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INTRODUCTION

The University is committed to providing a safe and healthy learning, teaching and research environment. The goals of the University's biological safety program are to protect the researchers, staff, and students from exposure to infectious agents, to prevent environmental contamination, to enhance the research atmosphere, and to comply with federal, state, and local regulations.

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Institutional Biosafety Committee (IBC). The manual provides university safety guidelines for those working with biohazards. This manual outlines general poli0 1 T*(an)3.995(d)3.007( )-88.007(p)3.00

Deans/Department Chairs

Deans/Department Chairsare responsible for the implementation of safe practices and procedures in their schools or departments. They should be aware of and approve all research conducted under their purview. They must ensure departmental compliance with applicable laws, regulations and guidelines covering the use of biological agents in their facility.

Institutional Biosafety Committee

The Institutional Biosafety Committee (IBC) is charged by the University Provost to formulate policy and procedures related to the use of biohazardous agents, including: human pathogens, viruses, biological toxins and recombinant DNA (rDNA). As mandated by the National Institutes of Health, experiments involving human gene transfer, formation of transgenic animals and the generation of rDNA or synthetic nucleic acid molecules must be reviewed and approved by the IBC. There are certain experiments that are exempted from NIH guidelines but these low risk projects must still be registered with the IBC so the committee can keep track of rDNA protocols on campus. In addition, all experiments involving infectious agents needs to be approved by the IBC before work can begin. The IBC application to register research projects is available for Research and Sponsored Programs Compliance.

Research & Sponsored Programs

Research & Sponsored Programsoversees funding for research projects that are awarded federal and state grants or use University money to conduct research at Lamar University. They coordinate the Institutional Animal Care and Use Committee (IACUC), the Institutional Biosafety Committee, and the Institutional Review Board (IRB) for research projects involving animals or human subjects. They work in conjunction with EHS & Risk Management to ensure that compliance requirements are met before funding is released.

Employees/Students

Employees/Students are responsible for complying with safety guidelines and procedures required for the tasks performed and reporting unsafe conditions to the PI or EHS & Risk Management. They should seek guidance from their PI or EHS & Risk Management when they are uncertain how to handle, store or dispose of any hazardous or biohazardous material. They should not begin working in the laboratory until all technical and safety training has been completed.

CLASSIFICATION OF BIOHAZARDS

Bacteria, viruses, fungi or other infectious agents are studied in the laboratory to find a cause or cure for the diseases associated with these organisms. Since many of these agents are pathogenic to humans, animals, or other forms of life, their use poses risks, which vary with each agent and the way it is used. The National Institutes of Health (NIH) and the Centers for Disease Control and Prevention (CDC) publish guidelines for work with infectious microorganisms. The publication, entitled

appropriate proceduresand containment to use while working with a particular agent in the lab. Laboratoriesand animal facilities are classified according to their designfeatures, construction and containment facilities to safely work with biological agents and infectious materials. These designations,called biosafety levels (BSL)and animal biosafety levels (ABSL)provide appropriate containment for the various risk group agents.

CONTAINMENT BARRIERS

The term "containment" is used in describingsafe methods for managinginfectious agentsin the laboratory environment where they are being handled or maintained. The purpose of containment is to reduce or eliminate exposureof laboratory workers and the outside environment to potentially hazardousagents.The threeelementsof containmentinclude facility design,safety equipment and laboratory practice and techniques.

Primary containment is the protection of personnel and the immediate laboratory environment from exposureto infectious agents.It is accomplished by good microbiological technique and the use of appropriate safety equipment. The use of vaccinesmay provide an increased level of personal protection.

Secondary containment is the protection of the environment external to the laboratory from exposure to infectious materials. It is accomplished by providing by a combination of facility design and operational practices. The risk assessment of the work to be done with a specific agent will determine the appropriate combination of work practices, safety equipment and facility design to provide adequatecontainment.

The most important element of containment is strict adherence to standard microbiological practices and techniques. Persons working with infectious agents or infected materials must be aware of potential hazards, and must be trained and proficient in the practices and techniques required for handling such material safely. The PI or laboratory supervisor is responsible for providing or arranging for appropriate training of personnel.

Each laboratory should develop an operational manual which identifies specific hazards that will or may be encountered, and which specifies practices and procedures designed to minimize or eliminate risks. Personnelshould be advisedof specialhazardsand should be required to read and to follow the required practicesand procedures.A scientisttrained and knowledgeablein appropriate laboratory techniques,safety proceduresand hazardsassociatedwith the handling of infectious agentsmust direct laboratoryactivities.

