Policy

A  Purpose

The purpose of this manual is to specify controls and safe handling practices for microorganisms (viruses, bacteria, fungi, rickettsia, mycoplasma, protozoans, multicellular parasites, and prions), toxins, recombinant DNA molecules, human blood or tissues, and animal cell cultures.

B  Scope

This written program applies to all University of Utah research performed at the University Hospital and medical center, the Huntsman Cancer Institute, main campus, or at off campus facilities. Students are covered as well as part and full time employees.

C  Responsibilities

C.1  Institutional Biosafety Committee (IBC) shall:

1. Meet as required for review of recombinant DNA (R-DNA) research in accordance with National Institutes of Health (NIH) guidelines.
2. Review this Biosafety Manual and the current inventory of R-DNA activity. In the event of any significant violations or accidents, they shall report the incident to the NIH Office of Recombinant DNA Activities.
3. Determine the necessity for health surveillance and prophylaxis for research projects.

C.2  Environmental Health and Safety shall:

Provide consultation and technical information on the safe handling of biological agents and toxins.

1. Be responsible for updating the University Biosafety Manual.
2. Coordinate and provide oversight for the annual certification of biological safety cabinets by an outside contractor.
3. Review and recommend purchases of biological safety cabinets and other related safety equipment.
4. Advise in the disinfection of facilities and equipment.
5. Assist in the development of safety and exposure control plans and training programs.

C.3  Principal Investigators and/or Laboratory Supervisors shall:

1. Receive approval from the IBC prior to conducting R-DNA research.
2. Register potentially infectious agents with Environmental Health and Safety.
3. Maintain and annually review laboratory specific standard operating procedures (e.g. bloodborne pathogen exposure control plans, etc).
4. Ensure their research laboratory staff and students are trained on the contents of this manual and follow its requirements.
5. Survey laboratories for compliance with standards and policies regarding safe handling and use of biological agents and toxins.
6. Enforce compliance with the approved standards and policies of the University.
7. Encourage employees to report any changes in their health status.
8. As applicable, advise the R-DNA committee (IBC), Institutional Review Board for Research with Human Subjects (IRB), Institutional Animal Care and Use Committee (IACUC), and EHS of any significant changes in approved protocol involving use of biological agents and/or toxins.
9. Comply with shipping requirements for biohazardous substances and toxins.

C.4 Researchers, Technicians and Students will:

1. Adhere to the established policies, SOP's, and guidelines for biological safety as trained.
2. Inform immediate supervisor of any unsafe practices or conditions in the work area.
3. Report any change in health status to the supervisor if there is a possibility it may be work related. Report all biological spills and incidents to the supervisor.

Guidelines

A General Introduction

A.1 Eating, drinking, smoking, or storage of foods must not be permitted in the laboratory.

A.2 Personnel must wash their hands after handling infectious material, removal of gloves, and before leaving the laboratory.

A.3 Control the biohazard area.

1. Keep laboratory doors and windows closed while work is in progress.
2. Post a warning sign, such as the universal biohazard symbol, when infectious material is present in the area. This warning sign should identify the agent and indicate the requirements for entry.
3. Limit access to the laboratory during procedures involving biohazardous agents.

B General Procedures to Minimize Exposure

B.1 Aerosols

1. Aerosols refer to liquid droplets or solid particulates dispersed in air. Aerosols are too small a particle to be seen by the unaided eye and remain suspended in air for a period of time. The production of aerosols while handling infectious agents accounts for the greatest source of laboratory-acquired infections.
2. Generation of aerosols may be caused in the use of centrifuges, blenders, shakers, magnetic stirrers, sonicators, pipettes, vortex mixers, syringes and needles, freeze-dried samples,
vacuum sealed samples, mortar and pestles, culture tubes, inoculating loops, and separatory funnels.

3. Control of aerosols.
4. Perform activities in a biological safety cabinet; or chemical fume hood when appropriate.
5. Keep tubes stoppered when vortexing or centrifuging.
6. Allow aerosols to settle prior to opening centrifuges, blenders, or mixed tubes.
7. Place cloth soaked with disinfectant over work surface to deactivate possible spills or droplets of biohazardous agents. Soaked gauze can be wrapped around ampoules while breaking, needles while being removed from a vial, or stoppers being removed from tubes.
8. Slowly reconstitute or dilute contents of an ampoule.
9. Mix solutions by discharging the secondary fluid down the side of the container or as close as possible to the surface of the primary solution.
10. Allow inoculating needle to cool before touching biological specimens.

B.2 Pipetting
1. Never mouth pipette.
2. No infectious mixture should be prepared by bubbling air through the liquid with the pipette.
3. No infectious materials should be forcibly discharged from pipettes.

B.3 Syringes and needles
1. Avoid the use of syringes and needles if possible. Use the needle-locking type or a disposable syringe needle unit.
2. Needles should not be re-sheathed, bent, broken or removed from disposable syringes. Needles and syringes should be discarded in biosafety labeled sharps containers for later autoclaving. Do not discard needles into disinfectant pans containing pipettes or other glassware.

C Classification of Agents on the Basis of Hazard
These agents as listed by the Centers for Disease Control and Prevention (CDC) are those biological agents known to infect humans as well as select animal agents that may pose theoretical risks if inoculated into humans. Included are lists of representative genera and species known to be pathogenic; mutated, recombined, and non-pathogenic species and strains are not considered. Non-infectious life cycle stages of parasites are excluded. This is a list of the more commonly encountered agents and is not meant to be all inclusive. They are divided into Risk Groups which correspond to the equivalent Biosafety Level. The Pathogen Safety Data Sheets provided by the Public Health of Canada are another source of information which can assist in the risk assessment of an agent.
C.1 Risk Group 1 (RG1) Agents

RG1 agents are not associated with disease in healthy adult humans. Examples of RG1 agents include asporogenic Bacillus subtilis or Bacillus licheniformis, Escherichia coli K12, and recombinant AAV constructs, in which the transgene does not encode either a potentially tumorigenic gene product or a toxin molecule and are produced in the absence of a helper virus.

Those agents not listed in Risk Groups (RG's) 2, 3 and 4 are not automatically or implicitly classified in RG1; a risk assessment must be conducted based on the known and potential properties of the agents and their relationship to agents that are listed.

