



DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER DETACHMENT

LIMA, PERU
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IN REPLY REFER TO

NMRCINST 5100.1C
07 Feb 2003

NMRCD INSTRUCTION 5100.1C

From: Officer-in-Charge, U.S. Naval Medical Research Center
Detachment Lima, Peru

Subj: NMRCD OCCUPATIONAL HEALTH AND BIOSAFETY PROGRAM

Ref: (a) OPNAVINST 5100.23 Series
(b) 29 CFR 1910.1030 of 6 December 1991 entitled
"Bloodborne Pathogens"
(c) HHS Publication No. (CDC) 93-8395, 4TH Edition, May
1999
(d) BUMEDINST 6230.15
(e) BUMEDNOTE 6230 dated 20 Apr 98
(f) NMRIINST 5100.4 Series
(g) NMRIINST 5100.7 Series
(h) NMRIINST 6230.0
(i) NMRIINST 6231.0

Encl: (1) Laboratory Biosafety Level Criteria - Biosafety level 2
(2) Laboratory Biosafety Level Criteria - Biosafety level 3
(3) Vertebrate Animal Biosafety Level Criteria - Animal
Biosafety Level 2
(4) Vertebrate Animal Biosafety Level Criteria - Animal
Biosafety Level 3
(5) Universal Precautions
(6) Pre-Employment Physical Examination
(7) Exposure Control Plan: Exposure Determination
(8) Medical Surveillance Form
(9) NMRCD Employee Biosafety Training, Physical Exam,
Serology, and Blood Banking Documentation form

1. Purpose. To establish an occupational health and biosafety program for the protection of personnel and the environment from biological and chemical hazards associated with the NMRCD laboratories and research programs.

2. Cancellation. NAMRIDINST 5100.1B and 5100.4.

3. Applicability. This regulation applies to all departments and all investigators conducting biological research, working in or using the laboratory or animal facilities and resources of NMRCD Lima and Iquitos Peru.

4. Background. NMRCD personnel work with certain relatively infectious and potentially harmful biological agents. This instruction sets the standards of safety for those working with dangerous biological agents, describes the medical surveillance program for infectious agents, sets minimum training standards, and is a source of information for personnel working in laboratories which use these agents. The information herein is required reading for all personnel who have access to any of NMRCD's research laboratories or animal facilities.

5. Responsibilities.

a. The Officer-in-Charge:

(1) Insures that all departments conform to the standards and guidelines defined in this instruction and its references.

(2) Appoints a Chairman of the Occupational Health and Biosafety Program, and approves or disapproves his/her recommendations.

(3) Appoints a military physician to act as the Command Medical Officer to implement all medical components of this occupational health and safety instruction.

(4) Insures the coordination of the Occupational Health and Biosafety Program with other command medical activities and safety programs as deemed appropriate.

(5) Notify NMRC and local officials of any accident, which results in contamination of the environment or the loss of life or hospitalization of personnel.

b. Department Heads:

(1) Ensure that all personnel, including visiting scientists/technicians and students, read and comply with standards and guidelines defined in this instruction.

(2) Provide training for department personnel as defined in this regulation.

(3) Ensure that all laboratory accidents are reported to the Occupational Health and Biosafety Chairman, Command Medical Officer, and Command Safety Officer.

(4) Provide the Command Safety Officer with a list of all infectious agents in use within the department's laboratory spaces.

(5) Ensure the shipment of any biological specimens is in accordance with reference (c).

(6) Notify the Officer-in-Charge through the Command Safety Officer of any plan to begin work with new infectious agents.

c. Command Safety Officer:

(1) Conducts periodic inspections (at least once quarterly) of all laboratory spaces to ensure compliance with this instruction, and identify any potential biosafety hazards.

(2) Advises Officer-in-Charge, Command Medical Officer, and all department heads on matters pertaining to occupational health and biosafety.

(3) Provides Annual Command-wide training as required by this instruction.

(4) Reviews yearly all research and technology work units to insure existing facilities and equipment are adequate to safely conduct the proposed research.

(5) Classifies the Biosafety Level, as defined in reference (c), of all the laboratory spaces based on input from department heads.

d. Command Medical Officer

(1) Assists the Occupational Health and Biosafety Chairman in ensuring the Command's compliance with all medical aspects of this instruction.

(2) Medically evaluates, requests tests, and treats all American personnel involved in laboratory accidents. Coordinates medical evaluation, testing and treatment of all non-American personnel involved in laboratory accidents. Maintains files of such evaluations.

(3) Assists the Occupational Health and Biosafety Chairman in providing Command-wide training as required by this instruction.

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(4) Assesses the need for physicals and vaccinations of laboratory workers, and interface with U.S. Embassy medical unit to facilitate immunizations of eligible personnel. Interfaces with host national medical system to facilitate physicals and immunizations of other personnel.

(5) Establishes an Exposure Control Plan as defined in reference (a).

e. All personnel working in the NMRCD laboratory spaces must read and comply at all times with this instruction.

6. Procedures.

a. Work Practices:

(1) At a minimum, Biosafety level 2 standards and special practices, containment equipment, and facilities, as described in reference (b) shall be used for all activities involving any clinical specimens, body fluids, and tissues from humans or from infected or inoculated laboratory animals. These standards and practices are reproduced in enclosure (1).

(2) Activities such as producing research laboratory scale amounts of HIV, manipulating concentrated virus preparations, and conducting procedures that may produce aerosols or droplets shall be performed in a BSL-2 facility with the additional practices and containment equipment recommended for Biosafety Level 3. The BSL 3 standards are reproduced as enclosure (2).

(3) Any animal experiments must be conducted under the same BSL criteria as the infecting agent. As a minimum, BSL-2 guidelines will be followed. The BSL 2 standards are reproduced as enclosure (3).

(4) Universal blood and body fluid precautions, also known as "Universal Precautions" shall be used for **ALL** specimens from **ALL** patients. These precautions are reproduced in enclosure (4).

(5) Laboratory coats shall be worn at all times while working in the laboratory. If coats are to be worn outside of the work area, a separate "clean" coat should be worn. Under no circumstances should a "dirty" coat be worn outside of the working spaces, since part of the intent of the coat is to keep infectious organisms within the confines of the laboratory. In addition, the sleeves of the lab coat should be long enough to completely cover

the sleeves of the laboratory worker's clothing. If not, the sleeves of the clothing beneath should be rolled up so that they can be covered. Long-sleeve coats are to be used as a "dirty" coat. Lab coats are to be laundered regularly.

(6) Contact lenses, especially the soft ones, will absorb certain solvents and also constitute a hazard during splashes or spills. They offer no protection and may trap caustic material against the cornea prevent tears from washing a caustic substance away. You are advised not to wear contact lenses in the laboratory. **(When contact lenses are the only prescription eyewear available, safety goggles are to be worn at ALL times within the laboratory. Contact lenses will not be inserted, removed or physically handled at any time in the laboratory. The use of safety goggles is mandatory within the laboratory until another form of prescription eyewear can be obtained)**

(7) Shoes with open toes and/or high heels are not permitted in the laboratory or animal containment areas.