When standard laboratory practices are not sufficient to control the hazard associated with a particular

agent or laboratory procedure, additional measures may be needed. The PI is responsible for selecting additional safety practices, which must be in keeping with the hazard associated with the agent or procedure.

Laboratory personnel safety practices and techniques must be supplemented by appropriate facility design and engineering features, safety equipment and management practices.

Safety Equipment (Primary Barriers): Safety equipment includes biological safety cabinets, enclosed containers (i.e., safety centrifuge cups) and other engineering controls designed to remove or minimize exposures to hazardous biological materials. The biological safety cabinet (BSC) is the principal device used to provide containment of infectious splashes or aerosols generated by many microbiological procedures. The BSC provides personnel, product and environment protection.

Safety equipment also may include items for personal protection such as personal protective clothing, respirators, face shields, safety glasses or goggles. Personal protective equipment is often used in combination with other safety equipment when working with biohazardous materials.

Facility Design (Secondary Barriers): The design of a facility is important in providing a barrier to protect people working inside and outside the laboratory, and to protect people or animals in the community from infectious agents which may be accidentally released from the laboratory. Facilities must be designed to meet the requirements of the laboratory's function and the recommended biosafety level for the agent being manipulated.

Biosafety Level 2 is applicable to work done with a broad spectrum of indigenous moderate-risk agents present in the community and associated with human disease of varying severity. Primary hazards to personnel working with these agents relate to accidental percutaneous or mucous membrane exposures or ingestion of infectious materials. Procedures with high aerosol or splash potential must be conducted in primary containment equipment such as biosafety cabinets. Primary barriers such as splash shields, face protection, gowns and gloves should be used as appropriate. Secondary barriers such as hand washing and waste decontamination facilities must be availableIn addition to BSL 1 procedures, level 2 also requires the following special practices:

1. Access to the laboratory is limited or restricted by the PI 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 PI has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory or animal room.
2. The PI 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 the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB skin testing).
5.

centrifuge safety buckets are used, and if these rotors or safety buckets are opened only in a biological safety cabinet.

13. Face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials to the face when the microorganisms must be manipulated outside the BSC.
14. Protective laboratory coats, gowns, aprons, or uniforms designated for laboratory use are worn while in the laboratory. This protective clothing is removed and left in the laborat nanani14.004( )3

flow of air without re-circulation to spaces outside of the laboratory. If the laboratory has windows that open to the exterior, they are fitted with fly screens.

exposures, and the exposure evaluation procedures. Personnel receive annual updates or additional training as necessary for procedural changes.

8. The PI is responsible for ensuring that, before working with organisms at Biosafety Level 3, all personnel demonstrate proficiency in standard microbiological practices and techniques, and in the practices and operations specific to the laboratory facility. This might include prior experience in handling human pathogens or cell cultures, or a specific training program provided by the PI or other competent scientist proficient in safe microbiological practices and techniques.
9. 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 alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. Plasticware 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 that 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, state, or federal regulations.
10. 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 ved l5(y)]Tels - backed (y)]Telsaper towel( )-6 on non-perforated work surfaceswithin biological safety cabinets.
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b. Contaminated equipment must be decontaminated before removal from the facility for repair or maintenance or packaging for transport, in accordance with applicable local, state, or federal regulations.

12. Cultures, tissues, specimens of body fluids, or wastes are placed in a container that prevents leakage during collection, handling, processing, storage, transport, or shipping.
13. All potentially contaminated waste materials (e.g., gloves, lab coats, etc.) from

Animal Biosafety Level 1 is suitable for work involving well characterized agents that are not known to cause disease in healthy adult humans, and that are of minimal potential hazard to laboratory personnel and the environment.

Animal Biosafety Level 2 is suitable for work with those agents associated with human disease. It addresses hazards from ingestion, mucous membrane exposure, percutaneous exposure, and inhalation.

Ethyl alcohol and isopropyl alcohol diluted to 70 - 85% in water are useful for surface disinfection of materials that may be corroded by a halogen or other chemical disinfectant.

SPILL PROCEDURES

A spill kit should be kept in each laboratory where work with potentially infectious materials is conducted. Basic equipment includes disinfectant (such as 10% chlorine bleach), a package of paper towels, gloves and goggles, biohazard bags, etc.

The biosafety cabinet requires regular maintenance and certification by a professional technician to assure that it protects you, your experiments, and the environment. Each cabinet should be certified when it is installed, each time it is moved or repaired, and at least annually.