C.2 Risk Group 2 (RG2) Agents

RG2 agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

1. Bacterial Agents
   • Acinetobacter baumannii (formerly Acinetobacter calcoaceticus)
   • Actinobacillus
   • Actinomyces pyogenes (formerly Corynebacterium pyogenes)
   • Aeromonas hydrophila
   • Amycolata autotrophica
   • Archanobacterium haemolyticum (formerly Corynebacterium haemolyticum)
   • Arizona hinshawii - all serotypes
   • Bacillus anthracis
   • Bartonella henselae, B. quintana, B. vinsonii
   • Bordetella including B. pertussis
   • Borrelia recurrentis, B. burgdorferi
   • Burkholderia (formerly Pseudomonas species) except those listed in RG3
   • Campylobacter coli, C. fetus, C. jejuni
   • Chlamydia psittaci, C. trachomatis, C. pneumoniae
   • Clostridium botulinum, Cl. chauvoei, Cl. haemolyticum, Cl. histolyticum, Cl. novyi, Cl. septicum, Cl. tetani
   • Corynebacterium diphtheriae, C. pseudotuberculosis, C. renale
   • Dermatophilus congolensis
   • Edwardsiella tarda
   • Erysipelothrix rhusiopathiae
   • Escherichia coli - all enteropathogenic, enterotoxigenic, enteroinvasive and strains bearing K1 antigen, including E. coli O157:H7
2. Bacterial Agents

- Haemophilus ducreyi, H. influenzae
- Helicobacter pylori
- Klebsiella - all species except K. oxytoca (RG1)
- Legionella including L. pneumophila
- Leptospira interrogans - all serotypes
- Listeria
- Moraxella
- Mycoplasma, except M. mycoides and M. agalactiae which are restricted animal pathogens
- Neisseria gonorrhoeae, N. meningitidis
- Nocardia asteroides, N. brasiiliensis, N. otitidiscaviarum, N. transvalensis
- Rhodococcus equi
- Shigella including S. boydii, S. dysenteriae, type 1, S. flexneri, S. sonnei
- Sphaerophorus necrophorus
- Staphylococcus aureus
- Streptobacillus moniliformis
- Streptococcus including S. pneumoniae, S. pyogenes
- Treponema pallidum, T. carateum
- Vibrio cholerae, V. parahemolyticus, V. vulnificus
- Yersinia enterocolitica

2. Fungal Agents

- Blastomyces dermatitidis
- Cladosporium bantianum, C. (Xylohypha) trichoides
- Cryptococcus neoformans
- Dactylaria galopava (Ochroconis galopavum)
- Epidermophyton
- Exophiala (Wangiella) dermatitidis
- Fonsecaea pedrosoi
3. Parasitic Agents

- Ancylostoma human hookworms including A. duodenale, A. ceylanicum
- Ascaris including Ascaris lumbricoides suum
- Babesia including B. divergens, B. microti
- Brugia filaria worms including B. malayi, B. timori
- Coccidia
- Cryptosporidium including C. parvum
- Cysticercus cellulosae (hydatid cyst, larva of T. solium)
- Echinococcus including E. granulosus, E. multilocularis, E. vogeli
- Entamoeba histolytica
- Enterobius
- Fasciola including F. gigantica, F. hepatica
- Giardia including G. lamblia
- Heterophyes
- Hymenolepis including H. diminuta, H. nana
- Isospora
- Leishmania including L. braziliensis, L. donovani, L. ethiopia, L. major, L. mexicana, L. peruvania, L. tropica
- Loa loa filaria worms
- Microsporidium
- Naegleria fowleri
- Necator human hookworms including N. americanus
- Onchoerca filaria worms including, O. volvulus
- Plasmodium including simian species, P. cynomologi, P. falciparum, P. malariae, P. ovale, P. vivax
- Sarcocystis including S. sui hominis
- Schistosoma including S. haematobium, S. intercalatum, S. japonicum, S. mansoni, S. mekongi
- Strongyloides including S. stercoralis
- Taenia solium
- Toxocara including T. canis
- Toxoplasma including T. gondii
- Trichinella spiralis
- Trypanosoma including T. brucei brucei, T. brucei gambiense, T. brucei rhodesiense, T. cruzi
- Wuchereria bancrofti filaria worms

4. Viruses
   - Adenoviruses, human - all types
   - Alphaviruses (Togaviruses) - Group A Arboviruses
     1. Eastern equine encephalomyelitis virus
     2. Venezuelan equine encephalomyelitis vaccine strain TC-83
     3. Western equine encephalomyelitis virus
   - Arenaviruses
     1. Lymphocytic choriomeningitis virus (non-neurotropic strains)
     2. Tacaribe virus complex
     3. Other viruses as listed in the reference source
   - Bunyaviruses
     1. Bunyamwera virus
     2. Rift Valley fever virus vaccine strain MP-12
     3. Other viruses as listed in the reference source
   - Calciviruses
   - Coronaviruses
   - Flaviviruses (Togaviruses) - Group B Arboviruses
     1. Dengue virus serotypes 1, 2, 3, and 4
     2. Yellow fever virus vaccine strain 17D
     3. Other viruses as listed in the reference source
   - Hepatitis A, B, C, D, and E viruses
   - Herpesviruses - except Herpesvirus simiae (Monkey B virus) (see RG4 - Viral Agents)
     1. Cytomegalovirus
     2. Epstein Barr virus
     3. Herpes simplex types 1 and 2
4. Herpes zoster
5. Human herpesvirus types 6 and 7
   • Orthomyxoviruses
     1. Influenza viruses types A, B, and C
     2. Other tick-borne orthomyxoviruses as listed in the reference source
   • Papovaviruses
     1. All human papilloma viruses
   • Paramyxoviruses
     1. Newcastle disease virus
     2. Measles virus
     3. Mumps virus
     4. Parainfluenza viruses types 1, 2, 3, and 4
     5. Respiratory syncytial virus
   • Paroviruses
     1. Human parovirus (B19)
   • Picornaviruses
     1. Coxsackie viruses types A and B
     2. Echoviruses - all types
     3. Polioviruses - all types, wild and attenuated
   • Prions
     1. Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)
   • Retroviruses
     1. Lentivirus/Human immunodeficiency virus (HIV) types 1 and 2, simian immunodeficiency virus (SIV)
     2. Human T cell lymphotropic virus (HTLV) types 1 and 2
   • Rhabdoviruses
     1. Vesicular stomatitis virus (lab adapted strains)

C.3 Risk Group 3 (RG3) Agents
RG3 agents are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available.
   1. Bacterial Agents Including Rickettsia
      • Bartonella
• Brucella including B. abortus, B. canis, B. suis
• Burkholderia (Pseudomonas) mallei, B. pseudomallei
• Coxiella burnetii
• Francisella tularensis
• Mycobacterium bovis (except BCG strain), M. tuberculosis
• Pasteurella multocida type B - "buffalo" and other virulent strains
• Rickettsia akari, R. australis, R. canadensis, R. conorii, R. prowazekii, R. rickettsii, R. siberica, R. tsutsugamushi, R. typhi (R. mooseri)
• Yersinia pestis
2. Fungal Agents
• Coccidioides immitis (sporulating cultures; contaminated soil)
• Histoplasma capsulatum, H. capsulatum var. duboisii
3. Parasitic Agents
• None
4. Viruses and Prions
• Alphaviruses (Togaviruses) - Group A Arboviruses
  1. Semliki Forest virus
  2. St. Louis encephalitis virus
  3. Venezuelan equine encephalomyelitis virus (except the vaccine strain TC-83, see RG2)
  4. Other viruses as listed in reference sources
• Arenaviruses
  1. Flexal
  2. Lymphocytic choriomeningitis virus (LCM) (neurotropic strains)
• Bunyaviruses
  1. Hantaviruses including Hantaan virus
  2. Rift Valley fever virus
• Flaviviruses (Togaviruses) - Group B Arboviruses
  1. Japanese encephalitis virus
  2. Yellow fever virus
  3. Other viruses as listed in reference sources
• Poxviruses
  1. Monkeypox virus
• Prions
1. Transmissible spongiform encephalopathies (TME) agents (Creutzfeldt-Jacob disease and kuru agents)

- Retroviruses
  1. Lentivirus/Human immunodeficiency virus (HIV) types 1 and 2, simian immunodeficiency virus (SIV)—for industrial scale or high concentrations of virus.
  2. Human T cell lymphotropic virus (HTLV) types 1 and 2

- Rhabdoviruses
  1. Vesicular stomatitis virus

C.4 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. The University of Utah does not have containment facilities that support BSL-4 research.

