BIOLOGICAL SAFETY MANUAL

Institutional Biosafety Committee

Burrell College Office of Research and Sponsored Programs
3501 Arrowhead Dr.
Las Cruces, NM 88001
Phone: (575) 674-2338
Fax: (575) 674-2309
https://bcomnm.org/research/orsp/biosafety/

The Burrell College Office of Research and Sponsored Programs prepared materials contained in the Biological Safety Manual. We reviewed multiple biological safety manuals from other institutions. This document draws heavily from the New Mexico State University Biological Safety Manual.

Use of biohazardous materials at Burrell College is regulated by federal, state and local requirements. The Dean of the College has assigned the responsibility for ensuring compliance to the Institutional Biosafety Committee (IBC). The IBC maintains the Biosafety Program to eliminate or minimize risks to the health of investigators, the community, and the environment.

All Burrell College principal investigators who use biohazardous materials must have an approved IBC application. This manual is intended to provide information on the IBC application, administrative biosafety, regulations, and selected biosafety activities to faculty, staff, and students working with biohazardous materials.

The IBC is committed to supporting the teaching and research mission at Burrell College by working with faculty, staff, and students to ensure continued growth in biomedical research. Please forward comments and suggestions that may enhance future editions of this manual.

This manual has been reviewed by members of the IBC, and will be revised periodically to update regulations, guidelines, policies, and the names of college offices or titles. Substantive changes require approval from the IBC and the Executive Committee of the College. Appendices contain operational procedures, which may be updated as needed; these updates shall not require the IBC approval unless a change substantively affects a provision or policy of the Biosafety Program.

RECORD OF REVIEW

Version 1.1: Effective 11/25/2019
Version 1.2: Effective 10/07/2020

BURRELL COLLEGE OF OSTEOPATHIC MEDICINE

EMERGENCY PREPAREDNESS

ASSISTANCE TELEPHONE NUMBERS

- Office of Research and Sponsored Programs…….. (575) 674-2338
- BioScience Research Laboratory Director…….. (575) 674-2326
- BioScience Research Laboratory Manager……. (575) 674-1761
- Las Cruces Fire Department (Non-emergency)…….. (575) 528-3473
- Las Cruces Police Department (Non-emergency)…….. (575) 526-0795
- Burrell College Security…….. (575) 674-2299
- Poison Control (West Texas Region)……..(800) 222-1222
- Burrell College Compliance Office……. (575) 674-2339

EMERGENCY TELEPHONE NUMBERS

- Fire..... 911
- Police 911
- Ambulance..... 911

What is an emergency? An emergency exists any time there is a fire, someone needs immediate medical attention, a crime is in progress, or if a chemical, biohazard or radiological spill threatens safety and health. **If you are not sure which office to call, contact the Las Cruces Police Department.**

In case of any emergency, laboratory personnel should remain calm and do only what is necessary to protect life, without jeopardizing their own safety.

1. Summon help immediately by calling 911.
2. Render assistance to persons involved. Do not move an injured person unless he or she is in danger of further harm.
3. Warn personnel in adjacent areas of any potential hazards to their safety.
4. In case of splash contact/exposure to chemical or biological hazards, flood the exposed area for 15 minutes with running water and immediately remove any contaminated clothing. Rinse contaminated skin or eyes with plenty of water for 15 minutes. Seek medical attention as soon as possible, and report all exposures to your supervisor.

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I. INTRODUCTION

The purpose of this manual is to provide information on fundamental elements of biological safety pertaining to research at the Burrell College of Osteopathic Medicine campuses and research centers. This information is derived from United States Government regulations, college policy and publications available in the public domain. Research activities conducted at Burrell College and Burrell College-affiliated sites may involve the use of biohazardous agents and other regulated materials or a potential for exposure to biohazardous agents. This manual provides guidance on research materials, facilities, work practices, and applicability to Burrell College research projects to establish and maintain a compliant research program. Of course, no single document or manual can account for every eventuality encountered in a dynamic teaching and research environment. Accordingly, this manual will be reviewed and if necessary, revised to communicate new regulations and reflect changes to established guidelines and College policy.

Burrell College is committed to the highest standards of integrity in all areas of research and academic activities. The college, through the Office of the Assistant Dean for Research, has established the Institutional Biosafety Committee (IBC), which oversees the use of biohazardous agents and/or recombinant nucleic acid molecules by college faculty, staff and students, or at college facilities. The IBC strives to develop awareness toward protecting the health of researchers, the community and the environment through an effective biological safety program that emphasizes risk assessment and biological containment. While the Principal Investigator remains responsible for overall compliance with regulations and policy for activities conducted at their direction, the IBC and the Office of Research and Sponsored Program (ORSP) are responsible for facilitating College safety by implementing programs that serve the faculty, students, employees and clients of the Burrell College of Osteopathic Medicine. This manual is a part of that effort.

