

## 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*<sup>-</sup> and *pgm*<sup>-</sup> 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](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-3 covering 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-3. 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 Section V-B, *Footnotes and References of Sections I-IV*)." It will be amended to read:

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 *holartica* LVS.

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

*Yersinia pestis pgm*<sup>-</sup> (lacking the 102 kb pigmentation locus).

*Yersinia pestis lcr*<sup>-</sup> (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:

Add: Japanese encephalitis virus strain SA 14-14-2.

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*:

Add: Coronaviruses:

Add: SARS-associated coronavirus

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

Dated: October 3, 2011.

**Jacqueline Corrigan-Curay,**

*Acting Director, Office of Biotechnology  
 Activities, National Institutes of Health.*

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**BILLING CODE 4140-01-P**

## 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 be 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:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Fax:* (202) 493-2251.
- *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.

• *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-  
 9826.

**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 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.
  - (12) Briefing on the activities of Ocean  
 Energy Safety Advisory Committee.
  - (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