(8) Expel excess air, liquid and bubbles from a syringe vertically into a cotton pledget moistened with a proper disinfectant, or into a small bottle of sterile cotton. Do not use the syringe to expel forcefully a stream of infectious fluid into an open vial or tube for the purpose of mixing. In instances where the protective needle sheath must be replaced following the use of a syringe, forceps should always be used to minimize the possibility of exposure via accidental inoculation. Do not discard syringes and needles into pans containing pipettes or other glassware that must be sorted out from the syringe and needles. Needles should be discarded in a proper sharps container.

(9) Use only Pyrex type glass or ampoules designed specifically for freeze-drying. Insure that the lyophilizer is properly disinfected after each use. When possible, perform the procedure within a Biosafety Cabinet. A considerable hazard exists when opening freeze-dried specimens containing biohazardous materials. Opening should be done within a biosafety cabinet. The ampoule should first be well scored then wrapped in disinfectant wetted gauze and then carefully broken at the score.

(10) If breakage occurs of a tube containing biohazardous material during centrifugation and is evidenced by an imbalance being noticed in the operation of the centrifuge, shut the rotor motor off, let the unit set for about 30 minutes, add disinfectant

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to the carrier containing the broken tube. If the tube, which broke, was contained in a removable rotor, remove it to a Biological Safety Cabinet and perform these same procedures. Put gloves on before handling any broken tubes and use forceps where possible.

(11) Operate blending and cell disruption and grinding equipment in a Biological Safety Cabinet.

(12) Wear protective clothing to cover exposed body parts and a face shield or eye goggles to protect against splashing when handling liquid nitrogen.

(13) Miscellaneous precautions and recommendations.

(a) Water baths used to inactivate, incubate, or test infectious substances should contain a disinfectant. Sodium azide should not be used as it creates a serious explosion hazard. Caustic disinfectants, which harm the baths, are also not to be used.

(b) Deepfreeze, liquid nitrogen, and dry ice chests and refrigerators should be checked and cleaned out periodically to remove any broken ampoules or tubes, and then decontaminated. Use rubber gloves and respiratory protection during cleaning. All materials in refrigerators or ultra-low freezers should be properly labeled. The degree of hazard represented by contaminated liquid nitrogen reservoirs will be largely dependent upon the infectious potential of the stored organisms, their stability in liquid N₂, and their ability to survive in the airborne state.

(c) Ensure that all hazardous fluid cultures or viable powdered infectious materials in glass vessels are transported, incubated, and stored in easily handled, non-breakable, leak proof containers that are large enough to contain the contents of the primary container in case of leakage or breakage of the glass vessel.

(d) All inoculated petri plates or other inoculated solid media should be transported and incubated in leak proof pans or leak proof containers.

(e) Vacuum pumps or lines should be double trapped to prevent the contamination of the vacuum lines. Also a suitable filter should be placed within the lines to prevent aerosols from entering the lines and being dispersed at the pump.

(f) Shaking machines should be examined carefully for their potential to cause breakage of flasks or other containers being shaken. Screw-capped durable plastic or heavy walled flasks should be used. These should be securely fastened to the shaker platform.

(g) Exits and aisles must not be obstructed or blocked in any way. Doors to the laboratory should be kept closed to minimize aerosol contamination into and out of the laboratory.

(h) Decontaminate all glassware exposed to potentially infectious materials. Dispose of broken or discarded glassware in separate containers (broken glass along with paper and trash is a hazard to the custodial staff).

(14) Face shields should be used in areas where impacts and splashes may occur. Eye protection commensurate with the hazard should be worn when performing potentially hazardous tasks. The laboratory supervisor or the principal investigator should determine what protection is called for in specific tasks.

(15) Standards for Insectary Safety.

(a) Access to insectary: The exterior door and screened doors will not be opened at the same time.

(b) Disposal of unneeded eggs, larvae and pupae will be done only after these are made nonviable by treatment with hot water or chemicals.

(c) Infected or exotic mosquitoes must be double caged and numerically accounted for. "Loose" mosquitoes will be caught or killed immediately.

7. Medical Surveillance Program.

a. Blood Tests. Prior to commencing work, all personnel with access to the medical research laboratories shall have blood drawn for the following purposes:

(1) Serology, to assess resistance to hepatitis B and to determine whether immunization against hepatitis B is indicated. Normally, assays for anti-HBs, will be performed before vaccination and within 1-2 months following completion of the series.

(2) A serum sample for the NMRCD serum bank, to be frozen for possible future reference use. Should it be thought that a person might have an occupationally acquired infection, this sample would be used to determine baseline antibody titers to the agent.

(3) Complete Blood Count, to screen for immune deficiency by looking for neutropenia, leukemia or other abnormalities in the white and red cell counts. Such patients would receive further testing to for evaluate immune deficiency before being allowed to work with infectious pathogens.

(4) HIV antibody screen for personnel working with live HIV, to document status at the beginning of employment. Being HIV positive is not necessarily disqualifying for employment. For their own safety, immunodeficient persons will not be employed in tasks that involve working with other dangerous pathogens.

(5) Post Immunization Serology. After completing the course of Hepatitis B immunization, an anti-HBs screen will be drawn to verify the effectiveness of the vaccination series. If protective antibody levels are still not detected, a second series of the vaccine will be given and an anti-HBs screen conducted. If the concentration is still inadequate (less than 10 mIU/ML), note will be made in the individual Occupational Health Record and the individual considered non-immune.

b. Physical Examination. All new employees should have a complete physical exam prior to commencing work. The doctor of the patient's choice or a NMRCD physician licensed in Peru may do this exam. It should be kept on file with the Occupational Health Officer. The purpose is to identify any conditions, which might make work with infectious pathogens especially hazardous to the individual, and also to document the state of the person's health at commencement of employment for medico-legal reasons. The examining physician will complete enclosure (5) during the pre-employment physical examination.

8. IMMUNIZATION PROGRAM.

a. Certain infectious agents can be made less hazardous to the individual by immunization. For military personnel and civilian DOD employees, including foreign nationals, immunization requirements are set by references (d) and (e). These instructions require that federal civilian employees of the armed forces who are at risk of exposure to an infectious disease associated with their occupation should be immunized with an appropriate vaccine, upon

the recommendations of the responsible preventive medicine authority. These immunizations will be administered without charge to the employee.

b. Employees in Health Care Facilities. Susceptible and/or occupationally exposed health care employees, including volunteers who have direct contact with patients, or work at field research sites, will be provided appropriate vaccines against measles, mumps, and rubella, unless a current vaccination or a protective titer is documented. For contract personnel, such immunizations will be provided if agreed upon and so stated in the contract agreements. This policy will be instituted in all health care settings, regardless of age or sex of health care provider. Employees, including volunteers who have contact with or potential exposure to human blood or blood products, whether in patient care, laboratory, or health care settings, will be provided hepatitis B virus (HBV) vaccine also. Other immunizations based on occupational risk of exposure in the hospital or clinic setting may also be provided.

c. Employees at risk of exposure to rabid animals or rabies virus. Employees such as laboratory or field personnel whose duties involve transporting, handling, or disposal of potentially rabid animals, will receive pre-exposure human diploid cell vaccine (HDCV) prophylaxis and appropriate boosters following current ACIP recommendations or the manufacturer's package insert.

d. Based on the above instructions, the following immunization policies are in effect at NMRCD:

(1) Hepatitis B Virus Vaccine. This vaccine is recommended for personnel having direct contact with blood or blood products. This includes all laboratory personnel, nurses, physicians, corpsmen, and janitors. Receipt of the vaccine is voluntary for civilians; however, persons refusing the vaccine may be prohibited from working in a laboratory where this virus is present. The vaccine will not be given to those with anti-HBs or to HBV carriers. Within 1-2 months after completion of the series, recipients will have anti HBs testing to document immunity, and will be reimmunized if negative.