II. SCOPE AND APPLICABILITY

General

The policy and regulatory content of this manual applies to activities in biomedical research venues that use biohazardous agents. Burrell College faculty and staff conduct or sponsor research and teaching activities likely to involve biohazardous agents. The means for declaring these activities is the Institutional Biosafety Committee (IBC) Application. The form is available online from the Institutional Biosafety Committee webpage at https://bcomnm.org/research/ibc/. Projects involving humans require additional approval by the Institutional Review Board (IRB). Burrell College does not currently allow research activities using animals, radioactive materials, or radiation generating equipment. Any future work with animals or radiation will require the establishment of an Institutional Animal Care and Use Committee (IACUC) and Radiation Safety Committee, respectively, which will be responsible for overseeing such work.

Research

This manual applies to clinical, laboratory, and fieldwork. Persons conducting laboratory research using viable organisms, environmental biological samples, animal or human organs, tissues, cell lines or internal body fluids, biological toxins, recombinant organisms or synthetic nucleic acid molecules must submit a completed and signed IBC application. Research shall not be initiated until the application is approved.

III. DEFINITIONS

Biohazardous Agents are defined as:

1) Any microorganism (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substance, including prions, or naturally occurring, bioengineered, or synthesized component of any such microorganism or infectious substance that is capable of causing:
   a) Death, disease or other biological malfunction in a human, an animal, a plant or another living organism;
   b) Deterioration of food, water, equipment, supplies, or materials of any kind; or
   c) A deleterious alteration of the environment.
2) Any toxic material or product of plants, animals, microorganisms (including but not limited to bacteria, viruses, fungi, rickettsiae, or protozoa), or infectious substances, or a recombinant or synthesized molecule (whatever the origin and method of production), which includes any poisonous substance or biological product that:
   a) May be engineered as a result of biotechnology;
   b) Is produced by a living organism; or
   c) Is an isomer or biological product, homologue, or derivative of such a substance.
3) Infectious or pathogenic biological agent in humans, animals or plants defined by:
   a) CDC as biosafety level (BSL) 2-4 (*BMBL*, current edition) or
   b) NIH as risk group (RG) 2-4 agent (*NIH Guidelines*, current revision).
4) A regulated biological agent or toxin as identified by
   a) Title 42 Code of Federal Regulations (CFR) Part 73 (The Transfer, Use, and Possession of Select Biological Agents and Toxins);
   b) Title 7 CFR Part 331 and Title 9 CFR Part 121 list of High Consequence Livestock Pathogens and Toxins that pose a severe threat to "animal health or animal products" or to "plant health or plant products"
5) Recombinant and synthetic nucleic acids, defined by the *NIH Guidelines* as:
   a) molecules that i) are constructed by joining nucleic acid molecules and ii) that can replicate in a living cell, i.e., recombinant nucleic acids;
   b) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or
   c) molecules that result from the replication of those described in (a) or (b) above.

Containment means the physical control of pathogens, infections agents, and recombinant DNA within a laboratory and includes specific work practices and security measures that control access to materials within the laboratory.

Infectious Agent means any organism, protein, or nucleic acid molecule that is capable of invading body tissues, replicating itself and causing disease.

Infectious waste, as defined by New Mexico Administrative Code Title 20 Chapter 9 Part 2, (February 2019, http://www.nmcpr.state.nm.us/) means "a solid waste that carries a probable risk of transmitting disease to humans or animals, and includes the following which shall be considered infectious waste:

a) cultures and stocks of infectious agents and associated biologicals, including: cultures from medical and pathological laboratories; cultures and stocks of infectious agents from research and industrial laboratories; waste from the production of biologicals; discarded live and attenuated vaccines except for residue in emptied containers; and culture dishes, assemblies and devices used to conduct diagnostic tests or to transfer, inoculate, and mix cultures;

b) human pathological wastes, including tissues, organs, and body parts that are removed during surgery, autopsy, other medical procedures, or laboratory procedures, but not including hair or nails;

c) human and body fluid waste, including: (i) liquid waste human blood; (ii) blood products; (iii) items with human blood (caking, flaking, saturated or dripping); (iv) items with human blood, including serum, plasma, and other blood components, which were used or intended for use in patient care, specimen testing, or the development of biological products or pharmaceuticals ; (v) intravenous bags that have been used for blood transfusions; (vi) items, including dialysate, that have been in contact with the blood of patients undergoing hemodialysis at hospitals or independent treatment centers; (vii) items contaminated by body fluids from persons at trauma scenes, during surgery, autopsy, other medical procedures, or laboratory procedures; (viii) specimens of blood products, and their containers; and (ix) other potentially infectious materials as defined by the U.S. Department of Labor Occupational Safety and Health Administration at 29 CFR 1910.1030(b), including the following body fluids: semen, vaginal secretions, cerebrospinal fluid, synovial fluid, pleural fluid, pericardial fluid, peritoneal fluid, amniotic fluid, saliva in dental procedures, any body fluid that is visibly contaminated with blood, and all body fluids in situations where it is difficult or impossible to differentiate between body fluids;

d) contaminated animal carcasses, body parts, blood, blood products, secretions, excretions, and bedding of animals that were known to have been exposed to zoonotic infectious agents or non-zoonotic human pathogens, including during research (including research in veterinary schools and hospitals), production of biologicals, or testing of pharmaceuticals.

