themselves, that information will not usually be redacted. The CDC Freedom of Information Act coordinator will, however, review such revelations in accordance with the Freedom of Information Act and if deemed appropriate, will redact such information. Disclosures of information concerning third parties will be redacted.

III. Public Comment Period

Written comments on the document will be accepted until October 14, 2011 in accordance with the instructions below. All material submitted to NIOSH should reference Docket Number NIOSH–245. All electronic comments should be formatted as Microsoft Word or pdf files and make reference to docket number NIOSH–245. To submit comments, please use one of these options:

- Present oral comments at the public meeting and provide a written copy of comments to the NIOSH Docket Office.
- Send NIOSH comments using the online form at *http://www.cdc.gov/niosh/docket/review/docket245/comments.html.*
- Send comments by e-mail to *nioshdocket@cdc.gov?subject=245.*
- *Facsimile:* (513) 533–8285.
- *Mail:* NIOSH Docket Office, Robert A. Taft Laboratories, MS–C34 4676 Columbia Parkway, Cincinnati, Ohio 45226.

All information received in response to this notice will be available for public examination and copying at, NIOSH Docket Office, 4676 Columbia Parkway, Room 111, Cincinnati, Ohio 45226. A complete electronic docket containing all comments submitted will be available on the NIOSH docket home page at *http://www.cdc.gov/niosh/docket/,* and comments will be available in writing by request. NIOSH includes all comments received without change in the docket, including any personal information provided.

CONTACT PERSON FOR MORE INFORMATION: Lauralynn Taylor McKernan, ScD, CIH, NIOSH, 4676 Columbia Parkway, MS–C32, Cincinnati, OH 45226, telephone (513) 533–8542, fax (513) 533–8230, E-mail *LMcKernan@cdc.gov.*

Dated: July 19, 2011.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2011–18755 Filed 7–22–11; 8:45 am]

BILLING CODE 4163–19–P

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, PHS, Department of Health and Human Services.

ACTION: Proposed Minor Action under the *NIH Guidelines.*

SUMMARY: The Office of Biotechnology Activities (OBA) is updating Appendix B of the *NIH Guidelines* by specifying 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 adding the risk group for several viruses not previously listed in Appendix B. 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 establishes 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 of organisms are classified in Appendix B at a lower RG than that of the parental organism. However, there are a number of additional, well-established attenuated strains employed in research subject to the *NIH Guidelines* 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 therefore 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). Specifying the risk groups for these 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 currently specified as a member of a family of viruses otherwise classified as RG2. Therefore, Appendix B is being updated to address these viruses as well.

In addition to considering the risk assessment articulated in the BMBL, OBA also consulted with members of the NIH Recombinant DNA Advisory Committee (RAC) as well as other subject matter experts from NIH, CDC, and academia. Of note, the RAC discussed the appropriate containment for two attenuated strains of *Yersinia pestis* (*lcr*$^{(-)}$ and *pgm*$^{(-)}$ mutants) at its June 16, 2010, meeting when the committee considered which antibiotic markers could be used in these strains without requiring RAC review under Section III–A–1-a. (A webcast of that discussion is available at *http://oba.od.nih.gov/rdna_rac/rac_past_meetings_2010.html.*) The RAC recommendations regarding containment for work with these attenuated strains of *Yersinia pestis* are being implemented by amending Appendix B to indicate that these specific strains are RG2 organisms rather than RG3 organisms.

This update does not include all attenuated strains identified in the BMBL. OBA has tried to select attenuated strains commonly used in recombinant DNA research. OBA has also not modified the RG for viruses for which the *NIH Guidelines* already provides specific containment recommendations. For example, human immunodeficiency virus (HIV) is currently classified as a RG3 virus in Appendix B of the *NIH Guidelines.* However, Section II–A–3 makes specific recommendations regarding when BL2 is acceptable for research with HIV and OBA's guidance titled Biosafety Considerations for Research with Lentiviral Vectors (see *http://oba.od.nih.gov/rdna_rac/rac_guidance_lentivirus.html*) provides additional containment recommendations for lentiviral vectors derived from HIV.

Revision of Appendix B is considered a Minor Action under Section IV–C–3 of the *NIH Guidelines* and therefore can be implemented by OBA after consultation

with the RAC Chair and one or more RAC members as needed. This consultation is complete. However, in the interest of soliciting broad public input, OBA is submitting this action for public comment and will finalize the changes after reviewing any comments.

DATES: The public is encouraged to submit written comments on this minor action. Comments may be submitted to the OBA in paper or electronic form at the OBA mailing, fax, and e-mail addresses shown below under the heading **FOR FURTHER INFORMATION CONTACT**. The NIH will consider all comments submitted by September 9, 2011. All written comments received in response to this notice will be available for public inspection at the NIH OBA office, 6705 Rockledge Drive, Suite 750, Bethesda, MD 20817–7985, weekdays between the hours of 8:30 a.m. and 5 p.m.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these changes, please contact OBA by e-mail at *oba@od.nih.gov,* telephone (301–496–9838), or mail to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, Bethesda, Maryland 20892–7985.

Background: Appendix B of the *NIH Guidelines* is a list of biological agents that are classified into risk groups on the basis of their ability to cause disease in healthy adults and the availability of preventive or therapeutic interventions. Agents listed in Appendix B have been classified into one of four risk groups:

- RG1 agents are those that are not associated with disease in healthy adult humans;
- RG2 agents are those that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available;
- RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available; and
- RG4 agents are those that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

For the most part, the agents listed in Appendix B are wild-type, fully pathogenic strains. However, laboratory research that is subject to the *NIH Guidelines* frequently employs strains that are attenuated. An attenuated strain is not necessarily avirulent but generally is less pathogenic than the wild-type strain, and therefore the biosafety risk posed by research with an attenuated strain is not necessarily equivalent to that posed by the wild-type strain. As the RG of an agent is the starting point for the risk assessment to determine containment for research with that agent, OBA is amending Appendix B to provide more specific guidance for these attenuated strains.

In addition to designating RGs for several attenuated strains, four additional changes will be made to Appendix B. The classification of attenuated strains of Vesicular stomatitis virus will be clarified. West Nile Virus (WNV) and Chikungunya virus are currently not specifically listed in the RG classification. WNV will now be listed as a RG3 Flavivirus and Chikungunya virus will be listed as a RG3 Togavirus. In addition, the coronavirus that is the causative agent of severe acute respiratory syndrome (SARS) will be listed as a RG3 coronavirus. All coronaviruses are currently RG2 viruses. The BMBL currently recommends BL3 containment for research with these three viruses.

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, Utah112

**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 (RG2 Viruses) of the *NIH Guidelines:*

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.

The following will be added to Appendix B–II–D:

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 (RG3 Viruses and Prions) of the *NIH Guidelines:*

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: July 18, 2011.

Jacqueline Corrigan-Curay,

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

[FR Doc. 2011–18726 Filed 7–22–11; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: The Safe Schools/Healthy Students (SS/HS) Initiative National Evaluation (OMB No. 0930–0297)—Revision

SAMHSA's Center for Mental Health Services (CMHS) will conduct a study to evaluate the relationships between different grantee characteristics and implementation strategies to outcomes at the project, school, and student level. Data collected by this study will facilitate an examination of contextual