DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of Biotechnology Activities; Recombinant DNA Research: Action Under the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)

AGENCY: National Institutes of Health (NIH), Public Health Services (PHS), Department of Health and Human Services, (DHHS).

ACTION: Notice of Final Action under the NIH Guidelines.

SUMMARY: The Office of Biotechnology Activities (OBA) is updating Appendix B of the NIH Guidelines to specify the risk group (RG) classification for several common attenuated strains of bacteria and viruses that are frequently used in recombinant DNA research. OBA is also specifying the risk group for several viruses not previously listed in Appendix B. In addition, a reference to Appendix B will be added to Section II–A of the NIH Guidelines, which addresses the risk assessment for research with recombinant DNA.

Background: The NIH Guidelines provide guidance to investigators and local Institutional Biosafety Committees (IBCs) for setting containment for recombinant DNA research. Section II–A, Risk Assessment, instructs investigators and IBCs to make an initial risk assessment based on the RG of the agent (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard). The RG of the agent often correlates with the minimum containment level required for experiments subject to the NIH Guidelines.

The classification of agents into various RG categories is based largely on their ability to cause human disease and the availability of treatments for that disease. For the most part, the organisms listed in Appendix B are wild-type, non-attenuated strains and a distinction is not made between the RG classification for the wild-type organism and a corresponding attenuated strain. A few attenuated strains are classified in Appendix B at a lower RG than that of the wild-type organism. However, there are a number of well-established attenuated strains commonly employed in research that are not specifically listed and thus by default are included in the same RG as the wild-type organism. Therefore, the biosafety level (BL) specified for research subject to the NIH Guidelines may be identical for experimentation with either the attenuated or the wild-type strain.

OBA has conducted an evaluation of certain attenuated strains, focusing on those for which a risk assessment had been undertaken and containment recommendations determined in the Centers for Disease Control and Prevention (CDC)/NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) (5th edition). In addition, the NIH Recombinant DNA Advisory Committee (RAC) discussed the appropriate containment for two attenuated strains of Yersinia pestis (lcr+ and pgm−) mutants at its meeting on June 16, 2010. (A webcast of that discussion is available at http://oba.od.nih.gov/rdna_rac/rac_past_meetings_2010.html.)

Specifying the risk groups for attenuated strains in Appendix B of the NIH Guidelines will lead to more uniform containment recommendations that are commensurate with the biosafety risk. In addition, OBA has identified several RG3 viruses that are not currently specified in Appendix B or are a member of a family of viruses otherwise classified as RG2. Therefore, Appendix B is being updated to address these viruses as well.

OBA consulted the NIH RAC as well as other subject matter experts from NIH, CDC, and academia. These proposed changes were published in the Federal Register (76 FR 44339) on July 25, 2011, and one comment was received. This comment, from the American Biological Safety Association (ABSA), suggested that “OBA should consider adding additional information to Section II–A regarding the assignment of Risk Group to commonly used attenuated strains.” Section II–A of the NIH Guidelines provides a framework for conducting a comprehensive risk assessment. These proposed changes to Appendix B and ABSA’s comment were discussed at the September 13, 2011, meeting of the RAC. OBA and the RAC appreciated ABSA’s comments and will add a reference to Appendix B to the last sentence of the first paragraph of Section II–A to the last sentence of the first paragraph of Section II–A–3 currently reads: “Certain attenuated strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard and Section V–B, Footnotes and References of Sections I–IV).” In addition to the change to the first paragraph of Section II–A–3, the following additions will be made to Appendix B–II–A. Risk Group 2 (RG2)—Bacterial Agents Including Chlamydia: Coxiella burnetii, Nine Mile strain, plaque purified, clone 4.

*Francisella tularensis* subspecies novicida (also referred to as *Francisella novicida*) strain, Utah 112.

*Francisella tularensis* subspecies holarctica LVS.

*Francisella tularensis* biovar tularensis strain ATCC 6223 (also known as strain B38).

Yersinia pestis pgm− (lacking the 102 kb pigmentation locus).

Yersinia pestis lcr+ (lacking the LCR plasmid).

The following footnote will be added regarding research with attenuated strains of *Francisella*:

*For research involving high concentrations, BL3 practices should be considered (See Appendix G–II–C–2).

The following changes/additions will be made to Appendix B–II–D Risk Group 2 (RG2)—Viruses:

**Alphaviruses (Togaviruses)**—Group A

- Arboviruses: “Venezuelan equine encephalomyelitis vaccine strain TC-83” will be changed to: Venezuelan equine encephalomyelitis vaccine strains TC-83 and V3526.

**Alphaviruses (Togaviruses)**—Group A Arboviruses:

- Add: Chikungunya vaccine strain 181/25.

**Arenaviruses**:

- Add: Junin virus candid #1 vaccine strain.