e) biological wastes and waste contaminated with bloody excretions, exudates, or secretions from: (i) humans who are isolated to protect others from rare diseases such as viral hemorrhagic fevers (Ebola, Lassa, Marburg) or other emerging infectious diseases whose biological wastes and waste contaminated with bloody excretions, exudates, or secretions are deemed infectious waste as described by advisory agencies such as the Centers for Disease Control (CDC); (ii) isolated animals known or suspected to be infected with rare diseases such as bovine spongiform encephalopathy (BSE) or other emerging infectious diseases identified by an advisory agency;

f) discarded sharps, used or unused (unless in original packaging), generated at a facility, that have, or are likely to have, come in contact with infectious agents while involved in human or animal patient care, treatment, or research, including hypodermic needles, syringes (with the attached needle), Pasteur pipettes, scalpel blades, blood vials, needles with attached

tubing, culture dishes, suture needles, slides, cover slips, and other broken and unbroken glass or plastic ware, unless properly treated or otherwise specifically exempted;

g) infectious waste does not include:

(i) wastes generated in a household (except for infectious wastes generated by home health care professionals);

(ii) human corpses, remains, and anatomical parts that are intended for interment or incineration as specified in Paragraphs (4) and (5) of Subsection E of 20.9.8.13 NMAC, or are donated and used for scientific or medical education, research, or treatment;

(iii) etiological agents being transported for purposes other than waste processing or disposal pursuant to the requirements of the United States Department of Transportation (49 CFR 171.1-190) and the New Mexico Department of Transportation and other applicable shipping requirements;

(iv) reusable or recyclable containers or other non-disposable materials, if they are cleaned and disinfected by a method approved by the secretary pursuant to NMSA 1978 74-9-3 P, or if there has been no direct contact between the surface of the container and materials identified as "infectious waste;"

(v) soiled diapers that do not contain materials identified as infectious waste;

(vi) body excretions such as feces and secretions such as nasal discharges, saliva, sputum, sweat, tears, urine, and vomitus unless visibly contaminated with blood or waste from a person or animal as described in Subparagraph (e) of Paragraph (5) of Subsection I of 20.9.2.7 NMAC; or

(vii) used or unused syringes that have not come into contact with human blood or other bodily fluids or infectious agents and do not have a needle attached."

Laboratory Biosafety Levels (BSL-1, BSL-2, BSL-3, BSL-4) refer to a set of laboratory work practices, facility requirements, equipment and training that are used to mitigate hazards when working with biological agents. The levels are designated in ascending order, by degree of protection provided to personnel, the environment, and the community. Biosafety levels are defined in the CDC/NIH publication, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, which can be accessed online from www.cdc.gov .

Laminar Air Flow means unidirectional airflow at a constant velocity.

Pathogen means an organism, e.g., bacteria, virus, prion, fungus, or parasite that can cause disease in humans, animals, or plants.

IV. ROLES AND RESPONSIBILITIES

The College President has ultimate responsibility for establishing and maintaining health and safety programs and establishing a system for assessing safety performance for the College.

College Administration including all Vice-Presidents, Deans and Department Heads are responsible for:

1) Ensuring that facilities and equipment provided meet requirements for a safe work environment, or modifying those activities to come into compliance with applicable rules, regulations and standards.
2) Ensuring individuals under their management are in compliance with College, State and Federal environmental, health and safety policies, practices and programs.
3) Ensuring areas under their management are in compliance with College, State, and Federal environmental health, safety policies and programs.
4) Establishing priorities and committing resources for correction of environmental health and safety deficiencies.
5) Establishing procedures for disseminating safety-related policies and information;
6) Establishing procedures to implement policies.
7) Assessing safety performance to evaluate their areas of responsibility and reporting findings back to central administration.
8) Immediately notifying Burrell College Compliance Officer when they become aware of a violation of any College, State, or Federal environmental health or occupational safety rule or regulation. This includes any contact with a State or Federal regulatory agency regarding such a violation.

Supervisors, faculty, principal investigators, first-line supervisors, and all other persons in authority are responsible for:

1) Providing safe and healthy environments for those areas and personnel for whom they have supervisory or administrative responsibility, incorporating safety and health issues as an integral part of all activities at Burrell College.
2) Being continuously cognizant of the safety and health needs of all co-workers and employees for whom they are responsible.
3) Initiating and enforcing preventive measures to control hazards.
4) Communicating with administrators and safety staff to ensure that necessary support such as engineering and administrative controls, personal protective equipment, occupational medical examinations and local exhaust ventilation are in place and adequate for operations.
5) Ensuring employees are trained prior to beginning new tasks.
6) Reporting injuries and illnesses to the Human Resources Director and the Institutional Biosafety Committee.
7) Reviewing incident and injury reports for their area(s) and implementing corrective actions.
8) Serving as a focal point for employee safety and health concerns.

9) Immediately notifying the Compliance Officer when they become aware of a violation of any College, State or Federal environmental health or occupational safety rule or regulation. This includes any contact with a State or Federal regulatory agency regarding such a violation.