1. Bacterial Agents
   - None

2. Fungal Agents
   - None

3. Parasitic Agents
   - None

4. Viral Agents
   - Arenaviruses
     1. Guanarito virus
     2. Lassa virus
     3. Junin virus
     4. Machupo virus
     5. Sabia
   - Bunyaviruses (Nairovirus)
     1. Crimean-Congo hemorrhagic fever virus
   - Filoviruses
     1. Ebola virus
     2. Marburg virus
   - Flaviruses (Togaviruses) - Group B Arboviruses
     1. Tick-borne encephalitis virus complex including Absetterov, Central European encephalitis, Hanzalova, Hypr, Kumlinge, Kyasanur Forest disease, Omsk hemorrhagic fever, and Russian spring-summer encephalitis viruses
• Herpesviruses (alpha)
  1. Herpesvirus simiae (Herpes B or Monkey B virus)
• Paramyxoviruses
  1. Equine morbillivirus
• Hemorrhagic fever agents and viruses as yet undefined

C.5 Animal Viral Etiologic Agents in Common Use

The following list of animal etiologic agents is appended to the list of human etiologic agents. 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.

1. Baculoviruses
2. Herpesviruses
   • Herpesvirus ateles
   • Herpesvirus saimiri
   • Marek's disease virus
   • Murine cytomegalovirus
3. Papovaviruses
   • Bovine papilloma virus
   • Polyoma virus
   • Shope papilloma virus
   • Simian virus 40 (SV40)
4. Retroviruses
   • Avian leukosis virus
   • Avian sarcoma virus
   • Bovine leukemia virus
   • Feline leukemia virus
   • Feline sarcoma virus
   • Gibbon leukemia virus
   • Mason-Pfizer monkey virus
   • Mouse mammary tumor virus
   • Murine leukemia virus
   • Murine sarcoma virus
   • Rat leukemia virus
C.6 Murine Retroviral Vectors

Murine retroviral vectors (MSCV) to be used for human transfer experiments (less than 10 liters) that contain less than 50% of their respective parental viral genome and that have been demonstrated to be free of detectable replication competent virus can be maintained, handled, and administered under BSL-1 containment.

D Biosafety Levels (BSL)

The four biosafety levels correspond directly to the four risk groups of microorganisms listed in Section C. The agents of minimal hazard are Biosafety Level 1 (BSL-1), with the more dangerous microorganisms at Biosafety Level 4 (BSL-4). The following descriptions were taken from Biosafety in Microbiological and Biomedical Laboratories (http://www.cdc.gov/od/ohs/biosfty/biosfty.htm).

Table 1: Summary of recommended Biosafety Levels for Infectious Agents

<table>
<thead>
<tr>
<th>Level</th>
<th>Practices and Techniques</th>
<th>Safety Equipment</th>
<th>Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Standard Microbiological practices.</td>
<td>No primary barriers required. Lab coats and gloves; eye, face protection as needed.</td>
<td>Lab bench and sink required</td>
</tr>
<tr>
<td>2</td>
<td>Level 1 practices plus: limited access; biohazard warning signs; sharps precautions; decontamination of all infectious wastes.</td>
<td>Biological safety cabinets for manipulations of agents that cause splashes or aerosols of infectious materials. Lab coats and gloves; eye, face protection as needed.</td>
<td>Level 1 plus: Autoclave</td>
</tr>
<tr>
<td>3</td>
<td>Level 2 practices plus: controlled access; decontamination of all waste; decontamination of all clothing before laundering.</td>
<td>Biological safety cabinets or other physical containment devices used for all open manipulation of agents. Lab coats, gloves, face, eye and respiratory protection as needed.</td>
<td>Level 2 plus: Physical separation; self-closing, double door access; exhausted air not recirculated; negative airflow into lab.</td>
</tr>
<tr>
<td>4</td>
<td>Level 3 practices plus: clothing change before entering; shower on exit; all material decontaminated on exit from the facility.</td>
<td>All procedures conducted in biological safety cabinet in combination with full-body, air-supplied, positive-pressure suit.</td>
<td>Level 3 plus: Separate building or isolated zone; dedicated supply, exhaust, and decontamination system</td>
</tr>
</tbody>
</table>
D.1 Biosafety Level 1 (Risk Group 1 Agents)

Biosafety Level 1 is suitable for work involving agents of known or of minimal potential hazard to laboratory personnel and the environment. The laboratory is not separated from the general traffic patterns in the building. Work is generally conducted on open bench tops. Special containment equipment is not required or generally used. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with general training in microbiology or a related science.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 1:

1. Standard Microbiological Practices
   - Access to the laboratory is limited or restricted at the discretion of the Principal Investigator/Supervisor when experiments are in progress.
   - Work surfaces are decontaminated once a day and after any spill of viable material.
   - All contaminated liquid or solid wastes are decontaminated before disposal.
   - Technical pipetting devices are used; mouth pipetting is prohibited.
   - Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators located outside of the work area.
   - Persons wash their hands after they handle viable materials and animals and before leaving the laboratory.
   - All procedures are performed carefully to minimize the creation of aerosols.
   - It is recommended that laboratory coats, gowns, or uniforms be worn to prevent contamination or soiling of street clothes.

2. Special Practices
   - Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before removed from the laboratory.
   - An insect and rodent control program is in effect.

3. Containment Equipment
   - Special containment equipment is generally not required for manipulation of agents assigned to BSL-1.

4. Laboratories Facilities
   - The laboratory is designed so that it can be easily cleaned.
   - Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
   - Laboratory furniture is sturdy with surfaces for easy cleaning and decontamination. No cloth chairs. Spaces between benches, cabinet and equipment are accessible for cleaning.
   - Each laboratory contains a sink for hand washing.
If the laboratory has windows that open, they are fitted with fly screens.

D.2  **Biosafety Level 2 (Risk Group 2 Agents)**

Biosafety Level 2 is similar to Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs in that (1) laboratory personnel have specific training in handling pathogenic agents and are directed by competent scientists; (2) access to the laboratory is limited when work is being conducted; and (3) certain procedures in which infectious aerosols are created are conducted in biological safety cabinets or other physical containment equipment.

The following standard and special practices, equipment and facilities apply to agents assigned to BSL-2.

1.  **Standard Microbiological Practices**
   - Access to the laboratory is limited or restricted by the Principal Investigator/Supervisor when work with infectious agents is in progress.
   - Work surfaces are decontaminated at least once a day and after any spill of viable material.
   - All infectious liquid or solids wastes are decontaminated before disposal.
   - Mechanical pipetting devices are used; mouth pipetting is prohibited.
   - Eating, drinking, smoking, and applying cosmetics are not permitted in the work area. Food may be stored in cabinets or refrigerators designated and used for this purpose only. Food storage cabinets or refrigerators should be located outside of the work area.
   - Persons wash their hands after handling infectious materials and animals when they leave the laboratory.
   - All procedures are performed carefully to minimize the creation of aerosols.