(2) Rabies Vaccine (Human Diploid Cell Vaccine) will be required of all veterinary staff animal handlers, and all personnel participating in field trips. The prevalence of rabies, and the

remoteness from medical care justify this requirement. Persons who do not receive the vaccine may be Prohibited from participating in field trips by the Officer-in-Charge.

(3) Tetanus/diphtheria. Initial vaccination and appropriate boosters are required for all personnel.

(4) Typhoid. Required for personnel who travel frequently to higher risk areas. Required for all American military personnel and assigned investigators from whom residency in Peru represents increased risk.

(5) Polio vaccine. Initial series and booster required for personnel who travel to higher risk areas. Required for all American military personnel and assigned investigators for whom residency in Peru represents increased risk.

(6) Measles, mumps, and rubella vaccines. Required for personnel who travel frequently to higher risk areas. Required for all American military personnel and assigned investigators for whom residency in Peru represents increased risk.

(7) Influenza Vaccine. Influenza vaccine is available in both northern and southern hemisphere formulations. Personnel who travel frequently should receive the appropriate influenza immunizations for the hemisphere(s) in which they travel. As influenza can be quite deadly to indigenous jungle people who have no corresponding natural immunity, all personnel who travel to jungle regions must be vaccinated annually.

e. The schedule for immunizations is as follows:

(1) HBV: 0, 30, and 180 days. An accelerated schedule of 0, 30, 60 days may be used if necessary (Engerix B only) with a booster dose at 12 months. For personnel at risk of occupational exposure from sharp injuries (e.g. medical personnel, laboratory technicians, phlebotomists and janitors) and certain immunocompromised personnel, test for anti-HBs 1-2 months after the third dose. Revaccinate non-responders with a three dose series and retest anti-HBs for the record only. Indicate ultimate responder status in individual occupational health files.

(2) Rabies HDCV: 0, 7, 21-28 days. Test for antibody in accordance with current ACIP of NMRC guidelines.

(3) Tetanus/diphtheria: Every 10 years after the primary series is complete (give booster if dirty wound and last booster >5 years ago).

(4) Typhoid: A single dose injectable Typhim Vi (Aventis Pasteur) every two years for American military personnel and employees. A single dose of Peruvian-approved typhoid vaccine every two years for FSN's whose duties place them at increased risk of exposure.

(5) Polio: Primary series, plus 1 dose as an adult.

(6) Measles, Mumps, Rubella: one dose or documented immunity.

(7) Influenza: one dose of northern and/or southern hemisphere formulations each year.

(8) The Command Medical Officer will prepare letters routed through the Officer-in-Charge directing personnel to report for needed interviews, serology or immunizations.

f. Procedures in the Event of Exposure.

(1) If an accident occurs while handling a biological agent, you should follow several simple but important steps.

(2) First, if there was a spill, attempt to contain the spill with absorbent material. Remove outer lab clothing if it was contaminated and leave it in the contaminated area.

(a) Turn off hazardous equipment such as centrifuges and bunsen burners. Turn on germicidal lamps in the area if there are any.

(b) Warn fellow laboratory workers that an accident has occurred and ask them to leave the area. After insuring there is no danger of fire, leave the area yourself.

(c) Notify department heads that an accident has occurred and what agents were involved in the accident. Insure that no one enters the laboratory area until the supervisory

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personnel determine it is safe to do so. If clothing other than your lab-wear was contaminated, remove the clothing and take a shower. Someone will bring you clothing from General Services. Do not take contaminated clothing out of area.

(d) Report to the Command Medical Officer and complete Enclosure (6). Medical personnel will decide appropriate treatment and follow-up procedures depending upon the infectious agent.

(e) After the area is determined to be cleared, supervisory personnel will decide the best method for decontamination and then proceed. All personnel involved in the decontaminating procedure shall wear PPE clothing. Once the area has been cleared, the PPE clothing and all contaminated articles from the accident area shall be suitably decontaminated by physical or chemical means, following procedure guidelines for the agent involved.

(f) Any person exposed to the accident involving biological agent(s) should have blood drawn for later use in assessing those who may have been infected.

g. Training: All new employees must receive training in biosafety by their Department Head before beginning work with infectious agents. The training must be documented (enclosure 7) and must include satisfactory completion of an oral or written examination based on reference (a). This training should be updated every 6 months with an oral examination and laboratory observation. The two parts of the training are:

(1) Laboratory-Wide Biosafety Training

(a) Review of the components of the standard on blood borne pathogens, 29 CFR 1910.1030, and an explanation of its contents.

(b) The epidemiology and symptoms of bloodborne diseases.

(c) Explanation of how blood-borne pathogens are transmitted.

(d) Explanation of the NMRCD exposure control plan and its availability to employees.

(e) Review of how to recognize tasks that may involve exposure to blood and other infectious materials.

(f) Information on hepatitis B vaccine, including benefits, efficacy, safety, administration, and that it is free of charge.

(g) Explanation of what to do if an emergency involving exposure to blood or infectious agents occurs, and who to contact.

(h) Explanation of procedures to follow in the event of an exposure, how to report it, and the medical follow-up that will be provided.

(i) The employer's responsibilities after an exposure incident.

(j) Review of the signs and color-coding required for work areas and containers.

(2) Biosafety Training by Division Heads

(a) Explanation of the usage and limits of methods to prevent or reduce exposure to infectious materials.

(b) Review of the location, use, kinds, handling, decontamination, and disposal of personal protective equipment.

(c) Selection of the proper personal protective equipment.

(d) Procedures to be followed if the employee becomes pregnant.

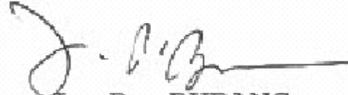
(e) Review of the potential hazards involved in handling the infectious materials under study in the employee's division.

(f) Explanation of the need for periodic review of work practices for biosafety and for periodic refresher training sessions to be documented on the training documentation form.

(g) Opportunity for questions and comments during the training.

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(h) Discussion of errors or safety problems
encountered during the preceding 6 months.



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LABORATORY BIOSAFETY LEVEL 2 (BSL-2) CRITERIA

1. A biosafety level 2 Laboratory is suitable for work involving agents of moderate hazard to personnel and the environment. Laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists. Access to the laboratory is limited when work is being conducted. Extreme precautions are taken with contaminated sharp items. Certain procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

a. Standard Microbiological Practices:

(1) Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress.

(2) Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.

(3) Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the work areas. Food is stored outside the work area in cabinets or refrigerators designated for this purpose only.

(4) Mouth pipetting is prohibited; mechanical pipetting devices are used.

(5) Policies for the safe handling of sharps are instituted.

(6) All procedures are performed carefully to minimize the creation of splashes or aerosols.

(7) Work surfaces are decontaminated on completion of work or at the end of the day and after any spill or splash of viable material with disinfectants that are effective against agents of concern.

(8) All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination

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method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are placed in a durable, leak proof container and closed for transport from the laboratory.