All Burrell College faculty, staff, and students are responsible for:

1) Participating in mandated training programs provided by ORSP, their supervisors, and other instructors.
2) Properly using college-supplied materials and equipment.
3) Using good judgment in carrying out work assignments and following established procedures.
4) Promptly reporting unsafe conditions, health hazards, injuries and illnesses to the responsible supervisor.
5) Giving due consideration to personal safety and the safety of others
6) Strictly adhering to Federal, State, and College safety requirements and guidelines.
7) Knowing that disregard or chronic negligence of established policies and procedures can result in disciplinary action.

The Office of Research and Sponsored Programs is responsible for:

1) Conducting annual inspection of facilities identified on IBC applications to ensure that laboratory standards are rigorously followed.
2) Maintaining a biosafety library of reference publications and training materials.
3) Providing biosafety training.
4) Reporting to the College any significant problems and violations of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and other standards of safety for the use of biohazardous research materials.
5) Reporting any significant research-related accidents or illnesses to the NIH Office of Biotechnology Activities and the College.
6) Reviewing emergency plans developed for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant nucleic acid molecules or biohazardous materials.
7) Providing advice on laboratory security.
8) Providing technical advice to Principal Investigators, staff, and the IBC on biosafety guidelines, standards, and practices.
9) Being aware of and reviewing testing programs designed to demonstrate the integrity of containment equipment and facility safeguards.
10) Supervising emergency laboratory decontamination measures.
11) Maintaining a database of IBC applications submitted for review and approval.
12) Facilitating shipping of biological materials to ensure safety and compliance.

V. ADMINISTRATIVE BIOSAFETY

Administrative biosafety pertains to procedural and documentary record keeping on policy and regulatory compliance for the laboratory. The primary administrative biosafety documents at Burrell College are the IBC application, the Activity Modification Report, training records and the Proposal Transmittal Form from the Office of Research and Sponsored Programs. The IBC application is addressed in Section VI of this manual.

Other documents that may have a Biosafety component are the application forms for the Institutional Review Board (IRB) for research with human subjects. These applications are forwarded to the IBC for concurrent review when proposals include the use of recombinant nucleic acids and/or infectious agents.

Additionally, there are government and vendor-generated documents related to regulatory and policy compliance. For example, purchasing research materials from a commercial vendor necessarily creates a paper trail of the transaction. Documents related to the acquisition, transfer and use of some research materials are legally significant to the Principal Investigator and the college. In some instances, there are statutory requirements for archiving these documents. Generally, records for obtaining and transfer of research materials should be kept for three years or more after the completion of the research or the researcher is no longer in possession of the material, financial records must be kept for seven years, and records for employee health should be kept for 30 years after separation of employment.

The Office of Research and Sponsored Programs and the Principal Investigator must work together to ensure the college maintains accurate records of research and documentation of regulatory compliance. Faculty and staff are not authorized to sign any legally binding document of terms and conditions on behalf of the college. The Assistant Dean for Research is responsible for signing all agreements related to research activities.

Grants and Contracts Proposal Award Review

All research grants under consideration for funding or having been awarded funding are internally reviewed for use of hazardous chemicals, infectious materials and recombinant DNA. The PI is responsible for obtaining review and approval from each respective Burrell College oversight committee and compliance with Burrell College safety policies. For example, the hazardous chemical inventory must be updated at least annually.

The Assistant Dean for Research has established the following internal review to ensure compliance with the regulations and Burrell College safety policy.

The Assistant Dean for Research reviews records to ensure that necessary committee approvals (IBC and/or IRB) have been obtained and are in good standing. ORSP notifies the PI if a necessary approval is lacking and must be obtained.

Principal Investigators (PIs) must submit an IBC application for any research involving infectious agents or recombinant DNA. All applications are administratively reviewed. Potential results of the administrative review are 1) approval without further action or 2) the application will be reviewed and voted upon by the IBC. The PI will be informed of the result.

Permits

Depending on the nature of the organisms or biological material and the type of experiment (laboratory or clinical site), a permit may be required. The trial sponsor or the Burrell College Principal Investigator may submit the permit application for a specific research grant. In all cases, it is the researcher's responsibility to learn of federal and state permitting requirements for their respective projects, and coordinate with Burrell College ORSP and other appropriate Burrell College administrative offices. Examples of permit issuing agencies are the U.S. Department of Health and Human Services and the U.S. Environmental Protection Agency.

There are restrictions on some items intended for import and export (including naturally occurring and genetically modified organisms, animals, animal tissues, and some regulated technologies). Issuance of a permit to possess, transfer, or use a particular research material is predicated on the applicant's agreement to fulfill specific terms and conditions defined in the permit.