1. Class I cabinets protect personnel and the environment, but not research materials. They provide an inward flow of unfiltered air, similar to a chemical fume hood, which protects the worker from the material in the cabinet. The environment is protected by HEPA filtration of the exhaust air before it is discharged into the laboratory or to the outside via the building exhaust.
2. Class II (Types A1, A2,B1, B2, and formally A/B3) biological safety cabinets provide personnel, environment, and product protection. Air is drawn around the operator into the front grille of the cabinet, which provides personnel protection. In addition, the downward laminar flow of HEPA-filtered air within the cabinet provides product protection by minimizing the chance of cross-contamination along the work surface of the cabinet. Because cabinet air passes through the exhaust HEPA filter, it is contaminant-free (environment protection), and may be recirculated back into the laboratory (Type A) or ducted out of the building (Type B).
3. Class III cabinets (sometimes called Class III glove boxes) were designed for work with infectious agents that require Biosafety Level 4 containment, and provide maximum protection to the environment and the worker. The cabinet is gas-tight with a non-opening view window, and has rubber gloves attached to ports in the cabinet that allow for manipulation of materials in the cabinet. Air is filtered through one HEPA filter as005(Ai)5(re 8(v

Stainless steel containers and pans. Stainless steel is a good conductor of heat and is less likely to increase sterilizing time, though it is more expensive than polypropylene.

Preparation and Loading of Materials

Fill liquid containers only half full.
Loosen caps, or use vented closures.
Always put bags of biological waste into pans to catch spills.
Position biohazard bags on their sides, with the bag neck taped loosely.
Leave space between items to allow steam circulation.
Household dishpans melt in the autoclave. Use autoclavable polypropylene or stainless steel pans.

Cycle Selection

Use liquid cycle (slow exhaust) when autoclaving liquids, to prevent contents from boiling over.
Select fast exhaust cycle for glassware.
Use fast exhaust and dry cycle for wrapped items.

Time Selection

Take into account the size (and thus surface area to volume ratio) of the articles to be autoclaved. A 2-liter flask containing 1 liter of liquid takes longer to sterilize than four 500 ml flasks each containing 250 ml of liquid.

1. Temperature Monitoring – check indicating thermometers during each complete cycle to ensure the attainment of a minimum temperature of two hundred fifty degrees Fahrenheit (250ºF) or (121ºC) for at least one-half (1/2) hour or longer, depending on quantity and compaction of the load and in order to achieve sterilization of the entire load. Remember that greater time and/or temperatures may be necessary to effectively sterilize a load.
2. Heat Sensitive Tape Monitoring – use heat-sensitive tape or other device for each load that is processed to indicate the load has undergone the steam sterilization process. Remember this tape only indicates that the proper temperature has been reached, but does not indicate it was heated for the proper time.
3. Biological Indicator Monitoring – use a biological indicator such as Bacillus stearothermophilus placed at the center of a load processed under standard operating conditions to confirm the attainment of adequate sterilization conditions. If the autoclaves are run weekly, then the indicators should be performed monthly. If the frequency is less, than indicators are run quarterly or with each load as appropriate.

Annual Safety Inspection of Autoclaves

All autoclaves mechanical and monitoring systems should be serviced and checked annually by a service provider to ensure that the unit is running correctly. Check with the autoclave manufacture for service providers in the area.

EMERGENCY PROCEDURES

All accidents, exposures and needle sticks must be reported to the Principal Investigator (PI) and the Compliance Coordinator) for correct follow-up and risk assessment. Depending on the injury and the materials used in the lab, different approaches can be taken on the type of first aid that can be utilized. When working with human material or known pathogens, seek medical attention immediately. Do not use strong disinfectants or scrub brushes that can abrade the skin as this can cause additional damage and increase the chances of pathogens penetrating the body. Wash cuts and punctures.

Severe Injuries

1. Call 911 for assistance and transportation to the nearest emergency room.

2. A department representative should accompany the injured person to the medical facility and provide information to personnel about the accident/exposure.

