

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-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⁻ (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:

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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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