Even if an oversight body does not request that a particular protocol be reviewed by the RAC, the NIH Director, after consultation (if needed) with appropriate regulatory authorities, may initiate RAC review if (a) the protocol has one or more of the characteristics listed above (i, ii, or iii) and public RAC review and discussion would provide a clear and obvious benefit to the scientific community or public; or (b) the protocol otherwise raises significant scientific, societal, or ethical concerns.

Completion of the registration process is defined as: (1) Receipt by the Principal Investigator of a letter from the NIH OSP indicating that protocol registration process is complete and that enrollment may proceed; or (2) receipt by the Principal Investigator of a letter from the NIH after public RAC review that summarizes the committee's key comments and recommendations (if any).

A complete human gene transfer protocol package must be submitted at least eight weeks before a scheduled RAC meeting to be reviewed at that upcoming meeting.

After a human gene transfer experiment is publicly reviewed by the full RAC at a regularly scheduled meeting, the NIH OSP will send a letter summarizing the RAC's key comments and recommendations (if any) regarding the protocol to the Principal Investigator(s), oversight bodies, and regulatory authorities as appropriate. Completion of RAC review is defined as receipt by the Principal Investigator(s) of a letter from the NIH OSP summarizing the committee's findings. Unless the NIH determines that there are exceptional circumstances, the letter containing recommendations and comments made following public review will be sent within 10 working days after the completion of the RAC meeting at which the protocol was reviewed.

RAC meetings will be open to the public except where trade secrets or confidential commercial information are reviewed. To enable all aspects of the protocol review process to be open to the public, information provided in response to Appendix M–I–A should not contain trade secrets or confidential commercial or financial information. An application submitted to the NIH OSP shall not contain any document that is designated as 'confidential' in its entirety. In the event that a determination has been made that a specific portion of a document submitted as one of the items described in Appendix M should be considered as confidential commercial or financial information or a trade secret, each item must be clearly identified as such. The cover letter (attached to the submitted material) shall: (1) Clearly designate the information that is considered as confidential commercial or financial information or a trade secret; and (2) explain and justify each designation to demonstrate *with specificity* how release of that information will reveal a trade secret or will result in substantial competitive harm.

There are no proposed amendments to Appendix M–I–C, Reporting Requirements and Appendix M–I–D, Safety Assessments in Human Gene Transfer Research.

The current appendices Appendix M–II, Description of the Proposal; Appendix M–III, Informed Consent; Appendix M–IV, Privacy; and Appendix M–V, Special Issues are proposed to be deleted in their entirety, except for Appendix M–III–B–2-b, Long Term Follow-Up which will be updated to include a reference to FDA's current guidance on this issue and will become Appendix M–II.

Appendix M–II is proposed to be amended as follows:

Appendix M–II. Long Term Follow-Up

To permit evaluation of long-term safety and efficacy of gene transfer, prospective subjects should be informed that they are expected to cooperate in long-term follow-up that extends beyond the active phase of the study. A list of persons who can be contacted in the event that questions arise during the follow-up period should be provided to the investigator. In addition, the investigator should request that subjects continue to provide a current address and telephone number.

The subjects should be informed that any significant findings resulting from the study will be made known in a timely manner to them and/or their parent or guardian including new information about the experimental procedure, the harms and benefits experienced by other individuals involved in the study, and any long-term effects that have been observed.

Additional guidance is available in the FDA Guidance for Industry: Gene Therapy Clinical Trials—Observing Subjects for Delayed Adverse Events (available at the following URL: *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/default.htm*).

Appendix M–VI Footnotes of Appendix M will be renumbered to Appendix M–III. Footnotes of Appendix M. There will be no amendment to the language.

Dated: October 9, 2015.

Francis S. Collins,

Director, National Institutes of Health.

[FR Doc. 2015–26388 Filed 10–15–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIEHS.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the National Institute of Environmental Health Sciences, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, NIEHS.

Date: November 15–17, 2015.

Closed: November 15, 2015, 7 p.m. to 10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 16, 2015, 8:30 a.m. to 11:50 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 11:50 a.m. to 1:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 16, 2015, 1:30 p.m. to 3 p.m.