- The importation of animals, crops, foodstuffs, or biological samples may require an import permit from the USDA, CDC and/or FDA.
- Materials and technologies listed on the Commerce Control List of items are prohibited from export. These materials and technologies are deemed by the U. S. Government to have a "dual use" beyond bona fide research and may pose a threat to the public health or national security.
- **Organisms that are known human pathogens or listed as a Select Agent or Toxin by HHS, or as a High-Consequence Livestock Pathogen or Toxin by the USDA, cannot be possessed, purchased, or transferred unless the College is registered with either or both federal agencies (depending on the agent or toxin).** The application for registration to transfer, possess, or use Biological Select Agents or Toxins is available on the internet at http://www.selectagents.gov. In addition to the application, registration requirements include a U.S. Department of Justice Security Risk Assessment (conducted by the FBI) of each person accessing Select Agents including the Responsible Official, and a facility inspection by the CDC or APHIS or both. This is a lengthy (8 – 12 months

minimum) and cumbersome process since some of the plans, program descriptions and other information requested in the application do not exist and must be generated from "scratch". If the need arises, the Assistant Dean for Research will submit the Select Agent permit application for Burrell College on behalf of a Principal Investigator interested in conducting research using Select Agents or Toxins. Research involving permissible amounts of National Select Agent Registry toxins must be approved by the Burrell College IBC prior to receipt of the material.

A copy of the permit must accompany all IBC applications involving permitted materials. The Principal Investigator is responsible for discovery of import restrictions and permit requirements. In the event that a permit requirement is unknown or uncertain, contact the appropriate agency directly, or contact the Office of Research and Sponsored Programs for assistance.

Purchase Orders

Many vendors have expanded the pre-conditions for the purchase of laboratory equipment, reagents and supplies routinely used in research. These conditions address regulatory and industry requirements (US Department of Commerce, USDA, HHS, US Postal Service, commercial shipping companies and the airline industry) as well as intellectual property and product development rights related to use of the item or material in question.

For example, the American Type Culture Collection (ATCC) is a biological supply house that sells cell lines, bacterial and viral stocks, and nucleic acid molecules. The ATCC requires each purchaser to enter into a Material Transfer Agreement (MTA) prior to fulfilling a purchase order. The MTA defines the specific terms and conditions for subsequent product use. ATCC products are restricted to research use in the laboratory of the purchaser. Purchasers are prohibited from subsequent distribution to colleagues (at Burrell College or other sites) without the expressed written consent of the ATCC. The purchaser agrees to destroy the material at the conclusion of their work.

Another document tendered by the ATCC is the "Customer Acceptance of Responsibility" (CAR) form. Acceptance of the terms and conditions of the CAR apply to the purchase of certain bacteria and viruses vended by the ATCC that are included on the U.S. Department of Commerce "commerce control list" of materials that may pose a risk to the public health, or have a potential for "dual use" and is therefore prohibited from export. A new CAR form is required for each purchase of these materials. In summary, any document that mentions legal liability should be vetted through the Office of the Assistant Dean for Research for acceptance by Burrell College.

Required Training

The following are descriptions of training sessions provided by ORSP to faculty, staff and students as required by OSHA regulation or Burrell College policy or both. Administrative review of IBC application submissions includes a review of training records for all persons listed on the IBC application, including the PI. Attendance or completion at appropriate training sessions is a condition of IBC approval. Personnel must complete the required training before they start working in the laboratory.

Hazard Communication training is mandated under OSHA and Burrell College Policy for all employees of the College who work with or near chemicals. This is a one-time requirement for each employee and student as long as the work environment remains the same. Repeat the HazCom training when significant changes occur in the job duties, materials, locations, or procedures.

Laboratory Standard training is required for faculty, staff, and students that work in a laboratory where hazardous or toxic chemicals are present. The initial class provides information on compliance with the regulations. Retraining every three (3) years is required for review of the Chemical Hygiene Plan and other relevant laboratory safety procedures.

Biosafety and Biosecurity training is required for faculty, staff and students identified on an IBC application for approval to handle biohazardous agents. Biosafety Awareness Training is available through CITI. Documentation of IBC approval will not be released until all persons have completed the Biosafety and Biosecurity training. Refresher training is required annually for each employee or student who handles biohazardous agents.

OSHA Bloodborne Pathogens (BBP) training is required for persons whose routine tasks and duties involve reasonably anticipated exposure to blood, internal body fluids, unfixed cells or tissues from humans or non-human primates. BBP training is also required for laboratory work with human immunodeficiency virus (HIV), hepatitis B virus (HBV), hepatitis C virus (HCV) or other bloodborne pathogens. Refresher training is required annually for each employee or student whose work meets the above criteria. Training is provided through CITI.

NIH Recombinant DNA (rDNA) Guidelines training is required for persons conducting research involving recombinant or synthetic nucleic acid molecules. Documentation of IBC approval will not be released until all persons have completed the NIH Recombinant DNA Guidelines training. Training is provided through CITI.

VI. THE IBC APPLICATION

The Institutional Biosafety Committee (IBC) Application is used to document the "who, what, where, and how" for all research projects involving biohazardous agents and recombinant nucleic acids at Burrell College and Burrell College-affiliated locations (see Section III for the definition of biohazardous agents). IBC applications may be exempt from the *NIH Guidelines*. In conformance with the *NIH Guidelines*, the Principal Investigator makes the initial determination to classify the experiments, and then the IBC reviews the application to confirm, or in some cases reevaluate, the classification. Exempt activities are usually administratively approved and non-exempt activities are reviewed and voted on by the IBC. As a matter of Burrell College policy, the final determination of exempt or non-exempt status rests with the IBC.

