DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH CENTER DETACHMENT
LIMA, PERU
UNIT NUMBER 3800
APO AA 34041 – 3800

IN REPLY REFER TO

NMRCDINST 6260.1B
15 January 2003

NMRCD INSTRUCTION 6260.1B

From: Officer-in-Charge
To: Distribution List No.2

Subj: INFECTIOUS DISEASE SAFETY PROGRAM

Ref: (a) NMRCINST 5100.4 Series
(b) NMRCINST 6220.1 Series
(c) DHEW Publ. No. CDC 75-8118
(d) NMRCINST 6700.1 Series
(e) NMRCDINST 5100.1 Series
(f) NMRCDINST 5100.9 Series

Encl: (1) Biological Safety Cabinets and Laminar Flow Hood, Information on

1. Purpose. To establish this Detachment's infectious disease safety program and, thereby, to provide protection of personnel from infectious hazards.

2. Cancellation. NMRCD Instruction 6260.1A is cancelled.

3. Background. It is the NMRCD policy to ensure that a safe working environment will be provided all personnel employed within the facilities of Lima and Iquitos Peru as defined in the safety Program references (a) through (f). This instruction emphasizes infectious hazards and complements references (c) through (e).

4. Policy. Safety is the responsibility of the entire staff. Practices that are safe with one class of infectious agent may not be applicable to different or more virulent agents. It is NMRCD's policy, therefore, that safety procedures will be continually reviewed and improved to insure appropriateness for current research. Infectious disease hazards exist with pathogenic microbial agents, laboratory animals, and human and animal tissues including blood and blood products.

5. Responsibilities.

a. Infectious Disease Safety Officer. The Infectious Disease Safety Officer shall be a collateral duty position established by a separate appointment letter. The Infectious Disease Safety Officer shall:

(1) At least annually, review approved research protocols to become informed of infectious disease hazards and make appropriate recommendations to improve safety.

(2) At least annually, site visit labs for observation and consultation on infectious disease safety practices and equipment.

(3) Provide instruction and guidance for persons exposed to infectious hazards and investigate any such exposure.

(4) Insure that Foreign Service National (FSN) personnel who are scheduled to work in laboratories or potential exposure areas receive re-employment physical examination in accordance with reference (e).

(5) Coordinate and provide for pre-employment and periodic immunizations as deemed necessary by NMRCD.

(6) Maintain records of personnel exposed to infectious hazards and maintain records of personnel referred to treatment for infectious disease.

b. Department Heads.

(1) Consult with the Infectious Disease Safety Officer regarding proposed research with infectious or potentially infectious material.

(2) Develop safety guidelines for research in-progress. Consider infectious disease safety practices, available physical facilities, and equipment in the design of proposals for new research.

(3) Consult with the Infectious Disease Safety Officer on requirements for physical exams, serum banking, and immunizations.

(4) Advise the Infectious Disease Safety Officer of all incidents of lab related infectious diseases.

(5) Select and assign personnel for laboratory and animal technical duties only after thorough evaluation of medical history to exclude those persons with known altered immune mechanisms from areas of significant risk of exposure to viruses. Inherited immune defects, chemotherapy, and pregnancy should be considered in this provision.

(6) Train and inform personnel regarding hazards and potential hazards to which they may be exposed. Inform personnel of early signs and symptoms of infection with those agents known to be in the laboratory. Train personnel in animal handling techniques appropriate for the particular investigation.

(7) A standard Biohazard notice shall be affixed at

the entrance of all labs which contain infectious disease hazards.

(8) Personnel access to biohazard areas will be strictly controlled. Children and visitors shall be excluded from biohazard areas.

(9) Determine the specific type of biological safety hood for use in specific investigation. The Infectious Disease Safety Officer can provide consultation on types of hoods and recommended applications for each. Enclosure (1) contains information relating to classes of hoods.

(10) Bring to the attention of the Infectious Disease Safety Officer for review, new procedures which constitute infectious hazards.

c. Individual Responsibility.

(1) Individuals who handle infectious materials, equipment, or animals shall insure full compliance with the provisions of this instruction.

(2) Individuals shall review with their Department Heads all procedures to insure that infectious agents are handled with optimum safety.

(3) Individuals shall insure compliance with medical screening procedures which are deemed necessary by their Department Heads.

(4) Accidents involving human ingestion, inhalation, injection, or direct skin contact with any infectious material will be reported to the Infectious Disease Safety Officer and the Department Head.

6. Action.

a. General.

(1) Infectious materials, equipment and dead animals shall be autoclaved or chemically sterilized before being washed or discarded. Disposable materials should be used whenever possible.