2.  **Special Practices**
   - Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable leak-proof container which is closed before being removed from the laboratory.
   - The Principal Investigator/Supervisor limits access to the laboratory. In general, persons who are at increased risk of acquiring infection or for whom infection may be unusually hazardous are not allowed in the laboratory or animal rooms. The director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
   - The Principal Investigator/Supervisor establishes policies and procedures whereby only persons who have been advised of the potential hazards and meet any specific entry requirements (e.g., immunization) may enter the laboratory or animal rooms.
   - When the infectious agent(s) in use in the laboratory require special provisions for entry (e.g., vaccination), a hazard warning sign, incorporating the universal biohazard symbol, is posted on the access door to the laboratory work area. The hazard warning sign
identifies the infectious agent, lists the name and telephone number of the Principal Investigator/Supervisor or other responsible person(s) for entering the laboratory.

- An insect and rodent control program is in effect.
- Laboratory coats, gowns, smocks, or uniforms are worn while in the laboratory. Before leaving the laboratory for non-laboratory area (e.g., cafeteria, library, administrative offices), this protective clothing is removed and left in the laboratory or covered with a clean coat not used in the laboratory.
- Animals not involved in the work being performed are not permitted in the laboratory.
- Special practices are taken to avoid skin contamination with infectious materials; gloves should be worn when handling infected animals and when contact with infectious materials is unavoidable.
- All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.
- Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the injection or aspiration of infectious fluids. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the sheath or guard or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discarding.
- Spills and accidents which result in overt exposures to infectious materials are immediately reported to the Principal Investigator/Supervisor. Medical evaluation, surveillance and treatment are provided as appropriate and written records are maintained.
- 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.
- A biosafety manual is prepared or adopted. Personnel are advised of special hazards and are required to read instructions on practices and procedures and how to follow them.

3. Containment Equipment

Biological safety cabinets (Class I or II) or other appropriate personal protective or physical containment devices are used whenever:

- Procedures with a high potential for creating infectious aerosols are conducted. These may 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 intra-nasally, and harvesting infected tissues from animals or eggs.
• High concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory if sealed heads or centrifuge safety cups are used and if they are opened only in a biological safety cabinet.

4. Laboratory Facilities

• The laboratory is designed so that it can easily be cleaned.
• Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.
• Laboratory furniture is sturdy with surfaces for easy cleaning and decontamination. No cloth chairs. Spaces between benches, cabinet and equipment are accessible for cleaning.
• Each laboratory contains a sink for hand washing.
• If the laboratory has windows that open, they are fitted with fly screens.
• An autoclave for decontaminating infectious laboratory wastes is available.

D.3 Biosafety Level 3 (Risk Group 3 Agents)

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

It is recognized, however, that many existing facilities may not have all the facility safeguards recommended for BSL-3 (e.g., access zone, sealed penetrations, and directional airflow, etc.). In these circumstances, acceptable safety may be achieved for routine or repetitive operations (e.g., diagnostic procedures involving the propagation of an agent for identification, typing, and susceptibility testing) in laboratories where facility features satisfy BSL-2 recommendations provided the recommended "Standard Microbiological Practices," "Special Practices," and "Containment Equipment" for BSL-3 are rigorously followed. The decision to implement this modification of Biosafety Level 3 recommendations should be made only by the Principal Investigator.

The following standard and special safety practices, equipment, and facilities apply to agents assigned to BSL-3:

1. Standard Microbiological Practices

• Work surfaces are decontaminated at least once a day and after any spill of viable material.
• All infectious liquid or solid wastes are decontaminated before disposal.
• Mechanical pipetting devices are used; mouth pipetting is prohibited.
• Eating, drinking, smoking, storing food, and applying cosmetics are not permitted in the work area.
• Persons wash their hands after handling infectious materials and animals and when they leave the laboratory.
• All procedures are performed carefully and accurately.

2. Special Practices
• Laboratory doors are kept closed when experiments are in progress.
• Contaminated materials that are to be decontaminated at a site away from the laboratory are placed in a durable, leak-proof container which is closed before being removed from the laboratory.
• The Principal Investigator/Supervisor 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 be unusually hazardous are not allowed in the laboratory or animal rooms. The director has the final responsibility for assessing each circumstance and determines who may enter or work in the laboratory.
• The Principal Investigator/Supervisor establishes policies and procedures whereby only persons who have been advised of the potential biohazards, who meet any specific entry requirements (e.g., immunization), and who comply with all entry and exit procedures may enter the laboratory or animal rooms.
• 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 number of the Principal Investigator/Supervisor 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.
• All activities 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.
• The work surfaces of biological safety cabinets and other containment equipment are decontaminated when work with infectious materials is finished. Plastic-backed paper toweling used on non-perforated work surfaces within biological safety cabinets facilitates clean-up.
• An insect or rodent control program is in effect.
• Laboratory clothing that protects street clothing (e.g., solid front or wrap-around gowns, scrubs, suits, and coveralls) is worn in the laboratory. Laboratory clothing is not worn outside the laboratory, and it is decontaminated before being laundered.
• Special care is taken to avoid skin contamination with infectious materials; gloves should be worn when handling infected animals and when contact with infectious materials is unavoidable.
• Molded surgical masks or respirators are worn in rooms containing infected animals.
Animals and plants not related to the work being conducted are not permitted in the laboratory.

All wastes from laboratories and animal rooms are appropriately decontaminated before disposal.

Vacuum lines are protected with high efficiency particulate air (HEPA) filters and liquid disinfectant traps.

Hypodermic needles and syringes are used only for parenteral injection and aspiration of fluids from laboratory animals and diaphragm bottles. Only needle-locking syringes or disposable syringe-needle units (i.e., needle is integral to the syringe) are used for the infection or aspiration of infectious fluids. Extreme caution should be used when handling needles and syringes to avoid autoinoculation and the generation of aerosols during use and disposal. Needles should not be bent, sheared, replaced in the sheet or guard or removed from the syringe following use. The needle and syringe should be promptly placed in a puncture-resistant container and decontaminated, preferably by autoclaving, before discarding.

Spills and accidents which result in overt or potential exposures to infectious materials are immediately reported to the Principal Investigator/Supervisor. Appropriate medical evaluation, surveillance, and treatment are provided and written records are maintained.

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

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

3. Containment Equipment

Biological safety cabinets (Class I, II, or III) or other appropriate combination of personal protective or physical containment devices (e.g., special protective clothing, masks, gloves, respirators, centrifuge safety cups, sealed centrifuge rotors, and containment caging for animals) are used for all activities with infectious materials which pose a threat of aerosol exposure. These include: manipulation of cultures and of those clinical or environmental materials which may be a source of infectious aerosols; the aerosol challenge of experimental animals; harvesting of tissues or fluids from infected animals and embryonated eggs, and necropsy of infected animals.

4. Laboratory Facilities

The laboratory is separated from areas which are open to unrestricted traffic flow within the building. Passage through two sets of doors is the basic requirement for entry into the laboratory from access corridors or other contiguous areas. Physical separation of the high containment laboratory from access corridors or other laboratories of activities may also be provided by a double-doored clothes change room (showers may be included), airlock, or other access facility which requires passage through two sets of doors before entering the laboratory.
• The interior surfaces of walls, floors, and ceilings are water resistant so that they can be easily cleaned. Penetrations in these surfaces are sealed or capable of being sealed to facilitate decontaminating the area.