Agenda: Poster Session.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 3 p.m. to 3:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 16, 2015, 3:45 p.m. to 5:25 p.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 5:25 p.m. to 5:55 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 16, 2015, 6:15 p.m. to 10 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Doubletree Guest Suites, 2515 Meridian Parkway, Research Triangle Park, NC 27713.

Open: November 17, 2015, 8:30 a.m. to 10:10 a.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 17, 2015, 10:10 a.m. to 10:40 a.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: November 17, 2015, 10:55 a.m. to 12 p.m.

Agenda: Scientific Presentations.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Closed: November 17, 2015, 12 p.m. to 1:30 p.m.

Agenda: To review and evaluate programmatic and personnel issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, Rooms 101 ABC, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Darryl C. Zeldin, Scientific Director & Principal Investigator, Division of Intramural Research, National Institute of Environmental Health Sciences, NIH, 111 TW Alexander Drive, Maildrop A2–09, Research Triangle Park, NC 27709, 919–541–1169, *zeldin@niehs.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: October 9, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–26341 Filed 10–15–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2015–0950]

Sewage Treatment Technology—Type Approval of Marine Sanitation Devices

AGENCY: Coast Guard, DHS.

ACTION: Notice of meeting.

SUMMARY: The Coast Guard will conduct a public workshop in Washington, DC to discuss sewage treatment technologies, issues concerning testing of marine sanitation devices for type approval, and issues concerning gray water. This workshop is intended to be an interactive exchange of information between policymakers, industry experts, and interested members of the public.

DATES: The workshop will be held on Tuesday and Wednesday, December 8 and 9, 2015 beginning at 9:30 a.m. and ending at 4 p.m., Eastern Time. This workshop is open to the public. Please note that the workshop has a limited number of seats and may close early if all business is finished. Contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) by December 4, 2015 to reserve seating. The comment period for the docket closes January 9, 2016.

ADDRESSES: The workshop will be held in conference rooms 8, 9, and 10 of the Department of Transportation Headquarters Building, 1200 New Jersey Ave. SE., Washington, DC 20590. The building is accessible by public transportation (Navy Yard subway station) or taxi. Parking for privately-owned vehicles is available nearby. Due to security requirements, each visitor must present a valid government-issued photo identification (for example, a driver's license) in order to gain entrance to the building. Contact the Coast Guard (see **FOR FURTHER INFORMATION CONTACT**) to facilitate the security process related to building access, or to request reasonable accommodation.

You may submit comments identified by docket number USCG–2015–0950 using the Federal eRulemaking Portal at *http://www.regulations.gov*. See **SUPPLEMENTARY INFORMATION** for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions concerning the workshop, please call or email Mr. Wayne Lundy, U.S. Coast Guard; telephone 202–372–1379, email *Wayne.M.Lundy@uscg.mil* or Ms. Katherine Weiler, Environmental Protection Agency; telephone 202–566–1280, email *Weiler.Katherine@epa.gov*.

SUPPLEMENTARY INFORMATION: Your comment is important to us. If you submit a comment, please include the docket number shown at the beginning of this notice 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 us (see **FOR FURTHER INFORMATION CONTACT**) 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 Web site's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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).

This workshop is sponsored by the Coast Guard and the Environmental Protection Agency and is intended to be an interactive exchange of information between policymakers, industry experts, and interested members of the public. The primary topics that will be discussed include:

- Sewage treatment technologies;
- Issues concerning testing of marine sanitation devices for type approval;
- Simple on board checks for verifying performance of marine sanitation devices;
- Impact of gray water on the environment;
- Impact on the ship from processing gray water;
- Technologies for processing of gray water;
- Analytes for considering technologies treating gray water;
- Issues associated with existing federal standards and MARPOL Annex IV equipment standards (International Maritime Organization (IMO) resolution MEPC.227(64));
- Impact of No Discharge Zones; and
- Revision of an industry consensus standard, ASTM F2363—''Standard Specification for Sewage and Graywater Flow Through Treatment Systems''.

Please note that the workshop has a limited number of seats and may close early if all business is finished.