(9) An insect and rodent control program is in effect.

b. Special Practices:

(1) Access to the laboratory is limited or restricted by the laboratory director when work with infectious agents is in progress. In general, persons who are at increased risk of acquiring infection, or for whom infection may have serious consequences, are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.

(2) The laboratory director establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet specific entry requirements (e.g. immunization) may enter the laboratory.

(3) A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Appropriate information to be posted includes the agent(s) in use, the biosafety level, the required immunizations, the investigator's name and telephone number, any personal protective equipment that must be worn in the laboratory, and any procedures required for exiting the laboratory.

(4) Laboratory personnel receive appropriate immunizations or tests for agents handled or potentially present in the laboratory (e.g. hepatitis B vaccine or TB skin testing).

(5) When appropriate, considering the agent(s) handled, baseline serum samples for laboratory and other at-risk personnel are collected and stored. Additional serum specimens may be collected periodically, depending on the agents handled or the function of the facility.

(6) Biosafety procedures are incorporated into standard

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operating procedures or in a biosafety manual adopted or prepared specifically for the laboratory by the laboratory director. Personnel are advised of special hazards and required to read and follow instructions on practices and procedures.

(7) The laboratory director ensures that the laboratory and the support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural or policy changes.

(8) A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

(a) Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no other alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic ware should be substituted for glassware whenever possible.

(b) Only needle-locking syringes or disposable syringe-needle units (i.e. needles integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard-walled container for transport to a processing area for decontamination, preferably by autoclaving.

(c) Syringes which re-sheathe the needle, needleless systems, and other safety devices are used when appropriate.

(d) Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated before disposal, according to any local government or federal regulations.

(9) Cultures, tissues, specimens of bodily fluids, or

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potentially infectious wastes are placed in a container with a cover that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(10) Laboratory equipment and work surfaces should be decontaminated with an effective disinfectant on a routine basis, after work with infectious materials is finished, and especially after overt spills, splashes, or other contamination by infectious materials. Contaminated equipment must be decontaminated according to any local or federal regulations before it is sent for repair or maintenance or packaged for transport in accordance with applicable local or federal regulations, before removal from the facility.

(11) Spills and accidents that result in overt exposure to infectious materials are immediately reported to the laboratory director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

(12) Animals not involved in the work being performed are not permitted in the laboratory.

c. Safety Equipment (Primary Barriers)

(1) Properly maintained biological safety cabinets, preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:

(a) Procedures with a potential for creating infectious aerosols or splashes are conducted. These may not include centrifuging, grinding, blending, vigorous shaking or mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or embryonate eggs.

(b) High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open if sealed rotor heads or centrifuge safety clips are used, and if these rotors or safety cups are opened only in a biological safety cabinet.

(2) Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of

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infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.

(3) Protective laboratory coats, gowns, smocks, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g. cafeteria, library, and administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; it should never be taken home by personnel.

(4) Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Wearing two pairs of gloves may be appropriate. Gloves are disposed of when overtly contaminated, and removed when work with infectious materials is completed or when the integrity of the glove is compromised. Disposable gloves are not washed, reused or used for touching "clean" surfaces (keyboards, telephones, etc.), and they should not be worn outside the lab. Alternatives to powdered latex gloves should be available. Hands are washed following the removal of gloves.

d. Laboratory Facilities (Secondary Barriers)

(1) Provide lockable doors for facilities that house restricted agents.

(2) Consider locating new laboratories away from public areas.

(3) Each laboratory contains a sink for hand washing. Foot, knee, or automatically operated sinks are recommended.

(4) The laboratory is designed so that it can be easily cleaned. Carpets and rugs in laboratories are inappropriate.

(5) Bench tops are impervious to water and resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment.

(6) Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other

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furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

(7) Install biological safety cabinets in such a manner that fluctuations of the room supply and exhaust air do not cause biological safety cabinets to operate outside their parameters for containment. Locate biological safety cabinets away from doors, from windows that can be opened, from heavily traveled areas, and from other potentially disruptive equipment so as to maintain the biological safety cabinets air flow parameters of containment.

(8) An eyewash station is readily available.

(9) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

(10) There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without circulation to spaces outside of the laboratory if the laboratory has windows that open to the exterior, they are fitted with fly screens.

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LABORATORY BIOSAFETY LEVEL 3 (BSL-3) CRITERIA

1. Biosafety Level 3 is applicable to clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents, which may cause serious or potentially lethal disease as a result of exposure by the inhalation route. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents, and are supervised by competent scientists who are experienced in working with these agents.

2. All procedures involving the manipulation of infectious materials are conducted within biological safety cabinets or other physical containment devices, or by personnel wearing appropriate personal protective clothing and equipment. The laboratory has special engineering and design features.

3. It is recognized however, that some existing facilities may not have all the facility features recommended for Biosafety Level 3 (i.e. double-door access zone and sealed penetrations). In these circumstances, an acceptable level of safety for the conduct of routine procedures (e.g. diagnostic procedures involving the propagation of an agent for identification, typing, susceptibility testing, etc.) may be achieved in a Biosafety Level 2 facility providing 1) the exhaust air from the laboratory room is discharged to the outdoors, 2) the ventilation to the laboratory is balanced to provide directional airflow into the room, 3) access to the laboratory is restricted when work is in progress, and 4) the recommended Standard Microbiological Practices, Special Practices, and Safety Equipment for Biosafety Level 3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the laboratory director.

a. Standard Microbiological Practices

(1) Access to the laboratory is limited or restricted at the discretion of the laboratory department head when experiments are in progress.

(2) Persons must wash their hands after handling infectious materials, after removing gloves, and when they leave the laboratory.

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(3) Eating, drinking, smoking, handling contact lenses, and applying cosmetics are not permitted in the laboratory. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food may only be stored outside the work area in cabinets or refrigerators designated for this purpose only.

(4) Mouth pipetting is prohibited; mechanical pipetting devices must be used.

(5) Policies for safe handling of sharps are instituted.

(6) All procedures are performed carefully to minimize the creation of aerosols.

(7) Work surfaces are decontaminated at least once a day and after any spill of viable material.

(8) All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method, such as autoclaving. Materials to be decontaminated outside the immediate laboratory are placed in a durable, leak proof container and closed for transport from the laboratory. Infectious waste from the BSL-3 laboratory should be decontaminated before removal for off-site disposal.

(9) An insect and rodent control program is in effect.

b. Special Practices

(1) Laboratory doors are kept closed when experiments are in progress.

(2) The laboratory department head controls access to the laboratory and restricts access to persons whose presence is required for program or support purposes. Persons who are at increased risk of acquiring infection or for whom infection may have serious consequences are not allowed in the laboratory or animal rooms. For example, persons who are immunocompromised or immunosuppressed may be at increased risk of acquiring infections. The laboratory department head has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory. No minors should be allowed in the laboratory.

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(3) The laboratory department head establishes policies and procedures whereby only persons who have been advised of the potential biohazard, who meet specific entry requirements (e.g. immunization), and who comply with all entry and exit procedures, enter the laboratory or animal rooms.

