submitted for each individual being nominated for consideration: (1) A statement that clearly states the name and affiliation of the nominee, the basis for the nomination (*i.e.,* specific attributes such as expertise in bioethics, evidence review, public health, laboratory, maternal and child health, or clinical expertise in heritable disorders, which qualify the nominee for service in this capacity), and that the nominee is willing to serve as a member of the Committee; (2) the nominee's name, address, and daytime telephone number and the home/or work address, telephone number, and email address; and (3) a current copy of the nominee's curriculum vitae. Nomination packages may be summited directly by the individual being nominated or by the person/organization recommending the candidate.

The Department of Health and Human Services will make every effort to ensure that the membership of the Committee is fairly balanced in terms of points of view represented. Every effort is made to ensure that individuals from a broad representation of geographic areas, gender, ethnic and minority groups, as well as individuals with disabilities are given consideration for membership. Appointments shall be made without discrimination on the basis of age, ethnicity, gender, sexual orientation, and cultural, religious, or socioeconomic status.

Individuals who are selected to be considered for appointment will be required to provide detailed information regarding their financial holdings, consultancies, and research grants or contracts. Disclosure of this information is necessary in order to determine if the selected candidate is involved in any activity that may pose a potential conflict with the official duties to be performed as a member of the Committee.

Jackie Painter,

Director, Division of the Executive Secretariat.

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BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institutes of Health (NIH) Office of Science Policy (OSP) Recombinant or Synthetic Nucleic Acid Research: Action Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)

SUMMARY: The NIH OSP is amending portions of the *NIH Guidelines* in order to provide investigators with biosafety guidance regarding the standards for containment of non-human primates (NHPs) in biosafety level (BL) 4 laboratories and to make such guidance consistent with the expectations articulated in the Centers for Disease Control and Prevention (CDC)/NIH Biosafety in Microbiological and Biomedical Laboratories 5th edition (BMBL). Specifically, the *NIH Guidelines* will allow for housing of NHPs in open caging in a dedicated animal holding room provided there are two physical barriers between that animal holding room and non-containment space within the laboratory, the animal holding room has negative air pressure with respect to any adjacent non-containment corridors, and there are specific decontamination protocols in place before the door to the animal holding room is opened to allow for the periodic transfer of new animals into the room. These amendments do not change the current containment requirements in the *NIH Guidelines* but rather offer an alternative for achieving primary containment without compromising safety.

In addition, the recertification requirement for biosafety cabinets in BL4 laboratories is updated in recognition of the technological standards for modern biosafety cabinets. The NIH OSP also is updating the validation requirements for equipment responsible for centralized heat decontamination of liquid effluents in laboratories working with large animals.

These amendments to the *NIH Guidelines* will be implemented immediately upon publication in the **Federal Register**. These changes were developed after extensive consultation with biosafety experts, directors of and principal investigators in BL4 facilities working with NHPs, and CDC's Division of Select Agent and Toxins (DSAT) leadership at a public workshop and discussion at a public Recombinant DNA Advisory Committee (RAC) meeting. Publication in the **Federal Register** will inform the scientific and biosafety communities.

FOR FURTHER INFORMATION CONTACT: If you have questions, or require additional information about these changes, please contact the NIH OSP by email at *SciencePolicy@od.nih.gov*, or telephone at 301–496–9838.

SUPPLEMENTARY INFORMATION: The first three editions of the BMBL and the *NIH Guidelines* were consistent in their approach to requiring primary containment for animal work in BL4 containment laboratories. However, in the early 1990s, the BMBL was amended and the fourth edition stated that animals housed in BL4 suit laboratories (*i.e.,* laboratories in which Class III cabinets are not used but instead personnel wear positive pressure protective suits) *should* be housed in a primary containment system (such as open cages covered with filtered bonnets and opened in laminar flow hoods or other equivalent containment systems). This language remains in the current BMBL (5th edition). With the change in the BMBL, primary containment caging was arguably preferred but no longer required under BL4 containment. In contrast, the *NIH Guidelines* have always required primary containment caging for all animals in BL4 laboratories.