The ability of the IBC to provide a timely review of applications depends in large part on the completeness of the information contained in the submission. The narrative sections required in the IBC application prompts the applicant to submit questions or solicit advice on matters related to procedural or facility biosafety for the proposed project to members of the IBC. All applications are administratively reviewed for completeness, regulatory and policy compliance prior to distribution to the IBC membership. Compliance is evaluated by checking the training records of the Principal Investigator (PI) and staff in the Burrell College training database. If necessary, the IBC Chair will contact the PI for additional information or clarification of information included in the application.

The application is either administratively approved or remanded to review and vote by the IBC. Approval granted administratively or by a vote of the IBC is valid for three years from the date of issue.

The PI on applications scheduled for IBC review will be notified via email of the scheduled IBC review date. Although not required, PIs are encouraged to be present at the IBC meeting while their application is being reviewed. Scheduling is coordinated through the ORSP.

Major and minor changes in the research and teaching conducted under an IBC-approved application must be communicated to the IBC in a timely manner. The Activity Modification Report form is used for communicating both major and minor modifications to approved applications. The form is available from the IBC webpage, which can be accessed from https://bcomnm.org/research/ibc/ and is included as Appendix B of this manual.

Section I: Administrative Information

The information requested in this section identifies the Principal Investigator, co-Principal Investigators (if any), the project title, the funding source and a proposed Biosafety Level for the project. The IBC may accept or revise the Biosafety level proposed by the applicant. The

"Category of Application" distinguishes new applications from continuing approvals and grant-specific applications from general research activities. The information provided may also be used to coordinate related internal administrative processes.

Section II: Institutional & Regulatory Approval / Registrations

The Institutional and Regulatory Approval / Registration section identifies projects subject to college oversight (other than the IBC) and Federal or State permit requirements. A brief description of each sub-sections follows.

Use of Human Subjects: The use of human study subjects is reviewed and approved by the Burrell College Institutional Review Board (IRB). The College maintains a Federal Wide Assurance as required under Title 45 of the Code of Federal Regulations Part 46, Protection of Human Subjects. No research involving human subjects, including the collection of data about or from human subjects using surveys, existing data, or specimens, can begin without IRB approval.

Federal Permits: Acquisition, possession, transfer (interstate, intrastate, import or export) and use of certain bacteria, viruses, rickettsia, parasites, biological or plant toxins, plants, plant pests, genetically modified organisms, and whole or parts of the genetic elements from these biological agents, require obtaining a permit. Permitting agencies include the US EPA, CDC, USDA Animal and Plant Health Inspection Service (APHIS), the NM Department of Agriculture (NMDA), and the New Mexico Department of Fish and Wildlife. It is incumbent on the Applicant to obtain the required permit(s) for materials to be used in the proposed research. There is no college-wide permit to acquire, possess, transfer (interstate, intrastate, import or export) or use permitted materials. Permit applications under review by the permitting entity at the time of application can be reported as such on the application; however, IBC approval is contingent on IBC receipt and administrative review of the permit. Due to the expanding regulatory and enforcement climate, applicants are encouraged to contact the ORSP for assistance with discovery of permit requirements and if necessary, assistance with the application process.

Section III: Location of Activities

The information provided in this section is used to verify that the facility is appropriate to support the scope of work proposed in the application. Identify each laboratory, preparation room, shared equipment space or rooms, and off-campus locations used for the proposed research.

Section IV: Type of Biologicals and Biosafety Activity

There are three sections that ask for information relevant to the risk assessment of the proposed research project. For each agent or material identified (bacteria, virus, fungi, parasite, toxin, other agent or component), this section asks the applicant to comment on the following:

- Strain or type of bacteria, cell line, or virus, or other biological materials,
- If a biological safety cabinet will be used for experiments with the listed materials,
- If there is a protective vaccine against the disease caused by the agent, and if the Public Health Service Advisory Committee on Immunizations Practices recommends the vaccine,
- Special precautionary measures warranted with the proposed research.

Responses to application items about recombinant DNA and the Biosafety Level demonstrate that the PI is familiar with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* and the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories*. For recombinant materials, the applicant identifies (i) the source(s) of DNA; (ii) the nature of the inserted DNA sequences; (iii) the host(s) and vector(s) to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions that will be implemented as specified in the *NIH Guidelines*.

Note: The *NIH Guidelines* describes a number of places where judgments are to be made. In all these cases, the Principal Investigator shall make the judgment on these matters as part of his/her responsibility to "make the initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines*" (see *NIH Guidelines* Section IV-B-7-c-(1)). For cases falling under *NIH Guidelines* Sections III-A through III-E, *Experiments Covered by the NIH Guidelines*, this judgment is to be reviewed and approved by the Institutional Biosafety Committee as part of its responsibility to make an "independent assessment of the containment levels required by the *NIH Guidelines* for the proposed research".