(4) When infectious materials or infected animals are present in the laboratory or containment module, a hazard warning sign incorporating the universal biohazard symbol, is posted on all laboratory and animal room access doors. The hazard warning sign identifies the agent, lists the name and telephone of the laboratory department head or other responsible person(s), and indicates any special requirements for entering the laboratory, such as the need for immunizations, respirators, or other personal protective measures.

(5) Laboratory personnel receive the appropriate immunizations or tests for the agents handled or potentially present in the laboratory (e.g., hepatitis B, or TB skin testing), and periodic testing as recommended for the agent being handled.

(6) Baseline serum samples are collected as appropriate and stored for all laboratory and other at-risk personnel. Additional serum specimens may be periodically collected, depending on the agents handled or the function of the laboratory.

(7) A biosafety manual specific to the laboratory is prepared or adopted by the laboratory department head and biosafety precautions are incorporated into the standard operating procedures. Personnel are advised of special hazards and are required to read and follow instructions on practices and procedures.

(8) Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural changes.

(9) The laboratory department head is responsible for ensuring that before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques and the practices and operations

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specific to the laboratory facility. This proficiency might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the laboratory department head or other competent scientist proficient in safe microbiological practices and techniques.

(10) A high degree of precaution must always be taken with any contaminated sharp items, including needles and syringes, slides, pipettes, capillary tubes, and scalpels.

(a) Needles and syringes or other sharp instruments should be restricted in the laboratory for use only when there is no other alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plastic-ware should be substituted for glassware whenever possible.

(b) Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for injection or aspiration of infectious materials. Used disposable needles must not be bent, sheared, broken, recapped, removed from disposable syringes, or otherwise manipulated by hand before disposal; rather, they must be carefully placed in conveniently located puncture-resistant containers used for sharps disposal. Non-disposable sharps must be placed in a hard walled container for transport to a processing area for decontamination, preferably by autoclaving.

(c) Syringes which re-sheathe the needle, needleless systems, and other safe devices are used when appropriate.

(d) Broken glassware must not be handled directly by hand, but must be removed by mechanical means such as a brush and dustpan, tongs, or forceps. Containers of contaminated needles, sharp equipment, and broken glass should be decontaminated before disposal, and disposed of according to any local or federal regulations.

(11) All open manipulations involving infectious materials are conducted in biological safety cabinets or other physical containment devices within the containment module. No work in open vessels is conducted on the open bench. Clean up is facilitated by using plastic-backed paper towelling on non-perforated work surfaces within biological safety cabinets.

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(12) Laboratory equipment and work surfaces should be decontaminated routinely with an efficient disinfectant after work with infectious materials is finished and especially after overt spills, splashes, or other contamination with infectious materials.

(a) Spills of infectious materials are decontaminated, contained and cleaned up by appropriate professional staff, or others properly trained and equipped to work with concentrated infectious material. Spill procedures are developed and posted.

(b) Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local or federal regulations.

(13) Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.

(14) All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from laboratories are decontaminated before disposal or reuse.

(15) Spills and accidents that result in overt or potential exposures to infectious materials are immediately reported to the laboratory department head. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

(16) Animal and plants not related to the work being conducted are not permitted in the laboratory.

c. Safety Equipment (Primary Barriers)

(1) Protective laboratory clothing, such as solid-front or wrap-around gowns, scrub suits, or coveralls are worn by workers when in the laboratory. Protective clothing is not worn outside the laboratory. Reusable clothing is decontaminated before being laundered. Clothing is changed when overtly contaminated.

(2) Gloves must be worn when handling infectious materials, infected animals, and when handling contaminated equipment.

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(3) Frequent changing of gloves accompanied by hand washing is recommended. Disposable gloves are not reused.

(4) All manipulations of infectious materials, necropsy of infected animals, harvesting of tissues or fluids from infected animals or embryonated eggs, etc., are conducted in a Class II or Class III biological safety cabinet.

(5) When a procedure or process cannot be conducted within a biological safety cabinet, then appropriate combinations of personal protective equipment (e.g., respirators, face shields) and physical containment devices (e.g., centrifuge safety cups or sealed rotors) are used.

(6) Respiratory and face protection are used when in rooms containing infected animals.

d. Laboratory Facilities (Secondary Barriers)

(1) The laboratory is separated from areas that are open to unrestricted traffic flow within the building, and access to the laboratory is restricted. Passage through a series of two self-closing doors is the basic requirement for entry into the laboratory from access corridors. Doors are lockable. A clothes change room may be included in the passageway.

(2) Each laboratory room contains a sink for hand washing. The sink is hands-free or automatically operated and is located near the room exit door.

(3) The interior surfaces of walls, floors, and ceilings of areas where BSL-3 agents are handled are constructed for easy cleaning and decontamination. Seams, if present, must be sealed. Walls, ceilings, and floors should be smooth, impermeable to liquids and resistant to the chemicals and disinfectants normally used in the laboratory. Floors should be monolithic and slip resistant. Consideration should be given to the use of coved floor coverings. Penetrations in floors, walls, and ceiling surfaces are sealed. Openings such as around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

(4) Bench tops are impervious to water and are resistant to

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moderate heat and the organic solvents, acids, alkalis, and those chemicals used to decontaminate the work surfaces and equipment.

(5) Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Chairs and other furniture used in laboratory work should be covered with a non-fabric material that can be easily decontaminated.

(6) All windows, if any, in the laboratory are closed and sealed.

(7) A method for decontaminating all laboratory wastes is available in the facility and utilized, preferably within the laboratory (i.e., autoclave, chemical disinfection, incineration, or other approved decontamination method). Consideration should be given to means of decontaminating equipment. If waste is transported out of the laboratory, it should be properly sealed and not transported in public corridors.

(8) Biological safety cabinets are required and are located away from doors, from room supply louvers, and from heavy traffic laboratory areas.

(9) A ducted air ventilation system is provided. This system creates directional airflow, which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of the exhaust air are not required, but may be considered based on site requirements, and specific agent manipulations and use conditions. The outside exhaust must be dispersed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Laboratory personnel must verify that the direction of the airflow (into the laboratory) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward airflow be provided at the laboratory entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of the laboratory. Audible alarms should be considered to notify personnel of HVAC system failure.

(10) HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the laboratory if the cabinet is tested and certified at least annually. When exhaust

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air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust and the exhaust duct). When Class III biological safety cabinets are used they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

(11) Continuous flow centrifuges or other equipment that may produce aerosols are contained in devices that exhaust air through HEPA filters before discharge into the laboratory. These HEPA systems are tested at least annually. Alternatively, the exhaust from such equipment may be vented to the outside if it is dispersed away from occupied areas and air intakes.

(12) Vacuum lines are protected with liquid disinfectant traps and HEPA filters, or their equivalent. Filters must be replaced as needed. An alternative is to use portable vacuum pumps (also properly protected with traps and filters).

(13) An eyewash station is readily available inside the laboratory.

(14) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

(15) The biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified, at least annually, against these procedures as modified by operational experience.

(16) Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment, the site conditions, or other applicable federal regulations.

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VERTEBRATE ANIMAL BIOSAFETY LEVEL 2 (ABSL-2) CRITERIA

1. Animal Biosafety Level 2 involves practices for work with those agents associated with human diseases. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure. ABSL-2 builds upon the practices, procedures, containment equipment, and facility requirements of ABSL-2.

a. Standard Practices:

(1) Access to animal rooms is limited to the fewest number of individuals possible. Personnel who must enter the rooms for program or service purposes when work is in progress are advised of the potential hazard.