Non-human primates are social animals and require environmental enrichment. Researchers in several U.S. BL4 laboratories engaged in NHP research approached the NIH OSP with concerns that primary containment caging in BL4 laboratories hindered the creation of an environment that allowed animals to benefit from adequate social interaction. Also based on risk assessments and experiences comparing several primary containment caging systems, the researchers concluded that primary containment caging may actually create new hazards for laboratory workers. These findings included interference with observation of the animals from outside the room leading to more frequent entries into the BL4 animal room to monitor the animals, and exacerbation of cramped working conditions created by the additional barriers required by some containment systems, which increases the difficulty of working in inflated pressure suits as well as the potential for damage to the pressure suit. In addition, investigators stated that current BL4 laboratory designs incorporate sophisticated engineering systems, which provide biosafety protection in a dedicated animal room equivalent to the primary containment caging required under the *NIH*

Guidelines. On March 28, 2014, the NIH OSP, together with the CDC Division of Select Agents (DSAT), held a meeting with investigators and biosafety personnel from nine BL4 laboratories in the U.S. and five international laboratories (agenda and roster available at *http://osp.od.nih.gov/office-biotechnology-activities/event/2014-03-28-120000-2014-03-28-211500/primary-containment-non-human-primates-biosafety-level-4-laboratories-challenges-and-best-practices*). That meeting was followed by a discussion at the June 11, 2014, meeting of the NIH RAC regarding housing of NHPs in BL4 laboratories (a webcast of that discussion is available at *http://videocast.nih.gov/summary.asp?Live=14300&bhcp=1*.)

As a result of these discussions and after consultation with CDC DSAT, the NIH OSP is amending the *NIH Guidelines* to allow the housing of NHP in open cages in a dedicated animal room provided certain conditions as articulated below are met.

In addition, OSP is updating the requirement for testing and certification of Class I and II biosafety cabinets at BL4 from every six months to annually, recognizing the technological advances in biosafety cabinet design and engineering that have occurred over the period since this performance measure was originally implemented.

Finally, Appendix Q of the *NIH Guidelines* currently requires that the centralized heat treatment catch tank system in BL4 large animal laboratories be validated every 30 days. To carry out this testing effectively, the system should be near capacity (*i.e.* ''under load''). Some laboratories do not use their catch tank systems on a regular basis; therefore, a mandatory 30 day validation would require them to demonstrate that the equipment is functioning when it is not in use or is not at capacity. This will not serve the intended purpose of demonstrating that the equipment is functioning as intended. Therefore, validation intervals will need to be set based on the utilization of the system provided it is done at least once a year.

To implement these changes, the following sections of the *NIH Guidelines* are to be amended:

Appendix G–II–D–2–l. currently states:

> Appendix G–II–D–2–l. Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems, such as Horsfall units (see Appendix G–III–K, *Footnotes and References of Appendix G*), open cages placed in ventilated enclosures, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.

Appendix G–II–D–2–1 is amended as follows with the addition of a new Appendix G–II–D–2–1–(2) that will address housing of NHPs:

Appendix G–II–D–2–l. Containment for Animal Research

Appendix G–II–D–2–l–(1). Laboratory animals involved in experiments requiring BL4 level physical containment shall be housed either in cages contained in Class III cabinets or in partial containment caging systems, such as Horsfall units (see Appendix G–III–K, *Footnotes and References of Appendix G*), open cages placed in ventilated enclosures, or solid-wall and -bottom cages placed on holding racks equipped with ultraviolet irradiation lamps and reflectors that are located in a specially designed area in which all personnel are required to wear one-piece positive pressure suits.

Appendix G–II–D–2–l–(2). Non-human primates (NHP) may be housed (1) under the containment conditions described in Appendix G–II–D–2–l–(1) above, or (2) in open cages within a dedicated animal holding room that serves as the primary barrier and in which all personnel are required to wear one-piece positive pressure suits. A room serving as a primary barrier must be air-tight and capable of being decontaminated using fumigation. If NHPs are to be contained in a dedicated animal holding room serving as the primary barrier, the following conditions shall be met:

(i) Access to the animal holding room from service corridors outside of the BL4 containment space shall require passage through two sets of doors, and the inner most door must be an air pressure resistant (APR) door;

(ii) For any animal holding room considered to be a primary barrier, APR door(s) providing direct ingress from the exterior service corridor shall be fitted with appropriate and redundant lock-out mechanisms to prevent access when the animal holding room is contaminated and in use. There should be more than one mechanism to ensure that this primary barrier door cannot be opened when the animal room is contaminated and the APR door shall not serve as an emergency exit from the BL4 laboratory. The APR door shall be appropriately tested to demonstrate that in the closed, locked-out mode, the door provides an air-tight barrier proven by pressure decay testing or other equivalent method;

(iii) Any door(s) allowing access into a corridor from which there is direct ingress to an animal holding room must be fitted with either (1) an APR door or (2) a non-APR door, providing directional airflow is maintained from the laboratory corridor space into the animal room. For the purpose of fumigation, animal rooms equipped with non-APR doors opening into the adjacent interior corridors shall be considered one space (*i.e.,* areas between air-tight doors shall be fumigated together).