3. Report accident to the PI and EHS & Risk Management.

Sharp Injury

1. Allow the wound to bleed under steady stream of water and wash area with soap and water.

2. Seek medical attention immediately.

3. Report the accident to the PI and EHS & Risk Management, and seek additional medical assistance if necessary.

Splashes to the Eye/Body

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MEDICAL SURVEILLANCE

Medical surveillance may be necessary for laboratory personnel that use agents known to cause disease in humans or

BIOLOGICAL WASTE DISPOSAL

Proper biological waste disposal will ensure safety for laboratory personnel, custodian staff, transporter, and the general public. The Texas Administrative Code, Title 30, Part 1, Chapter 326 on Medical Waste Management sets forth waste disposal regulations for biomedical and biohazardous waste generation, treatment, and disposal. These rules must be followed by all who generate biowaste on campus.

Biological waste includes infectious and non-infectious waste that may be generated in the laboratory, clinical, and campus setting. Examples of infectious or potentially infectious waste include human and animal pathogens, recombinant DNA, human blood and tissue. Examples of non-infectious waste include needles/syringes used for teaching purposes or in chemical labs, and materials that has not been contaminated with disease causing agent, such as petri dishes, media and animal carcasses.

All infectious waste must be placed in red biohazard bags or sharps container prior to disposal. Waste containers in the lab should remain closed with a lid when not in use. Step cans will satisfy this requirement. If using a cardboard box in the lab, the bags placed in the box should be sealed

Viruses and Prions
- Alphaviruses
  - St. Louis encephalitis virus
  - Venzualan equine encephalomyelitis
- Arenaviruses
  - Lymphocytic choriomeningitis virus (LCM)(neurotropic strains)
- Bunyaviruses
  - Hantaviruses including Hantaan virus
  - Rift Valley fever virus
- Poxviruses
  - Monkeypox virus
- Prions
  - Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)
- Retroviruses
  - Human immunodeficiency virus (HIV) types 1 and 2
  - Human t cell lymphotropic virus (HTLV) types 1 and 2
  - Simian immunodeficiency virus (SIV)
- Rhabdoviruses
  - Vesicular stomatitis virus

Risk Group 4 (RG4) Agents
* RG4 agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available.

Viral Agents
- Arenaviruses
  - Lassa virus
  - Junin virus
- Bunyaviruses (Nairovirus)
  - Crimean-Congo hemorrhagic fever virus
- Filoviruses
  - Ebola virus
  - Marburg virus
- Herpesviruses (alpha)
  - Herpesvirus simiae (Herpes B or Monkey B virus)
- Hemorrhagic fever agents and viruses as yet undefined

Animal Viral Agents in Common Use
* None of these agents is associated with disease in healthy adult humans; they are commonly used in laboratory experimental work.
* A containment level appropriate for RG1 human agents is recommended for their use. For agents that are infectious to human cells, e.g. amphotropic and xenotropic strains of murine leukemia virus, a containment level appropriate for RG2 human agents is recommended.
- Baculoviruses
- Herpesviruses
  - Murine cytomegalovirus
- Papovaviruses
  - Bovine papilloma virus
  - Simian virus 40 (SV40)
- Retroviruses

Appendix B

Select Agent List

HHS SELECT AGENTS AND TOXINS
Abrin
Botulinum neurotoxins
Botulinum neurotoxin producing species of Clostridium
Conotoxins
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern equine encephalitis virus Ebola viruses
Francisella tularensis Lassa fever virus Marburg virus
Monkeypox virus
Reconstructed 1918 Influenza virus Ricin
Rickettsia prowazekii
SARS-associated coronavirus
Saxitoxin
Shigatoxin
South American haemorrhagic fever viruses Junin Machupo Sabia Guarnarito

Staphylococcal enterotoxin
Tetrodotoxin
T-2 toxin
Tick-borne encephalitis complex (flavi) viruses
Kyasanur forest disease
Omsk hemorrhagic fever
Variola major virus (Smallpox virus) Variola minor virus (Alastrim) Yersinia pestis

SELECT AGENTS AND TOXINS (OVERLAP AGENTS)
Bacillus anthracis Brucella abortus Brucella melitensis
Brucella suis Burkholderia mallei
Burkholderia pseudomallei
Hendra virus Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

USDA SELECT AGENTS AND TOXINS
African swine fever virus African horse sickness virus
Avian influenza (highly pathogenic) Classical Swine fever virus
Foot and mouth disease virus Goat pox virus
Lumpy skin disease virus Mycoplasma capricolum Mycoplasma mycoides subspecies
Newcastle disease virus (VVND) Peste Des Petits Ruminants virus Rinderpest virus
Sheep pox virus
Swine vesicular disease

Verifying Autoclave Efficacy

1. Perform testing using a biological indicator (B. stearothermophilus)
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Completed Autoclave Logs should be maintained by the Department