(2) An appropriate surveillance program is in place. All personnel receive appropriate immunizations or tests for the agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate, a serum surveillance system should be implemented.

(3) A biosafety manual is prepared or adopted. Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures.

(4) Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should only be done in designated areas and are not permitted in animal or procedure rooms.

(5) All procedures are carefully performed to minimize the creation of aerosols or splatters.

(6) Equipment and work surfaces in the rooms are routinely decontaminated with effective disinfectant after work with infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

(7) All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of agent(s). All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse) are transported from the animal rooms in leak-proof, covered containers for appropriate

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disposal in compliance with applicable institutional or local requirements. The outer surface of the containers is disinfected prior to moving the material. Autoclaving of contents prior to incineration is recommended.

(8) Policies for the safe handling of sharps are instituted:

(a) Needles and syringes or other sharp instruments are restricted for use in the animal facility only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

(b) Syringes that re-sheathe the needles, needle-less systems, and other safe devices should be used when appropriate.

(c) Plastic ware should be substituted for glassware whenever possible.

(9) Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

(10) A Biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special requirements (e.g., the need for immunizations and respirators) for entering the animal room.

(11) An insect and rodent control program is in effect.

b. Special Practices:

(1) Animal care laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and the exposure evaluation procedures. Personnel receive annual updates, or additional training as necessary for procedural or policy changes. Records of all training provided are maintained. In general, persons who may be at increased risk of acquiring infection, or for whom infection might be unusually hazardous, are not allowed in the animal facility unless special procedures can eliminate the extra risk.

(2) Only those animals used for experiment(s) are allowed in the room.

(3) All equipment must be appropriately decontaminated prior to removal from the room.

(4) Spills and accidents, which result in overt exposures to infectious materials, must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

c. Safety Equipment (Primary Barriers)

(1) Gowns, uniforms, or laboratory coats are worn while in the animal room. The laboratory coat is removed and left in the animal room. Gowns, uniforms, and laboratory coats are removed before leaving the animal facility. Gloves are worn when handling infected animals and when skin contact with infectious materials is unavoidable.

(2) Personal protective equipment is used based on the risk assessment determinations. All personnel entering animal rooms that house nonhuman primates wear appropriate face/eye and respiratory protection.

(3) Biological safety cabinets, other physical containment devices, and/or personal protective equipment (e.g., respirators, face shields) are used whenever conducting procedures with a high potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals.

(4) When needed, animals are housed in primary biosafety containment equipment appropriate for the animal species. Filter top cages are always handled in properly designed and operating animal biological containment cabinets recommended for rodents.

d. Facilities (Secondary Barriers)

(1) The animal facility is separated from areas that are open to unrestricted personnel traffic within the building.

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(2) External doors are self-closing and self locking. Doors to animal rooms open inward, are self-closing, and are kept closed when experimental animals are present. Cubicle room interior doors may open outward or be horizontal or vertical sliding.

(3) The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces (walls, floors, and ceilings) are water resistant.

(4) Internal facility appurtenances, such as light fixtures, air ducts, and utility pipes, are arranged to minimize horizontal surface areas.

(5) Windows must be resistant to breakage and should be sealed.

(6) Floor drain traps should always be filled with an appropriate disinfectant.

(7) Exhaust air is discharged to the outside without being recirculated to other rooms. Ventilation should be provided in accordance with criteria from "*Guide for Care and Use of Laboratory Animals*" latest edition. The direction of airflow in the animal facility is inward; animal rooms should maintain negative pressure compared to adjoining hallways.

(8) Cages are washed manually or in an appropriate cage washer. The mechanical cage washer should have a final rinse temperature of at least 180 degrees F.

(9) An autoclave is available in the animal facility to decontaminate infectious waste.

(10) A hand-washing sink is in the animal room where infected animals are housed, as well as elsewhere in the facility.

(11) Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

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VERTEBRATE ANIMAL BIOSAFETY LEVEL 3 (ABSL-3) CRITERIA

1. Animal Biosafety Level 3 involves practices suitable for work with animals infected with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious or potentially lethal disease. ABSL-3 builds upon the standard practices, procedures, containment equipment, and facility requirements of ABSL-2.

2. Standard Practices:

a. Access to the animal rooms is limited to the fewest number of individuals possible. Personnel who must enter the rooms for program or service purposes when work is in progress are advised of the potential hazard(s).

b. An appropriate surveillance program is in place. All personnel receive appropriate immunizations or tests for agents handled or potentially present (e.g., hepatitis B vaccine, TB skin testing). When appropriate a serum surveillance system should be implemented.

c. Persons who maybe at increased risk of acquiring infection, or for whom infection might have serious consequences, are not allowed in the animal facility unless special procedures can eliminate the extra risk. This assessment should be made by the occupational health physician.

d. A biosafety manual is prepared and adopted. Personnel are advised of special hazards, and are required to read and follow instructions on practices and procedures.

e. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human use should be done in designated areas and are not permitted in animal or procedure rooms.

f. All procedures are carefully performed to minimize the creation of aerosols or splatters.

g. Equipment and work surfaces in the room are routinely decontaminated with an effective disinfectant after work with

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infectious agent, and especially after overt spills, splashes, or other contamination by infectious materials.

h. All wastes from the animal room (including animal tissues, carcasses, contaminated bedding, unused feed, sharps, and other refuse animal tissues) are transported from the animal room in leak-proof, covered containers for appropriate disposal in compliance with applicable institutional or local requirements. Incineration is recommended. The outer surface of the containers is disinfected prior to moving the material (see Special practices #3c below).

i. Policies for safe handling of sharps are instituted.

(1) Needles and syringes or other sharp instruments are restricted in the animal facility for use only when there is no alternative, such as for parenteral injection, blood collection, or aspiration of fluids from laboratory animals and diaphragm bottles.

(2) Syringes that re-sheathe the needle, needle-less systems, and other safe devices should be used when appropriate.

(3) Plasticware should be substituted for glassware whenever possible.

j. Personnel wash their hands after handling cultures and animals, after removing gloves, and before leaving the animal facility.

k. A biohazard sign must be posted on the entrance to the animal room whenever infectious agents are present. The hazard warning sign identifies the infectious agent(s) in use, lists the name and telephone number of the responsible person(s), and indicates the special requirements for entering the animal room (e.g., the need for immunizations and respirators).

l. All infectious samples are collected, labeled, transported, and processed in a manner that contains and prevents transmission of agent(s).

m. Laboratory and support personnel receive appropriate training on the potential hazards associated with the work involved, the necessary precautions to prevent exposures, and

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the exposure evaluation procedures. As necessary, personnel receive updates and/or additional training on procedural or policy changes. Records of all training provided are maintained.

n. Insect and rodent control program is in effect.

3. Special Practices.

a. Cages are autoclaved or thoroughly decontaminated before bedding is removed and before they are cleaned and washed. Equipment must be decontaminated according to any local, state, or federal regulations before being packaged for transport or removal from the facility for repair or maintenance.

b. A spill procedure is developed and posted. Only personnel properly trained and equipped to work with infectious materials are to clean up spills. Spills and accidents that result in overt exposure to infectious materials must be immediately reported to the facility director. Medical evaluation, surveillance, and treatment are provided as appropriate and written records are maintained.

c. All wastes from the animal room must be autoclaved prior to incineration or other appropriate terminal treatment.

d. Materials not related to the experiment (e.g., plants, animals) are not permitted in the animal room.