**Flaviviruses (Togaviruses)**—Group B Arboviruses:


**Rhabdoviruses**:

- Vesicular stomatitis virus—laboratory adapted strains including VSV—Indiana, San Juan, and Glasgow” will be changed to: Vesicular stomatitis virus non-exotic strains: VSV—Indiana 1 serotype strains (e.g. Glasgow, Mudd-Summers, Orsay, San Juan) and VSV—New Jersey serotype strains (e.g. Ogden, Hazelhurst).

The following additions will be made to Appendix B–III–D Risk Group 3 (RG3)—Viruses and Prions:

**Coronaviruses**:

Alphaviruses (Togaviruses)—Group A
Arboviruses:
Add: Chikungunya.
Flaviviruses (Togaviruses)—Group B
Arboviruses:
Add: West Nile virus (WNV).

DEPARTMENT OF HOMELAND SECURITY
Coast Guard
[Docket No. USCG–2011–0877]
National Offshore Safety Advisory Committee
AGENCY: United States Coast Guard.
ACTION: Committee Management; Notice of Federal Advisory Committee Meeting.

SUMMARY: The National Offshore Safety Advisory Committee (NOSAC) will meet on November 15, 2011, in Houston, Texas to discuss various issues related to safety of operations and other matters affecting the oil and gas offshore industry. The meeting will be open to the public.

DATES: NOSAC will meet Tuesday, November 15, 2011, from 9 a.m. to 4 p.m. Please note that the meeting may close early if the committee has completed its business or been extended based on the level of public comments.

ADDRESSES: The meeting will be held at Hilton Houston NASA Clear Lake, Discovery Ballroom, 3000 NASA Road One, Houston, Texas, 77058–4322.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the person listed in “FOR FURTHER INFORMATION CONTACT” 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. Comments must be submitted in writing no later than November 1, 2011, and must be identified by USCG–2011–0877 and may be submitted by one of the following methods:

- Fax: (202) 372–1926.

- 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 the docket number for this action. Comments received will be posted without alteration at 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: For access to the docket to read documents or comments related to this Notice, go to http://www.regulations.gov.

A public comment period will be held during the meeting on November 15, 2011, and speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact the individual listed below to register as a speaker.

FOR FURTHER INFORMATION CONTACT:
Commander Rob Smith, Designated Federal Officer of NOSAC, Commandant (CG–5222), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–0001 or Mr. Kevin Pekarek, Alternate Designated Federal Officer of NOSAC, Commandant (CG–5222), U.S. Coast Guard, 2100 Second Street, SW., Stop 7126, Washington, DC 20593–0001; telephone (202) 372–1386, fax (202) 372–1926. If you have questions on viewing or submitting material to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9626.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92–463). The National Offshore Safety Advisory Committee (NOSAC) provides advice and recommendations to the Department of Homeland Security on matters and actions concerning activities directly involved with or in support of the exploration of offshore mineral and energy resources insofar as they relate to matters within Coast Guard jurisdiction.

Agenda
The NOSAC will meet, review and discuss reports and recommendations received from the Medical Evacuation of Injured Divers subcommittee and the Mississippi Canyon Incident Report subcommittee. The Committee will then use this information to formulate recommendations to the agency.

A complete agenda is as follows:
(1) Roll call of committee members and determination of a quorum.
(2) Approval of minutes from the meeting on May 19, 2011, meeting.
(3) Committee Administration.
   a. Introduction of new members.
   b. Nominations for Committee Chair and Vice Chair for presentation to the Commandant.
   c. Discussion of Committee By-Laws.
   d. DFO announcements.
(4) Presentation and discussion of reports and recommendations from the subcommittees on:
   (a) Medical Evacuation of Injured Divers,
   (b) Mississippi Canyon Incident Reports subcommittee, to include the appointment of a Co-chairman.
(5) Establishment of a sub-committee to work on the task to evaluate the requirements for licensing mariners who will man and operate large OSVs.
(6) Offshore Operators Committee (OOC) update regarding medical evacuations from the OCS.
(7) An update on USCG regulations and Federal Register notices.
(8) USCG Briefing on Joint Investigation Team for DEEPWATER HORIZON drilling rig explosion and sinking.
(9) Update from the Bureau of Ocean Energy Management Regulation and Enforcement concerning their reorganization, rules and regulations, etc. Discussion to include USCG/BOEMRE Memorandum of Agreement OCS–06 and contracting of the National Research Council’s Marine Board to conduct a study on regulating worker safety in connection with the development of offshore renewable energy on the Outer Continental Shelf (OCS).
(10) EO 13580—Domestic Energy Development and Permitting in Alaska; USCG and BOEMRE processes involved.
(11) Updates on International Maritime Organization (IMO) activities of interest to the OCS community.
(13) Use of Liquefied Natural Gas (LNG) as fuel for internal engines.
(14) Period for Public comment.
(15) Adjournment of meeting.

A copy of each report is available at the https://www.fido.gov Web site or by contacting Kevin Y Pekarek. Use “code 68” to identify NOSAC when accessing this material. Once you have accessed the Committee page, click on the