Section V: Description of Activity

Section V requires the applicant to identify the procedures that will be used to conduct the activities. Part A asks for a description of the activity in terms easily understood by a non-

scientist. Useful information includes the research problem or question to be explored, brief description of methods, and the projected outcome or the intended use of the data to be obtained.

A sample lay summary for a teaching experiment might be "We will grow a well characterized, commercially obtained strain of *E. coli* that does not cause illness in healthy humans. We have obtained a group of genes of interest. We will express these genes in the *E. coli* to see if the gene works and the trait is expressed." Similar wording should be used for research projects.

Part B requires a list of procedures used in the experiment. For example, "We will use standard molecular biology techniques as described in "Molecular Cloning" by Maniatis et al, 2nd Edition, 1989. General procedures include bacterial cell culture, pipetting, centrifugation, nucleic acid purification and restriction, agarose gel electrophoresis. Support procedures include preparation of bacterial media (LB), buffer (PBS, Tris) and reagents, steam sterilization of pipette tips and other supplies, chemical decontamination of liquids, and autoclaving of contaminated solid waste. The (bacteria or virus) will be expanded in cell culture using the prepared media. No more than 2.0 L will be in culture at any given time. The cells will be harvested and lysed to recover cellular DNA or antigen by a series of filtration and centrifugation steps (identify steps). Aseptic procedures will be performed in a certified biological safety cabinet. Finally, we will prepare a solution of the recovered viral antigen and isolate DNA by agarose gel electrophoresis to discover if the component nucleic acids migrate across the gel according to our predicted model."

Part C item 1 contains a template version of routine substance disposal and decontamination procedures that are based on Burrell College policy and applicable regulations. Part C item 2 asks the PI to specify additional waste handling, decontamination, and disposal operations beyond those described in item 1.

Part D asks the PI to indicate if a biological safety cabinet (BSC) or clean air bench (CAB) will be used. For each piece of equipment used the PI must state the equipment location (building and room), the manufacturer, model, serial number and date of the most recent certification (BSC, CAB).

Section VI: Personnel

Section VI asks for the names of personnel assigned to work on the proposed project and for a description of their training and education. Experience with specific laboratory techniques and equipment is requested for each person listed in this section, including the PI. Examples include gel electrophoresis, cell culture, centrifugation, type of PCR, media and buffer preparation. When appropriate, state that a new hire or student has "no experience" and will be working under supervision with the experimental techniques and equipment. ***Under no circumstances will an inexperienced and untrained person be left unsupervised while performing experimental procedures and techniques.*** The PI maintains a record of all training. The IBC requires that inexperienced personnel be trained according to the following protocol:

1) Inexperienced personnel will read and understand the written descriptions of experimental procedures.
2) Inexperienced personnel will observe as the PI or other person trained by the PI demonstrates the experimental procedures and techniques.
3) Inexperienced personnel then perform experimental procedures and techniques under direct supervision of the PI or other person trained by the PI until the inexperienced personnel demonstrates competency in the experimental procedures and techniques.

ORSP will check training records for all personnel listed on the application, including the PI, and enter the training dates on the application form. The PI is responsible for ensuring that personnel complete the appropriate safety training for the work to be performed.

Section VII: Safety Plans

All personnel are subject to the Laboratory Safety Plan. The Laboratory Director will provide emergency contact information. Contact name, business phone and after-hours phone contact information will be posted at the laboratory entrance.

The laboratory safety plan provides information on the following:

1) The types of hazards (biological, chemical) are present in the lab
2) The safety training requirements for persons entering the lab
    a) Hazard Communication, Lab Standard, OSHA Bloodborne Pathogens, and Biosafety Awareness are required for all personnel entering the Burrell College BioSciences Research Laboratory;
3) The personal protective equipment (PPE) required to enter the laboratory.
4) Description of spill response procedures for biological and/or chemical incidents.
5) Who, beyond the Laboratory Director, to notify in the event of an emergency. Provide contact information.
6) Laboratory security (i.e., when are doors locked, access by visitors).

The Emergency Response Plan instructs occupants what to do in the event of a natural or man-made disaster. Natural disasters include fire, flood, or high-wind event that may pose a threat to the building integrity or occupants. Man-made disasters include spills involving large quantities of hazardous materials or an explosion. The plan includes posting an emergency egress map that identifies paths to exit the building and designates a rendezvous location outside the building. Additional information is available from Burrell College Assistant Vice President for Administration.