• Bench tops are impervious to water and resistant to acids, alkalis, organic solvents, and moderate heat.

• Laboratory furniture is sturdy with surfaces for easy cleaning and decontamination. No cloth chairs. Spaces between benches, cabinet and equipment are accessible for cleaning.

• Each laboratory contains a sink for hand washing. The sink is foot, elbow, or automatically operated and is located near the laboratory exit door.

• Windows in the laboratory are closed and sealed.

• Access doors to the laboratory or containment module are self-closing.

• An autoclave for decontaminating laboratory wastes is available, preferably within the laboratory.

• A ducted exhaust air ventilation system is provided. This system creates directional airflow that draws air into the laboratory through the entry areas. The exhaust air is not recirculated to any other area of the building, is discharged to the outside, and is dispersed away from occupied areas and air intakes. Personnel must verify that the direction of the airflow (into the laboratory) is proper. The exhaust air from the laboratory room can be discharged to the outside without being filtered or otherwise treated.

• The HEPA-filtered exhaust air from a Class II biological safety cabinet is discharged directly to the outside or through the building exhaust system. Exhaust air from Class II biological safety cabinet may be recirculated within the laboratory if the cabinet is tested and certified at least every six months. Biological safety cabinets can also be connected to the lab exhaust system by either a thimble (canopy) connection or a direct (hard connection).

D.4  Biosafety Level 4 (Risk Group 4 Agents)

Biosafety Level 4 is required for work with dangerous and exotic agents which pose a high individual risk of life-threatening disease. Members of the laboratory staff have specific and thorough training in handling extremely hazardous infectious agents, and they understand the primary and secondary containment functions of the standard and special practices, the containment equipment, and the laboratory design characteristics.

They are supervised by competent scientists who are trained and experienced in working with these agents.

Access to the laboratory is strictly controlled by the Principal Investigator/Supervisor. The facility is either in a separate building or in a controlled area within a building, which is completely isolated from all other areas of the building. A specific facility operations manual is prepared or adopted. The University of Utah does not have containment facilities that support BSL-4 research.
Table 2. Summary of Recommended Biosafety Levels for Activities in Which Experimentally or Naturally Infected Vertebrate Animals are Used.

<table>
<thead>
<tr>
<th>Level</th>
<th>Practices and Techniques</th>
<th>Safety Equipment</th>
<th>Facilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Standard animal care and management practices.</td>
<td>None</td>
<td>Basic</td>
</tr>
<tr>
<td>2</td>
<td>Laboratory coats; decontamination of all infectious wastes and of animal cages prior to washing; limited access; protective gloves and hazard warning signs as indicated.</td>
<td>Partial containment equipment and/or personal protective devices used for activities and manipulations of agents or infected animals that produce aerosols.</td>
<td>Basic</td>
</tr>
<tr>
<td>3</td>
<td>Level 2 practices plus: special laboratory clothing; controlled access.</td>
<td>Containment and/or personal protective devices used for all activities and manipulations of agents or infected animals.</td>
<td>Containment</td>
</tr>
<tr>
<td>4</td>
<td>Level 3 practices plus: entrance through clothes change room where street clothing is removed and laboratory clothing is put on; shower on exit; all wastes are decontaminated before removal from the facility.</td>
<td>Maximum containment equipment (i.e., Class III biological safety cabinet or partial containment equipment in combination with full-body, air-supplied positive-pressure personnel suit) used for all procedures and activities.</td>
<td>Maximum Containment</td>
</tr>
</tbody>
</table>

E  Working with Human Tissues

Biosafety Level 2 practices and procedures must be followed when handling human blood, blood products, body fluids and tissues because of the infectious agents they may contain. This is consistent with the concept known as “Universal Precautions”. The OSHA Bloodborne Pathogen Standard requires limiting exposure to blood and other potentially infectious materials since any exposure could result in transmission of bloodborne pathogens which could lead to disease or death.

A site specific (laboratory, clinic, etc.) Exposure Control Plan must be developed and made readily available to all at-risk employees. The primary goal is to prevent transmission of Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), Human Immunodeficiency Virus (HIV), and other bloodborne pathogens. HBV vaccination is available at the Madsen Clinic to all occupationally at-risk employees as well as students. Under no circumstances shall anyone work with cells derived from themselves or from first degree relatives since the host immune systems may not provide adequate protection.
Training on safe handling of human blood, blood products, body fluids and tissues is mandatory. EHS coordinates periodic train-the-trainer sessions for Principal Investigators and Supervisors. The most recent schedule is posted on the Research Administration (RATS) home page. An employee with no prior experience in handling human pathogens must be trained in the laboratory prior to handling infectious materials. Participation in work involving infectious agents will be allowed only after proficiency has been demonstrated to the satisfaction of the Principal Investigator or Laboratory Supervisor.

F   Cell Culture

The following must be handled at BSL-2 or higher containment level:

1. All cell lines of human/primate origin
2. Any cell lines derived from lymphoid or tumor tissue
3. All cell lines exposed to or transformed by any oncogenic virus
4. All cell lines exposed to or transformed by amphotropic packaging systems
5. All clinical material (e.g., samples of human tissues and fluids obtained after surgical resection or autopsy)
6. All cell lines new to the laboratory (until proven to be free of all adventitious agents)
7. All mycoplasma-containing cell lines – The cell line must be classified at the same level as that recommended for the agent when cell cultures are known to contain an etiologic agent, an oncogenic virus or amphotropic packaging system.

G   Recombinant DNA Research

Recombinant DNA molecules are defined as either: (1) molecules that are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (2) DNA molecules that result from the replication of a molecule described in (1).

Synthetic DNA segments which are likely to yield a potentially harmful polynucleotide or polypeptide (e.g., a toxin or a pharmacologically active agent) are considered as equivalent to their natural DNA counterpart. If the synthetic DNA segment is not expressed in vivo as a biologically active polynucleotide or polypeptide product, it is exempt from the NIH Guidelines. Genomic DNA of plants and bacteria that have acquired a transposable element, even if the latter was donated from a recombinant vector no longer present, are not subject to the NIH Guidelines unless the transposon itself contains recombinant DNA.

1. Federal Guidelines and Registering Experimental Protocols – All research conducted at the University of Utah involving recombinant DNA molecules must meet current NIH guidelines. All experimental protocols must be approved by the IBC and in special instances by a committee at the NIH or USDA as well. The principal investigator is responsible for determining the status of his/her experiments and filing the proper documents if review is required.

2. Emergency Plans – The NIH Guidelines instruct a set of emergency plans covering accidental spills and resulting personnel contamination for work involving R-DNA. Section Q of this document constitutes a basic spill plan. Research that is carried out at physical containment...
level BSL-2 or higher requires the principal investigator to prepare or adopt a biosafety manual. This manual may serve as the basis for preparing a more specific document.

H  Human Gene Transfer

All protocols involving the generation of R-DNA for human gene transfer must be registered and approved by the IBC prior to submission to outside agencies and the initiation of experimentation. Prior approval by the IRB is required before commencing gene therapy in humans.