4. Safety Equipment (Primary Barriers)

a. Uniforms or scrub suits are worn by personnel entering the animal room. Wrap-around or solid-front gowns should be worn over this clothing. Front-button laboratory coats are unsuitable. The gown must be removed and left in the animal room. Before leaving the animal facility, scrub suits and uniforms are removed and appropriately contained and decontaminated prior to laundering or disposal.

b. Personal protective equipment used is based on risk assessment determinations.

(1) Personal protective equipment is used for all activities involving manipulations of infectious materials or infected animals.

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(2) Personnel wear gloves when handling infected animals. Gloves are removed aseptically and autoclaved with other animal room wastes before disposal.

(3) Appropriate face/eye and respiratory protection (e.g., respirators and face shields) is worn by all personnel entering animal rooms.

(4) Boots, shoe covers, or other protective footwear, and disinfectant foot baths are available and used where indicated.

c. The risk of infectious aerosols from infected animals or their bedding can also be reduced if animals are housed in containment caging systems, such as open cages placed inward flow ventilated enclosures (e.g., laminar flow cabinets), solid wall and bottom cages covered with filter bonnet, or other equivalent primary containment systems.

d. Biological safety cabinets and other physical containment devices are used whenever conducting procedures with a potential for creating aerosols. These include necropsy of infected animals, harvesting of tissues or fluids from infected animals or eggs, or intranasal inoculation of animals. At BSL-3, all work should be done in a primary barrier; otherwise respirators should be worn by personnel in the room.

5. Facilities (Secondary Barriers)

a. The animal facility is separated from areas that are open to unrestrictive personnel traffic within the building.

b. Access to the facility is limited by a self-locking door. This exterior entry door may be controlled by a key lock, card key, or proximity reader. Entry into the animal room is via a double-door entry which includes a change room and shower(s). An additional double-door access (air-lock) or double-doored autoclave may be provided for movement of supplies and wastes into and out of the facility, respectively. Doors to animal rooms open inward and are self-closing. Doors to cubicles inside an animal room may open outward or slide horizontally or vertically.

c. The animal facility is designed, constructed, and maintained to facilitate cleaning and housekeeping. The interior surfaces

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(walls, floors, and ceilings) are water resistant. Penetrations in floors, walls and ceiling surfaces are sealed and openings around ducts and the spaces between doors and frames are capable of being sealed to facilitate decontamination.

d. A hand-free or automatically operated hand washing sink is provided in each animal room near the exit door. The sink trap is filled with an appropriate disinfectant after each use.

e. Internal facility appurtenances, such as light fixtures, air ducts and utility pipes, are arranged to minimize horizontal surface areas.

f. Any windows must be resistant to breakage. Where possible, windows should be sealed. If the animal facility has windows that open, they are fitted with fly screens.

g. If floor drains are provided, they are always filled with an appropriate disinfectant.

h. Ventilation should be provided in accordance with criteria from the *Guide for Care and Use of Laboratory Animals*, latest edition. A ducted exhaust air ventilation system is provided. This system creates directional airflow which draws air into the laboratory from "clean" areas and toward "contaminated" areas. The exhaust air is not recirculated to any other area of the building. Filtration and other treatments of exhaust air may not be required, but should be considered based on site requirements, and specific agent manipulations and use conditions. The exhaust must be dispensed away from occupied areas and air intakes, or the exhaust must be HEPA-filtered. Personnel must verify that the direction of the airflow (into the animal area) is proper. It is recommended that a visual monitoring device that indicates and confirms directional inward flow be provided at the animal room entry. Consideration should be given to installing an HVAC control system to prevent sustained positive pressurization of animal spaces. Audible alarms should be considered to notify personnel of HVAC system failure.

i. HEPA-filtered exhaust air from a Class II biological safety cabinet can be recirculated into the animal room if the cabinet is tested and certified at least annually. When exhaust air from Class II safety cabinets is to be discharged to the outside through the building exhaust air system, the cabinets must be connected in

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a manner that avoids any interference with the air balance of the cabinets or the building exhaust system (e.g., an air gap between the cabinet exhaust duct). When Class III biological safety cabinets are used, they should be directly connected to the exhaust system. If the Class III cabinets are connected to the supply system, it is done in a manner that prevents positive pressurization of the cabinets.

j. Cages are washed in a cage washer. The mechanical cage washer has a final rinse temperature of at least 180 degrees F.

k. An autoclave is available which is convenient to the animal rooms where the biohazard is contained. The autoclave is utilized to decontaminate infectious waste before moving it to other areas of the facility.

l. If vacuum service (i.e., central or local) is provided, each service connection should be fitted with liquid disinfectant traps and an in-line HEPA filter, placed as near as practicable to each use point or service cock. Filters are installed to permit in-place decontamination and replacement.

m. Illumination is adequate for all activities, avoiding reflections and glare that could impede vision.

n. The completed Biosafety Level 3 facility design and operational procedures must be documented. The facility must be tested for verification that the design and operational parameters have been met prior to operation. Facilities should be re-verified at least annually against these procedures as modified by operational experience.

o. Additional environmental protection (e.g., personnel showers, HEPA filtration of exhaust air, containment of other piped services, and the provision of effluent decontamination) should be considered if recommended by the agent summary statement, as determined by risk assessment of the site conditions, or other applicable federal, state, or local regulations.

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UNIVERSAL PRECAUTIONS

1. Since medical history and examination cannot reliably identify all patients infected with HIV or other blood-borne pathogens, blood and body fluid precautions should be consistently used for all patients. This approach, previously recommended by CDC, and referred to as "universal blood and body-fluid precautions" or "universal precautions," should be used in the care of all patients, especially including those in emergency-care settings in which the risk of blood exposure is increased and the infection status of the patient is usually unknown.

2. All health-care workers should routinely use appropriate barrier precautions to prevent skin and mucous-membrane exposure when contact with blood or other body fluids of any patient is anticipated. Gloves should be worn for touching blood and body fluids, and for performing venipuncture and other vascular access procedures. Gloves should be changed after contact with each patient. Masks and protective eye wear or face shields should be worn during procedures that are likely to generate droplets of blood or other body fluids to prevent exposure of mucous membranes of the mouth, nose and eyes. Gowns or aprons should be worn during procedures that are likely to generate splashes of blood or other body fluids.

3. Hands and other skin surfaces should be washed immediately and thoroughly if contaminated with blood or other body fluids. Hands should be washed immediately after gloves are removed.

4. All health-care workers should take precautions to prevent injuries caused by needles, scalpels, and other sharp instruments or devices during procedures: when cleaning used instruments, during disposal of used needles, and when handling sharp instruments after procedures. To prevent needle stick injuries, needles should not be recapped, purposely bent or broken by hand, removed from disposable syringes, or otherwise manipulated by hand. After they are used, disposable syringes and needles, scalpel blades, and other sharp items should be placed in puncture-resistant containers for disposal; the puncture-resistant containers should be located as close as practical to the use area. Large-bore reusable needles should be placed in a puncture-resistant container for transport to the reprocessing area.