(2) Infectious materials shall be refrigerated, incubated, or sterilized at the end of each workday to minimize hazards to others who may be required to enter the labs.

(3) Stock solutions of suitable disinfectants shall be maintained in each lab for use in cleaning work areas, decontaminating spills, and for discarding of pipettes and other

supplies.

(4) Infectious material, disposed of by way of the drainage system, shall first be sterilized.

(5) Water baths used to inactivate or incubate infectious material shall contain a suitable disinfectant to provide decontamination in the event of a spill.

(6) Vacuum lines shall be protected by traps or filters to prevent viable pathogens from entering the fixed system.

(7) Freezers and refrigerators shall be cleaned regularly and thoroughly to remove broken containers of infectious materials.

(8) Mouth pipetting is not allowed.

(9) Protective clothing shall be worn in biohazard areas only, contaminated clothing shall be changed frequently.

(10) There shall be no eating, drinking, smoking, cosmetic application, wearing of contact lenses without additional protection, handling of contact lenses, or storage of food in laboratories involved in work with infectious agents or animals.

(11) Blood, serum, and blood products from humans or other animals shall be considered as potentially infectious and handled accordingly.

(12) Biological safety hoods will be used for infectious materials where indicated and in accordance with specific Department rules using enclosure (1) for guidance. All infectious work will be conducted in vertical laminar air flow hoods. In no case should horizontal laminar air flow hoods be used. Biological safety hoods will be inspected upon installation or after removal and reinstallation and then on an annual basis by a contract initiated by the Detachment.

(13) Operational requirements for scientific microbial agents will be those recommended by the latest edition of the Center for Disease Control Safety Manual reference (c).

b. Tissue Culture Procedures.

(1) All tissue culture work will be conducted either in vertical laminar air flow hoods or in other hoods, specified by the OSHA, which move air away from the operator. In no case should horizontal laminar air flow hoods be utilized for tissue culture work. Biological safety hoods used for tissue culture

work will be inspected at least annually.

(2) All equipment and surfaces exposed to tissue culture material will be appropriately disinfected or sterilized before and after use. Pipettes, syringes, and other equipment used in handling tissue culture materials will be immersed in a suitable disinfectant prior to transfer to autoclaves. Care must be exercised when transporting material to the autoclave and solid unbreakable containers should be used.

(3) Pipetting aids shall be used at all times: NO MOUTH pipetting is allowed.

(4) All vacuum aspirative devices shall have at least one overflow reservoir or effluent overflow device in line with the vacuum source.

(5) Fully fastened laboratory coats and disposable gloves are recommended at all times and are required when the technician is working with human or nonhuman primate tissues. Coats and gloves shall not be worn outside the laboratory after being exposed to potentially infectious material. Coats must be properly decontaminated before removing from the lab.

(6) There shall be no eating, drinking, smoking, chewing of gum, application of cosmetics, wearing of contact lenses without additional protection, handling of contact lenses, or storage of food in laboratories where tissue culture work is conducted.

(7) The number of people entering tissue culture areas should be kept at a minimum and with only authorized individuals permitted. Persons under fifteen years of age shall not enter such areas.

(8) All centrifugation of tissue culture material shall be conducted in closed containers in shielded centrifuge heads. If caps are not available to provide an adequate seal, plastic tubes with caps will be used to minimize the risk of breakage and aerolization during centrifugation. The decanting of centrifuge tubes on the open laboratory bench should be avoided.

(9) Tissue culture material stored in freezers shall be placed in nonbreakable containers and labeled appropriately for easy identification.

(10) The multiple automated system harvester (MASH) will be vented in an exhaust hood so that the aerosol, normally produced by this apparatus, will not present a hazard. The affluent from a MASH apparatus will be appropriately disinfected prior to disposal. The system shall have an effluent overflow

safety device in-line with the vacuum source.

(11) New tissue culture procedures which the Department Head feels may present an unusual hazard shall be reviewed by the Infectious Disease Safety Officer.

(12) Accidents involving human ingestion, inhalation, injection or direct skin contact of tissue culture material will be reported to the Department Head and the Infectious Disease Safety Officer.

c. Animal Research

(1) Personnel will be assigned to animal technical duties only after selection and training to ensure knowledge of humane animal care and proper personnel protection measures appropriate for animal research procedures.

(2) Protective clothing will be worn by all personnel during animal procedures. Shoe covers should be worn by persons entering primate rooms.

(3) Disposable surgical masks must be worn by all persons entering primate rooms.

(4) Eating, drinking, smoking, and cosmetic application are prohibited in animal rooms.

(5) Animal restraint with physical or chemical techniques will be used as necessary to prevent injury. Care of bite wounds from all species is outlined in reference (b).