I  Transgenics

Investigators who create transgenic animals must complete a Transgenic Animal Registration Form and submit it to the IBC for approval. In addition, the protocol must receive approval from the IACUC.

Experiments to genetically engineer plants by R-DNA methods may require approval from the IBC. The NIH guidelines provide specific plant biosafety containment recommendations to prevent release of transgenic plant materials to the environment. Protocol must be registered with the IBC.

J  Selection of Biological Safety Cabinets

Biological Safety Cabinets serve as an effective primary barrier against biological or infectious agents by surrounding the immediate work area. It is the ideal complement to, not replacement for, careful work practices.

The cabinets are equipped with High Efficiency Particulate Air (HEPA) filters which have 99.97% efficiency against 0.3 micron particles. HEPA filters offer no protection against volatiles, such as ether, alcohol, etc.

Selection of the correct biological safety cabinet is based on the classification of the agent, the associated biosafety level for the particular agent, and chemicals which will be used in the research.

<table>
<thead>
<tr>
<th>Cabinet</th>
<th>Operations and Uses</th>
</tr>
</thead>
<tbody>
<tr>
<td>Horizontal Laminar Flow or Clean Bench</td>
<td>Filtered air flow across the work surface toward the operator, providing a protection for the product, but not the worker. Do not use for work with infectious materials, toxic chemicals, sensitizing agents, or radionuclides.</td>
</tr>
<tr>
<td>Class I</td>
<td>Only the exhaust air is filtered, therefore protection is provided to the user and to the environment, but not to the experiment. The operator’s hands and arms may be exposed to hazardous materials inside the cabinet. This cabinet may be used with low to moderate risk biological agents.</td>
</tr>
<tr>
<td>Class II</td>
<td>These have vertical laminar air flow with HEPA filtered supply and exhaust air. They protect the worker, the product, and the environment. For use with</td>
</tr>
<tr>
<td>Class, Type</td>
<td>Description</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>Class II, Type A</td>
<td>Recirculated 70% of the air inside the cabinet. Exhausts 30% into room after filtration. 75 fpm average face velocity. Do not use with volatile radionuclides or toxic chemicals.</td>
</tr>
<tr>
<td>Class II, Type B1</td>
<td>Recirculated 30% of the air inside the cabinet and exhausts the rest to the outside of the building. Maintains 100 fpm average velocity. Contaminated ducts are under negative pressure. May be used with minute amounts of volatiles.</td>
</tr>
<tr>
<td>Class II, B2</td>
<td>Referred to as Total Exhaust. No recirculation. 100% exhausted outside after filtration. Maintains 100 fpm average face velocity. All contaminated ducts are under negative pressure. Suitable where volatile toxic chemicals and radionuclides are required.</td>
</tr>
<tr>
<td>Class III, or Glove box</td>
<td>Is gas-tight and maintained under negative air pressure. Used to work with highly infectious, carcinogenic, or hazardous materials. All operations are conducted through rubber gloves attached to entry portals.</td>
</tr>
</tbody>
</table>

**Use of Biological Safety Cabinets**

1. **Preparations**
   - Turn blower on and purge air for at least five minutes prior to use to filter air inside.
   - Never work with the UV light illuminated. Skin and eye damage can occur from the direct and reflected light.
   - Wipe down the work surface with an appropriate disinfectant. Do not depend on the UV germicidal lamp to provide a sterile surface.
   - Everything needed to complete the particular procedure should be placed inside the cabinet prior to beginning work. Arrange in a logical manner to segregate clean and contaminated. Arm movements in and out of the cabinet may cause escape of aerosols.

2. **Use**
   - Always wear a laboratory coat and gloves.
   - Conduct work at least four inches inside the glass panel (sash). The further back in the hood, the better.
   - Minimize arm movements, keeping necessary movements slow and smooth.
   - Avoid use of a burner within the cabinet.
   - Place a disinfectant soaked towel on the work surface to contain any splatters or small spills which may occur.

3. **Upon Completion of Procedures**
   - All contaminated equipment is segregated with container surfaces covered and decontaminated.
• The cabinet blower should be left on for at least five minutes to purge the air.
• Remove equipment from the cabinet and decontaminate the work surfaces. Turn on the UV light.
• Wash hands and arms thoroughly with soapy water.

4. Certification

Biological safety cabinets are not to be used with hazardous materials until certified as meeting minimal safety specifications (e.g., NIH-03-112 or National Sanitation Foundation Standard 49) on site. They are to be certified in situ by a trained technician:
• When newly installed.
• Any time the cabinet has been moved.
• Annually.
• After repair or maintenance (e.g., filter replacement, work on the blower, etc.)

EHS will schedule the annual certification inspections through an outside contractor. Phone the Assistant Biosafety Specialist at (801)585-3345 for more information.

L  Personnel Exposure Control / Plans Procedures

1. Each area with potentially exposed employees must have an Exposure Control Plan. At a minimum, the plan will list tasks and procedures as well as job classifications where occupational exposure occurs. It must be reviewed annually. A draft plan is available at the link above.

2. Hepatitis B vaccinations must be made available to all employees who have the potential for an occupational exposure to blood or other potentially infectious materials within 10 days of assignment.

3. Following any exposure incident, the individual will immediately wash the affected area. The incident will be reported to the supervisor who will investigate. Circumstances causing the occurrence and measures to prevent recurrence will be documented. A confidential medical evaluation and follow-up must be made available to the employee, at no cost to him/her.

M  Training

Training must be accomplished prior to beginning duties and repeated at least annually. At a minimum it will consist of methods to minimize exposure, proper shipping procedures, and if working with blood or blood containing products, access to a copy of the OSHA Bloodborne Pathogen Standard, explanation of its contents, and a general explanation of the Exposure Control Plan. Training videos to assist supervisors with training are available from EHS.

N  Personal Protective Equipment

1. Protective clothing designed to keep street clothes and forearms free of contamination should be worn when working with microorganisms in the laboratory. Protective clothing should never be worn outside the laboratory. Long sleeve lab coats are recommended at minimum.
2. Protective gloves must be worn when working with infectious material. Gloves should be changed if damaged and removed before contact with clean surfaces such as the telephone or doorknob. Hands must be washed as soon as gloves are removed.

3. Surgical masks may be worn for product protection; not personal protection. Where personnel cannot be adequately protected via procedural or ventilation controls, respiratory protection may be required. Use of disposable respirators for personnel protection must follow procedures outlined in the University of Utah Respiratory Protection Program.

O Record Keeping

1. Medical records will be maintained for the duration of employment plus 30 years.
2. Training records will be maintained for at least 3 years.