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5. Although saliva has not been implicated in HIV transmission, to minimize the need for emergency mouth-to-mouth resuscitation, mouthpieces, resuscitation bags, or other ventilation devices, should be available for use in areas in which the need for resuscitation is predictable.

6. Health-care or laboratory workers who have exudative lesions or weeping dermatitis should refrain from all direct patient care; from handling patient-care equipment; and from handling blood, blood products, and body fluids until the condition resolves. Pregnant health-care and laboratory workers are not known to be at greater risk of contracting HIV infection than health-care workers who are not pregnant; however, if a health-care worker develops HIV infection during pregnancy, the infant is at risk of infection resulting from perinatal transmission. Because of this risk, pregnant health-care workers should be especially familiar with and strictly adhere to precautions to minimize the risk of HIV transmission.

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EXPLOSURE CONTROL PLAN, Part 1

Exposure Determination

A. Job classifications in which all employees have occupational exposure:

Biological Aide
Medical research assistant
Medical technician
Medical research technologist
Medical research scientist
Medical research specialist
Medical officer
Junior and senior investigators

B. Job classifications in which some employees have occupational exposure:

Medical research technician
Maintenance personnel
Janitor
Chauffuere

C. Task and procedures in which occupational exposure occurs for category (B) above:

Cleaning laboratory areas
Repairing medical equipment
Cultivation of infectious agents
Handling of human blood and blood products, body secretions and fluids

D. Job classifications in which there is exposure to infectious agents without the handling of human blood or blood products or human samples (e.g. Handling of animals who may harbor infections):

Animal caretaker
Assistant animal caretaker
Supervisory animal caretaker

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EXPOSURE CONTROL PLAN, Part 2:
SOP for Medical Surveillance:

1. Physical Examination. All new employees should have a complete physical examination to screen for a condition which might make work with infectious agents hazardous. Enclosure (6) should be completed by the physician and filled under medical surveillance.

2. Immunizations: Indications:

a. **Hepatitis B vaccine:** all personnel who work with or are Laboratory screening. Before beginning work, all personnel who routinely or occasionally handle potentially infectious material should have:

b. **CBC** (to screen for immune dysfunction).

c. **Hepatitis B surface antibody**= anti-HBsAb, (to evaluate for immunity to hepatitis B) if immunization is needed or if immunization was completed no less than 1 month prior and no more than two months prior. If there is a history of hepatitis B, testing for anti-HB_c and Hb_sAg should be considered.

d. One **serum sample**, to be frozen at -70°C and saved as reference in case of accidental exposure to infectious materials. An additional sample may be used for HIV testing if needed.

e. **G6PD** deficiency testing for possible primaquine prophylaxis may be needed. exposed to blood or blood products, unless they have documented immunity (anti-HB_s). This includes persons who clean equipment, which may be soiled with blood or blood products.

f. **Rabies vaccine:** all personnel who handle or transport animals capable of transmitting rabies virus, and those working at remote field sites.

g. **Tetanus/diphtheria vaccine:** all personnel at field sites.

h. **Typhoid vaccine:** all laboratory technicians working with Salmonella typhi and all personnel who are at increased risk of disease by virtue of their employment with NMRCD.

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i. **Polio vaccine:** All personnel who have no history of vaccination against polio and are at increased risk of disease to polio by virtue of their employment with NMRCD.

j. **Measles, mumps, and rubella vaccines:** all personnel working in hospitals or field sites, and in contact with patients, unless immunity is documented or birth before 1957.

4. Biosafety Training. All new employees must receive training in biosafety by their Department Head before beginning work with infectious agents. The training must be documented and must include satisfactory completion of an oral or written examination based on 29 CFR 1910.1030 of 6 December 1991 entitled Bloodborne Pathogens. This training should be updated every 6 months with an oral examination and laboratory observation.

5. Documentation of Exposures. If an employee has a parenteral or mucous membrane exposure to blood, body fluids, or other infectious material, INSTRUCTION 5100.1C should be followed, and the OIC, Biosafety officer, Command Medical Officer and Division Head informed.

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NMRCD Instruction 5100.1C

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EXPOSURE CONTROL PLAN, Part 3

Exposure Control Evaluation

BAC ENT PAR RCVG SPC-RCVG VET VIR

- A. Work Practices
 - 1. Hand washing facilities
 - 2. Handling of sharps
 - 3. Disposal of sharps
 - 4. Location of eating
And drinking supplies
 - 5. Disposal of blood and
infectious materials
 - 6. Hood usage
 - 7. Vacuum traps

- B. Personal Protection
 - 1. Gloves available.
 - 2. Usage of gloves
 - 3. Lab coat usage
 - 4. Eye protection
 - 5. Laundering practices
 - 6. Pipetting devices
 - 7. Eyewash station

- C. Housekeeping
 - 1. Worksite cleanliness
 - 2. Area decontamination
 - 3. Handling of materials
for decontamination
 - 4. Storage of biological
materials and blood or
body fluid samples
 - 5. Biohazard signs
 - 6. Entry restriction

Date of evaluation:
Comments:

Date of next evaluation:
Biosafety Officer:

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EXPOSURE CONTROL PLAN, Part 3

Exposure Control Evaluation

IQUITOS: CALLAO-HOUSE INSECTARY REFERENCE

- A. Work Practices
 - 1. Hand washing facilities
 - 2. Handling of sharps
 - 3. Disposal of sharps
 - 4. Location of eating
And drinking supplies
 - 5. Disposal of blood and
infectious materials
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 - 1. Gloves available.
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 - 1. Worksite cleanliness
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materials and blood or
body fluid samples
 - 5. Biohazard signs
 - 6. Entry restriction

Date of evaluation:

Comments:

Date of next evaluation:

Biosafety Officer:

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EXPOSURE CONTROL PLAN, Part 4:

Biosafety Training Components:

1. Laboratory-Wide Biosafety Training:

- a. Review of the components of the standard on bloodborne pathogens, 29 CFR 1910.1030, and an explanation of its contents.
- e. The epidemiology and symptoms of bloodborne diseases.
- c. Explanation of how blood-borne pathogens are transmitted.
- d. Explanation of the NMCD exposure control plan and its availability to employees.
- e. Review of how to recognize the tasks that may produce exposure to blood and other infectious materials.
- f. Information on hepatitis B vaccine, including benefits, efficacy, safety, administration, and that it is free of charge.
- g. Explanation of what to do if an emergency involving exposure to blood or infectious agents occurs, and who to contact.
- h. Explanation of procedures to follow in the event of an exposure, how to report it, and the medical follow-up that will be provided.
- i. The employer's responsibilities after an exposure incident.
- j. Review of the sign and color-coding required for work areas and containers.

2. Biosafety Training by Department Heads.

- a. Explanation of the usage and limits of methods to prevent or reduce exposure to infectious materials.
- b. Review of the location, use, kinds, handling, decontamination, and disposal of personal protective equipment.
- c. Selection of the proper personal protective equipment.
- d. Procedures to be followed if the employee becomes pregnant.

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e. Review of the potential hazard involved in handling the infectious materials under study in the employee's division.

f. Explanation of the need for periodic review of work practices for biosafety and for periodic refresher training sessions to be documented on the training documentation form.

g. Opportunity for questions and comments during the training.

h. Discussion of errors or safety problems encountered during the preceding 6 months.

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