(iv) Any door(s) used for access to the service corridor (the secondary barrier) shall be self-closing and of solid construction, designed not to corrode, split or warp;

(v) Access to the service corridor inside the secondary barrier shall be restricted and strictly controlled when animal rooms are in use. Whenever possible, the secondary barrier door(s) should be fitted with safety interlock switches designed to prevent it from opening when an animal holding room door (the primary barrier) is opened following room decontamination; if interlock devices cannot be used, specific administrative procedures shall be implemented to control access to the service corridor;

(vi) The service corridor shall maintain a negative pressure (inward directional airflow) relative to adjoining traffic corridors;

(vii) Prior to fumigation of the animal holding room, cages should be removed for autoclaving or chemical decontamination.

(viii) Caging should be chosen to reduce the amount of animal detritus that can be thrown out of the cage and onto the floor of the animal holding room;

(ix) The flow of personnel, material and equipment should be directed in order to minimize the spread of contamination from the animal holding room into adjacent areas of the laboratory.

(x) Following animal room decontamination, safeguards involving the use of personal protective equipment and appropriate administrative controls shall be implemented for the safe retrieval of biological indicators in order to prevent the spread of infectious agents in the event of a decontamination failure.

With regard to the frequency of class II biosafety cabinet recertification and testing, the *NIH Guidelines* require recertification/testing of biosafety cabinets at six-month intervals. However, modern biosafety cabinet

design specifications incorporate continuous electronic and physical monitoring systems that track multiple operational parameters such as pressure differential, air flow velocity and plenum pressure with added capabilities for remote control and monitoring. Continuous performance monitoring and redundant safety features obviate the need for frequent testing of modern biosafety cabinets under normal conditions of use. Also the testing of biosafety cabinets in biomedical high containment (BL4) laboratories entails a complete shutdown of the laboratory for decontamination with appropriate sterilants to allow technicians to access the equipment safely. This procedure increases risks to laboratory staff working with the sterilants (often in the form of toxic gasses) and requires a halt to all research activities for an extended period of time depending on the number of cabinets to be tested or recertified. The NIH is in agreement with the recommendation of the BMBL that class II biosafety cabinets be tested and certified at least annually, with the understanding that retesting may have to be performed as needed at the discretion of the Institutional Biosafety Committee (IBC), if for example, equipment is moved or subject to unusual conditions of use.

Appendix G–II–D–4–p currently states:

Appendix G–II–D–4–p. The treated exhaust air from Class I and II biological safety cabinets may be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at six-month intervals. The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of high efficiency particulate air/HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (*e.g.,* thimble unit connection (see Appendix G–III–L, Footnotes and References of Appendix G)) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

Appendix G–II–D–4–p is amended as follows:

Appendix G–II–D–4–p. The treated exhaust air from Class I and II biological safety cabinets may be discharged into the laboratory room environment or the outside through the facility air exhaust system. If exhaust air from Class I or II biological safety cabinets is discharged into the laboratory the cabinets are tested and certified at minimum on a yearly basis. More frequent testing and certification, based on the amount of use or other safety factors, shall be left to the discretion of the IBC. The exhaust air from Class III biological safety cabinets is discharged, without recirculation through two sets of high efficiency particulate air/HEPA filters in series, via the facility exhaust air system. If the treated exhaust air from any of these cabinets is discharged to the outside through the facility exhaust air system, it is connected to this system in a manner (*e.g.,* thimble unit connection (see Appendix G–III–L, *Footnotes and References of Appendix G*)) that avoids any interference with the air balance of the cabinets or the facility exhaust air system.

With regard to the periodic biologic validation of the centralized heat treatment process for all BL3 and BL4 facilities, the *NIH Guidelines* requires that this process be performed every 30 days while the BMBL recommends at least an annual biological validation. Similar to biosafety cabinets, modern catch tank systems for heat treatment of all laboratory effluents have also become more sophisticated and now incorporate redundant monitoring systems to track temperature and pressure parameters during each heat treatment cycle. In addition it should be noted that proper validation of the heat treatment catch tank system requires that testing be performed when the system is at or near capacity (*i.e.* ''under load'')—more frequent validation of a heat treatment system that is below capacity may not serve the intended purpose of demonstrating that the equipment is functioning as intended. An additional margin of safety is achieved by monitoring sterilization cycle parameters on a routine basis. We are, therefore, in agreement with the recommendation of the BMBL that validation be performed as frequently as necessary at the discretion of the IBC and at least once annually to ensure that the centralized effluent heat treatment system is performing as intended under the established process parameters. This amendment shall apply to heat treatment systems used in both large animal BL3 and BL4 facilities.