P Disinfection and Sterilization

1. Frequently disinfect floors, cabinet tops, and equipment where biohazard material is stored.
2. Sterilize all infectious materials and contaminated equipment prior to being washed, stored, or discarded.
3. Use autoclave or disposable materials whenever possible. Keep reusable and disposable items separate.
4. Mark holding containers as "NON-INFECTIONOUS - TO BE CLEANED" or "BIOHAZARDOUS - TO BE AUTOCLAVED"

5. Disinfectants - reduce the number of pathogenic organisms

- Alcohols: Ethyl or isopropyl alcohol at 70-80% concentration is a good all purpose disinfectant. It is not effective against bacterial spores and adenovirus.
- Phenolic compounds: Effective against vegetative bacteria, fungi, and lipid-containing viruses. Less effective versus spores. Unpleasant odor (e.g., Amphyl, Vesphene 2).
- Formaldehyde: At a concentration of 5-8% formalin, good disinfectant properties against vegetative bacteria, spores, and viruses. Irritant sensitizer and animal carcinogen.
- Quaternary Ammonium Compounds: Acceptable as disinfectant to control vegetative bacteria and non-lipid-containing viruses.
- Chlorine: Low concentration (50-500 ppm) active against vegetative bacteria and most viruses. Higher concentration (2500 ppm) required for bacterial spores. Strong irritant. Corrosive to metal surfaces. Must be made up fresh (no residual action) Laundry bleach (5.25% chlorine), Alcide. 10 ml laundry bleach per liter of water yields approximately 525ppm.
- Iodofors: Recommended for general use (75-150 ppm). Effective against vegetative bacteria and viruses but poor activity against spores. Brown or yellow solution is still active. Wescodyne diluted 1 to 10 is popular disinfectant for washing hands.
- Glutaraldehydes: Two percent solutions exhibit good activity against vegetative bacteria, spores, and viruses. Toxic and capable of eye damage (e.g., Cidex, Sporicidin, 3M Glutarex).
6. Sterilization

- **Steam Heat.** Required approximately 15 psi pressure with a chamber temperature of at least 250 degrees F (121 degrees C). The cycle time begins when the materials being sterilized reach the predetermined temperature. Then the length of time is dependent upon the volume size of the load (usually 30-60 min.). Monitor steam sterilization effectiveness with a biological indicator (e.g., Bacillus steroothermophilus).

- **Dry Heat.** Less effective than steam, and requires more time (two to four hours) and higher temperature (320-338 degrees F or 160-170 degrees C). Monitor effectiveness with biological indicator (e.g., Bacillus subtilis).

- **Ethylene Oxide (EtO).** Lethal for all known microorganisms and best for heat-resistant organisms or heat-sensitive equipment.

- **Temperature affects the penetration of EtO through microbial cell wall and wrapping and/or packaging materials.** The activity of EtO increases approximately 2.7 times for each 18 degrees F (10 degree C) rise in temperature (between ranges of 41 and 98.6 degrees F or 5 and 37 degrees C) using a concentration of 884 mg/L. Normal temperature range is 120-140 degrees F (49-60 degrees C).

- **A concentration of 500-1000 mg/L at 120 to 140 degrees F (49-60 degrees C) is normally recommended.**

- **Humidity recommended between 30 and 60 percent.**

- **Exposure time is determined by the factors above.** Follow the manufacturer’s recommendation and monitor with biological indicators (e.g., Bacillus subtilis var. niger).

- **Precautions.** Mixtures of 3-10% EtO in air can be explosive. Commercially available mixtures of EtO in freon or carbon dioxide are not explosive. Personal exposures to EtO may result in harmful physical effects. The current permissible exposure for EtO is one ppm for an eight hour time weighted average. Concentrations may exceed 1000 ppm as the sterilizer door is opened for aeration. Local exhaust at the door opening and a 15 minute wait before removing the articles to the mechanical aeration chamber will minimize exposures.

7. **Antiseptics.** Formulated to be used on skin or tissue- not a disinfectant (e.g., Betadine, Clinedine, Hibiclens).

Q **Spill Procedures**

Laboratories must develop procedures for dealing with spills and should have available appropriate equipment and materials. A basic spill kit could include a concentrated disinfectant (chlorine bleach or Wescodyne) a package of paper towels, sponges, household “rubber” gloves, forceps for broken glass and an autoclavable container.

1. **Spill in a Biological Safety Cabinet**
   - Leave the cabinet turned on.
   - Wearing gloves and laboratory coat, spray or wipe cabinet walls, work surfaces and equipment with the selected disinfectant. (A decontaminant detergent such as Wescodyne...
has the advantage of removing extraneous organic substances which may interfere with the contact between the microorganisms and the active agent of the decontaminant).

- If necessary flood work surface, drain pans and catch basins below the work surface with disinfectant. Allow at least 20 minutes contact time.
- Soak up the disinfectant and drain the catch basin below the work surface with disinfectant. Allow at least 20 minutes contact time.
- Autoclave all clean-up materials and protective clothing. Wash hands and exposed skin areas with disinfectant.
- If the spill overflows into the interior of the cabinet, more extensive decontamination of the cabinet may be necessary.

2. Spill: Biosafety Level 1 (BSL-1) in an Open Laboratory
   - Notify others in the area.
   - Remove any contaminated clothing and wash exposed skin with disinfectant.
   - Wearing gloves, lab coat and safety glasses, cover the spill with paper towels, pour concentrated disinfectant around spill allowing it to mix with the spill. Allow at least 20 minutes contact time.
   - Inform supervisor. Wait at least 30 minutes before reentering the laboratory to allow dissipation of aerosols created by the spill. During this time review cleanup procedures and assemble material.
   - Don protective clothing (long sleeved gown, gloves, and shoe covers). Depending on the nature of the spill, it may be advisable to wear a respirator with high efficiency particulate air (HEPA) cartridges.
   - Carefully lay disinfectant-soaked towels over the spill and pour disinfectant around the spill. To minimize aerosolization, do not pour disinfectant directly onto the spill. Use more concentrated disinfectant if the volume of material will significantly dilute the disinfectant.
   - Allow 20 minutes contact time.
   - Use forceps to place sharp objects into a sharps container. Wipe surrounding surfaces with disinfectant to cover all splash areas. Wipe flat surfaces to remove any aerosol which may have settled out on those surfaces.
   - Place all contaminated materials, including protective clothing, into a biohazard bag and autoclave.
   - Wash hands and exposed skin areas.

3. Spill: Biohazardous Radioactive Material
   Plan ahead. Contact the Radiological Health Department at (801)581-6141 regarding procedures that must be followed to prevent and mitigate spills of radioactive material. Develop a list containing the name, chemical form, and annual limit on intake (ALI) for all radioisotopes used in the laboratory. A spill involving material which is both a biohazard and radioactive requires recovery procedures different from those appropriate for aqueous, low
energy beta radiation emitters alone. Recovery from a spill requires consideration of the types or radionuclide, pathogenicity of the microorganism or its components, the chemical composition and volume of the spill. Spills involving carbon-14 and/or tritium present no external hazard. Good aseptic techniques will prevent internal radiation exposure to these nuclides and prevent personnel contamination with either the pathogen or the radioactive material.

However, higher energy beta or gamma radiation emitters and mixtures containing volatile radioisotopes may require additional protective measures. High temperature (autoclave or dry) and gas sterilization procedures involving radioisotopes must be approved in advance through the Radiological Health Department office.

When a spill occurs:

• Notify others in the room. Avoid inhaling airborne material and quickly evacuate the area. Close door and post with a warning sign.

• Remove contaminated clothing turning exposed side in upon itself. Place in a biohazard bag labeled with a radioactive material sticker.

• Thoroughly wash all exposed skin with disinfectant. Rinse for three minutes, dry and monitor for residual radioactive contamination. If radioactive contamination remains, repeat the disinfection and decontamination procedure. Do not use harsh or abrasive cleansers on skin.

