Yurkovich, Coast Guard; telephone 202–372–1389, email *Jacqueline.M.Yurkovich@uscg.mil*.

SUPPLEMENTARY INFORMATION:

Public Participation and Comments

We encourage you to submit comments on the lifejacket approval harmonization policy letter entitled, ADOPTION OF ANSI/CAN/UL 12402–5 AND –9, and the deregulatory savings analysis entitled, ''Approval for Personal Floatation Devices/Adoption of ANSI/CAN/UL 12402–5 and 9,'' which are available in the docket. The policy letter is also available on the USCG website, *https://www.dco.uscg.mil/CG-ENG,* listed as CG–ENG Policy 02–18. We will consider all submissions and may adjust our final action based on your comments. If you submit a comment, please include the docket number for this notice, indicate the specific section of the document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *http://www.regulations.gov*. If your material cannot be submitted using *http://www.regulations.gov,* contact the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. Documents mentioned in this notice, and all public comments, are in our online docket at *http://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments or other documents are posted.

We accept anonymous comments. All comments received will be posted without change to *http://www.regulations.gov* and will include any personal information you have provided. For more about privacy and the docket, you may review a Privacy Act notice regarding the Federal Docket Management System in the March 24, 2005, issue of the **Federal Register** (70 FR 15086).

Discussion

The United States Coast Guard (USCG) has statutory authority under Title 46, U.S. Code, Sections 3306(a) and (b), 4102(a) and (b), 4302(a), and 4502(a) and (c)(2)(B) to prescribe regulations for the design, construction, performance, testing, carriage, use, and inspection of lifesaving equipment on commercial and recreational vessels. Since 2008, the USCG has been working closely with Transport Canada (TC) and a diverse group of U.S. and Canadian stakeholders to harmonize PFD standards with the current international standard (ISO 12402) to create a single North American standard for PFD approval. A single North American standard will allow manufacturers the opportunity to produce more innovative equipment that meets the approval requirements of both the United States and Canada.

In 2015, Underwriters Laboratories Inc. published bi-national standards [1] to set forth performance requirements and manufacturing standards for PFDs that are being used when vessels are close to shore, or where a rescue may be imminent. UL 12402–5 sets forth the performance requirements for PFDs and, within UL 12402–5, there are two levels of performance: Level 50 and Level 70. A Level 70 PFD provides an equivalent level of safety to a Type III PFD currently approved under 46 CFR 160.064, 160.076, or 160.077–15, and certified to UL 1123 (Marine Buoyant Devices). A Level 50 PFD provides a reduced level of performance, and is not included in this policy. UL 12402–9 sets forth the test methods for determining compliance with UL 12402–5.

In April 2017, the USCG and TC signed a Memorandum of Understanding (MOU) outlining intended cooperation for approval of personal lifesaving appliances that comply with mutually acceptable standards, are tested by mutually accepted conformity assessment bodies or independent test laboratories, and are covered by a mutually acceptable follow-up program. In January 2018, TC published a policy stating it will accept UL 12402–5 as a substitute for its PFD standards in support of the MOU. The policy letter on which we are requesting comment builds on the efforts described above by establishing that the USCG will accept Level 70 PFDs complying

[1] ANSI/CAN/UL 12402–5, Standard for Personal Flotation Devices—Part 5: Buoyancy Aids (Level 50)—Safety Requirements (UL 12402–5), and ANSI/CAN/UL 12402–9, Standard for Personal Flotation Devices—Part 9: Test Methods (UL12402–9).