For large animal BL3 laboratories, the requirement for decontamination and inactivation (BL3–N) found at Appendix Q–II–C–1–b–(5) currently states:

Appendix Q–II–C–1–b–(5). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q–II–C–1–b–(5) is amended as follows:

Appendix Q–II–C–1–b–(5). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated at minimum on a yearly basis with an indicator organism. More frequent validation, based on the amount of use or other safety factors, shall be left to the discretion of the IBC.

For large animal BL3 laboratories, the requirement for animal facilities (BL3–N) found at Appendix Q–II–C–2–h currently states:

Appendix Q–II–C–2–h. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism.

Appendix Q–II–C–2–h is amended as follows:

Appendix Q–II–C–2–h. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated at minimum on a yearly basis with an indicator organism. More frequent validation, based on the amount of use or other safety factors, shall be left to the discretion of the IBC.

For large animal BL4 laboratories, the requirement for decontamination and inactivation (BL4–N) found at Appendix Q–II–D–1–b–(9) currently states:

Appendix Q–II–D–1–b–(9). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary

system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q–II–D–1–b–(9) is amended as follows:

Appendix Q–II–D–1–b–(9). Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. If required by design, regulation, local ordinance or policy, liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated at minimum on a yearly basis with an indicator organism. More frequent validation, based on the amount of use or other safety factors, shall be left to the discretion of the IBC. If required by design, regulation, local ordinance or policy, liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

For large animal BL4 laboratories, the requirement for animal facilities (BL4–N) found at Appendix Q–II–D–2–i currently states:

Appendix Q–II–D–2–i. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. Liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated every 30 days with an indicator organism. Liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Appendix Q–II–D–2–i is amended as follows:

Appendix Q–II–D–2–i. Liquid effluent from containment equipment, sinks, biological safety cabinets, animal rooms, primary barriers, floor drains, and sterilizers shall be decontaminated by heat treatment before being released into the sanitary system. If required by design, regulation, local ordinance or policy, liquid wastes from shower rooms and toilets shall be decontaminated with chemical disinfectants or heat by methods demonstrated to be effective. The procedure used for heat decontamination of liquid wastes shall be monitored with a recording thermometer. The effectiveness of the heat decontamination process system shall be revalidated at minimum on a yearly basis with an indicator organism. More frequent validation, based on the amount of use or other safety factors, shall be left to the discretion of the IBC. If required by design, regulation, local ordinance or policy, liquid wastes from the shower shall be chemically decontaminated using an Environmental Protection Agency-approved germicide. The efficacy of the chemical treatment process shall be validated with an indicator organism. Chemical disinfectants shall be neutralized or diluted before release into general effluent waste systems.

Dated: April 9, 2016.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

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BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; 60-Day Comment Request; NLM PEOPLE LOCATOR® System

Summary: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Library of Medicine (NLM), National Institutes of Health (NIH), will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Ways to enhance the quality, utility, and clarity of the information to be collected; and (4) Ways to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

To Submit Comments and For Further Information: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact: David Sharlip, NLM Project Clearance Liaison, Office of Administrative and Management Analysis Services, OAMAS, NLM, NIH, Building 38A, Room B2N12, 8600 Rockville Pike, Bethesda, MD 20894, or call non-toll-free number (301) 496–5441, or Email your request, including your address to: *sharlipd@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Proposed Collection: NLM People Locator System 0925–0612, Expiration Date: 07/31/2016, EXTENSION, National Library of Medicine (NLM), National Institutes of Health (NIH).

Need and Use of Information Collection: This collection of data is intended to assist in the reunification of family members and friends who are separated during a disaster. Experience in operational drills and during real-world disasters such as the January 2010 earthquakes in Haiti demonstrates that family members and loved ones are often separated during disasters and have significant difficulty determining each other's safety, condition, and location. Reunification can not only improve their emotional well-being during the recovery period, but also improve the chances that injured victims will be cared for once they are