• Inform the laboratory supervisor, notify the Radiological Health Department and monitor all potentially exposed personnel for radioactive contamination. Wait at least 30 minutes before reentering the laboratory to allow dissipation of aerosols created by the spill. During this time review cleanup procedures and assemble decontamination equipment.

• Depending on the severity and virulence of the spill, dress in protective clothing (long sleeved gown, gloves, and shoe covers). It may be advisable to wear a respirator with high efficiency particulate air (HEPA) cartridges. However, use of respirators requires knowledge of their application and appropriate fitting before beginning recovery procedures.

• Carefully lay disinfectant-soaked towels over the spill and pour disinfectant around the spill. To minimize aerosolization, do not pour disinfectant directly onto the spill. Use more concentrated disinfectant if the volume of material will significantly dilute the disinfectant.

• Allow 30 minutes contact time.

• Use forceps to place sharp objects into a sharps container. Wipe surrounding surfaces with disinfectant to cover all splash areas. Wipe flat surfaces to remove any aerosol which may have settled out on those surfaces.

• Place all contaminated materials, including protective clothing, into a disposable plastic container lined with a heavy plastic bag labeled with radioactive materials warning tape. Do not autoclave without approval from the Radiological Health Department. If it cannot be autoclaved, add additional disinfectant to ensure decontamination of all materials.
Following recovery efforts thoroughly wash all exposed skin with disinfectant. Rinse for three minutes, dry and monitor for residual radioactive contamination. If radioactive contamination remains, repeat the disinfection and decontamination procedure. Do not use harsh or abrasive cleansers on skin.

Allow time for thorough drying of all disinfected surfaces and then monitor the spill area for residual radioactive contamination. The presence of radioactivity on surfaces warrants repeated disinfection and decontamination efforts.

**R Disposal**

Infectious waste is regulated by the Salt Lake City-County Health Department. The key requirements with regard to infectious waste are proper labeling with subsequent disposal in a safe manner. For waste that has not been decontaminated, incineration, burial at an infectious waste landfill or in some cases discharge into the sanitary sewer system are acceptable disposal procedures. Waste which has been autoclaved can be disposed of with regular garbage only if it is obviously marked "autoclaved", and all biohazard labeling defaced so appropriate disposal is not questioned. Contact the EHS Associate Environmental Specialist at 801-581-6590 for specific instructions.

1. All waste from the University Hospital and School of Medicine is considered potentially infectious waste and transported by a licensed contractor to an approved site.

2. Animal carcasses must be returned to the Animal Resource Center for incineration. Phone 801-581-6430 for specific instructions.

3. Chemotherapy waste is collected from the Hospital by EHS for incineration.

**S Shipment**

1. Background

The most current regulations affecting the transportation of Dangerous Goods will go in to effect January 1, 2013. For the purposes of the Principal Investigator conducting biomedical research, all potentially infectious substances come under classification of Dangerous Goods. Carriers (e.g., FedEx and UPS) are legally bound to reject any packages that are not in compliance with these regulations.

The specific requirements of the Dangerous Goods Regulations are outlined in the International Air Transport Association (IATA) tariffs and the International Civil Aviation Organization (ICAO) tariff. The following represents the relevant details of the regulations.

All biohazard materials shipped off campus must be packed in special packaging which meets UN 6.2” packaging standards. Some of the vendors providing appropriate packaging are VWR, Uline, or NU Packaging.

2. Training
Strict government regulations must be followed when transporting hazardous materials. An infectious substance is regulated as a hazardous material under the U.S. Department of Transportation’s (DOT) Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180). Shipments must arrive at their destination in good condition and present no hazard during shipment. All individuals who package and ship infectious materials, potentially infectious materials and/or dry ice are required by federal law to complete Shipping Category B Infectious Substances and Dry Ice training every two years.

A Biological specimen, Category B (previously known as Clinical specimen and Diagnostic specimen), is an infectious substance that does not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. A Category A material is an infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs.

If you are shipping a Category A substance or are unsure about the regulations concerning shipping a diagnostic or infectious specimen, please call the Biosafety Officer at 801-581-6590.

To read the regulations concerning the transport of a diagnostic or infectious specimen, see:

- International Air Transportation Association (IATA) Dangerous Goods information

3. Category B Infectious Substances, Exempt Materials, or Dry Ice shipments are required to have the appropriate labels with the assigned UN numbers on the outer package.

- Number 3373 is assigned to Category B Infectious Substances.
- Number 1845 is assigned to dry ice shipments.
- “Exempt” is assigned to shipments that do not contain a known infectious substance.

4. Packaging

Shippers of infectious and potentially infectious substances must comply with these regulations and must ensure that shipments are prepared in such a manner that they arrive at their destination in good condition, and that they present no hazards to persons or animals during shipment. The packaging must include both inner packaging and outer packaging.

- Inner Packaging Specifications:
1. The primary receptacle must be leak-proof or sift-proof and must not contain more than 1L.
2. Sufficient absorbent material must be placed around the primary receptacle to absorb its entire contents if a leak occurs.
3. Leak-proof secondary packaging will contain the primary receptacle and absorbent material.
   a. For liquid shipments by aircraft, the primary receptacle or secondary packaging must be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95kPa.

• Outer Packaging Specifications:

1. Packaging materials must be of sufficient strength to meet the design type test standards. Items must be placed in a rigid container that will not break if dropped from less than 1.2 meters.
2. Do not use bubble wrap as packing material.
3. An itemized list of contents must be enclosed between the secondary packaging and the outer packaging.
4. All packages containing infectious substances and/or dry ice must be marked durably and legibly on the outside of the package with the required labels and the name and phone number of a person responsible for the shipment.
5. Dry ice must never be shipped or placed in a sealed container.

5. Physical Condition

1. Substances shipped at or above ambient temperature:
   1. Primary receptacle may only be of glass, metal, or plastic.
   2. Must provide a positive means of ensuring a leakproof seal; e.g., heat seal, skirted stopper, metal crimp seal.
   3. Screw caps must be re-enforced with adhesive tape.
2. Substances shipped refrigerated or frozen:
   1. Ice, wet or dry, must be placed outside the secondary packaging.
   2. Interior support must be in place to secure secondary packaging in its original position after the ice has dissipated.
   3. If wet ice is used; packaging must be leakproof.
   4. If dry ice is used, the outer packaging must permit the release of carbon dioxide.
The primary and secondary packaging must maintain containment integrity at the temperature of the refrigerant used, as well as, the temperature and pressure ranges of air transport to which the receptacle could be subjected if refrigeration is lost.

3. Lyophilized substances
   1. Primary receptacles must be either flame-sealed glass ampoules or rubber-stoppered glass vials with metal seals.

6. Importation and Exportation
   A license may be required from the Department of Commerce) to export certain biological agents. Please contact Biosafety Officer at (801)585-9325 regarding shipment of the following items:
   - etiologic agents
   - biological materials
   - animals
   - insects
   - snails
   - bats

7. Special handling Requirements
   Certain etiologic agents require special handling. Most of these agents are in BSL-3 (Risk Group 3) or BSL-4 (Risk Group 4). They must be shipped by registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery. Please contact Biosafety Officer at (801)585-9325 regarding shipment of these items.

References