(6) Animal disease control will be in accordance with reference (e) and will include source selection, quarantine, daily observation, laboratory diagnostic procedures, and treatment as indicated. Department Heads will be kept informed of the health status of assigned animals.

(7) Visitors will not be allowed access to animal rooms.

d. Medical Surveillance Program

(1) Monitoring for biohazards involving NMRCD personnel shall be established by the Infectious Disease Safety Officer and the Department Heads.

(2) The purposes of medical surveillance are:

(a) To provide a mechanism for detection of job-related illnesses,

(b) To determine the risk level for employees working in specific areas or with special agents,

(c) To determine the adequacy of protective equipment and procedures, and

(d) To verify that hazardous agents are not being introduced by NMRCD personnel into the general population.

(3) Personnel entering designated laboratories or posted biohazardous areas may be required to complete and submit medical information to the Infectious Disease Safety Officer. Personnel participating in surveillance programs shall report all significant illnesses. Personnel working with hazardous agents may receive periodic physical examinations as recommended by their Department Heads and the Infectious Disease Safety Officer.

(4) Pregnancy. Pregnant women working with biohazardous materials or with immunosuppresses patients and related samples shall be given early individual evaluation of task location risks. Women working with selected viruses will discontinue work with these agents as soon as pregnancy is reasonably certain since risk to the fetus is greatest during the first trimester of pregnancy. The Infectious Disease Safety Officer and the Department Head shall be notified when pregnancy is diagnosed in a woman exposed to biohazards.

(5) These regulations shall become effective upon distribution and receipt of this instruction.

J. P. BURANS

LAMINAR FLOW HOODS & BIOLOGICAL SAFETY CABINETS

CONVENTIONAL LAMINAR FLOW HOODS

Many laminar flow cabinets now in use provide product protection only. Horizontal flow cabinets and vertical clean benches are often used by investigators to protect tissue cultures or laboratory animals from airborne contamination. The user must recognize that this type of laminar flow cabinet affords no personnel protection. Horizontal laminar flow cabinets can, therefore, be used to provide a contamination-free environment for animals, but shall not be used for tissue culture or other potentially infectious materials.

CLASS 2 LAMINAR FLOW BIOLOGICAL SAFETY CABINETS

This is a partial containment cabinet developed to protect the worker and the experimental material from airborne contamination. Personnel protection is dependent on the inward flow of room air and the collection efficiency of the exhaust air filter. Unlike Class 1 cabinets, the Class 2 cabinet has an inward airflow which does not cross the work surface. The air is drawn into a front, lateral suction grill which is continuous with the forward-leading edge of the work surface. To protect the experiment from airborne contamination, the work surface is bathed by a downward flow of filtered air. The appropriate air volume is recirculated through high efficiency particulate air (HEPA) filters. Personnel and specimen protection is dependent on HEPA filter efficiency. The cabinets are capable of collecting 99.97% of airborne particles in the breathable particle size range; their efficiency is essentially 100% for airborne particles above this size.

A major difficulty with laminar flow cabinets is that of adequately monitoring performance. The requirement for initial monitoring of a new cabinet should be included as part of the purchase contract. Periodic monitoring will be obtained from commercial institutions.

Periodic decontamination of cabinets and filters is a requirement for which a paraformaldehyde technique has been developed. This procedure allows decontamination of the equipment in place with subsequent continued use of the filters. Replacement of filters that are contaminated and have not been treated presents a significant infectious disease hazard to the technician. Decontamination is, therefore, essential prior to replacement of potentially infected HEPA units.

Two types of approved cabinets are in this category. The Class II Type A has a fixed sash (8-10" work opening), recirculates 70% of the air at 70-100 fpm vertical flow. It uses 30% of air into the front slots at 50-75 fpm. This type is susceptible to cross circulation and can leak cabinet air into the room if improperly placed in reference to room air ducts. It does, however, have a slanted front and the use of a microscope or other equipment is thereby facilitated.

The Class II Type B cabinet has a movable sash (8-16" work opening). It recirculates 30-50% of the air at 50± fpm vertical velocity and discharges 50-70%

of the air through a filter with a separate blower. This type has a high frontal area inlet velocity and is less susceptible to cross circulation. It should not be used with the sash full up. The Type 2 is more expensive and requires exhausting to the exterior of the building, but is usable for more kinds of research than is the Type 1.

CLASS 3 ABSOLUTE CONTAINMENT CABINETS

The Class 3 cabinet is used to contain highly infectious microbiological agents. This enclosure is gas-tight and contained under negative air pressure. Work is performed through rubber gloves. The cabinet air supply is exhausted through dual HEPA filters or incinerated. Separate exhaust duct systems are required.