Section VIII: Principal Investigator Statement

The "Principal Investigator Statement" lists expectations for the safe conduct of IBC-approved research and attests to the PI's commitment to complying with all applicable regulatory and Burrell College policy requirements. Briefly, the statement informs the PI of the following requirements:

1) Conduct research and teaching activities in compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, current national standards in the Public Health Service publication, *Biosafety in Microbiological and Biomedical Laboratories*, and other applicable standards and regulations.
2) Ensure that laboratory workers receive training on emergency procedures, good laboratory work practices, the safe operation of laboratory equipment, and that they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the lab.
3) Provide staff with necessary personal protective equipment.
4) Report to the IBC of all instances of:
    a) Occupational injury or exposure to biohazardous agents or recombinant or synthetic nucleic acid molecules (through needle sticks, wounds, inhalation, ingestion, or splashes to the face).
    b) Events (known or likely) resulting in environmental release of biohazardous agents or recombinant or synthetic nucleic acid molecules.
    c) Instances of containment equipment breakdown and facility system failures.
5) Submit an Activity Modification Report for the following MINOR modifications of IBC-approved research:
    a) When new staff are added or removed.
    b) Laboratory renovation.
    c) Research relocation to a different laboratory.
    d) When the project is temporarily suspended or terminated.
    e) When research no longer involves animal cells or tissues, infectious or pathogenic organisms, or recombinant nucleic acid molecules.
6) Submit a new IBC Application for the following MAJOR modifications.
    a) Change in PI.
    b) The project expands to include animal cells or tissues, recombinant or synthetic nucleic acids, or biological agents that are infectious, pathogenic or toxic.
    c) Research needs to progress from BSL-1 to BSL-2 facility and work practices.
    d) Substantial changes in the IBC-approved procedures (new technology or novel recombinant genetic construct) or initial acquisition of new organisms or toxins. Submit description of changes to the IBC Chair through the Office for Research & Sponsored Programs for review on a case-by-case basis.
7) The signed Principal Investigator statement binds the signatory to the conditions that must be maintained to conduct the IBC-approved activities.

VII. BIOSAFETY LEVELS AND WORK PRACTICES

This section reviews the standard requirements for laboratory research conducted at Burrell College that involves biological procedures, including molecular and microbiological techniques, in cells, tissues and organisms.

The term, "biosafety level" describes a combination of administrative controls, work practices, safety equipment, and facility design requirements that are used to manage the conditions under which harmful biological agents can be safely maintained and manipulated. Information here is referenced from the following publications:

- **Biosafety in Microbiological and Biomedical Laboratories ("BMBL"), 5th Edition**, 2009, DHHS, Public Health Service, Centers for Disease Control and Prevention, Atlanta, Georgia, and National Institutes of Health, Bethesda, Maryland. Available at http://www.cdc.gov/biosafety/publications/bmbl5/index.htm
- ***NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* ("*NIH Guidelines*"), April 2016 or latest revision,** available at https://osp.od.nih.gov/biotechnology/nih-guidelines/

BSL-1 and BSL-2 describes standard practices, special work practices, safety equipment and facility requirements used for biomedical, microbiological and molecular biology research in laboratories, animal facilities, and greenhouses.

Research at Burrell College typically is conducted in laboratories using Biosafety Level 1 (BSL-1) and BSL-2 containment. Burrell College does not conduct research at BSL-3 or BSL-4.

Biosafety Level 1 (BSL-1) for Molecular and Microbiological Experiments

Biosafety Level 1 is suitable for work involving well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment. The laboratory is not necessarily separated from the general traffic patterns in the building. Work is generally conducted on open bench tops using standard microbiological practices. Special containment equipment or facility design is not required, but may be used as determined by appropriate risk assessment. Laboratory personnel have specific training in the procedures conducted in the laboratory and are supervised by a scientist with 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:

A. Standard Microbiological Practices for BSL-1

1. Access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments or work with cultures and specimens are in progress.
2. Persons wash their hands after they handle viable materials, after removing gloves, and before leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food or cosmetics for human use are not permitted in the work areas. Persons who wear contact lenses in laboratories should also wear goggles or a face shield. Food is stored outside the work area in cabinets or refrigerators designated and used for this purpose only.
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.
5. Policies for the safe handling of sharps, such as needles, scalpels, pipettes, and broken glassware, are implemented. Whenever practical, laboratory supervisors should adopt improved engineering and work practice controls that reduce risk of sharps injuries.
6. All procedures are performed carefully to minimize the creation of splashes or aerosols.
7. Work surfaces are decontaminated at least once a day and after any spill of viable material.
8. All cultures, stocks, and other regulated wastes are decontaminated before disposal by an approved decontamination method such as autoclaving. Materials to be decontaminated outside of the immediate laboratory are to be placed in a durable, leak-proof container that is closed prior to transporting from the laboratory. Materials to be removed from the facility for decontamination must be packed in accordance with applicable local, state, and federal regulations.
9. An effective integrated pest management program is required.
10. The laboratory supervisor must ensure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be

encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices: None for work at BSL-1

C. Safety Equipment (Primary Barriers) for BSL-1

1. Special containment devices or equipment such as biological safety cabinets are not generally required for manipulations of agents assigned to Biosafety Level 1.
2. Protective laboratory coats, gowns, or uniforms are recommended to prevent contamination or soiling of personal clothing.
3. Gloves should be worn if the skin on the hands is broken or if a rash is present. Alternatives to powdered latex gloves should be available.
4. Protective eyewear should be worn for conduct of procedures in which splashes of microorganisms or other hazardous materials is anticipated.

D. Laboratory Facilities (Secondary Barriers)

1. Laboratories should have doors for access control.
2. Each laboratory contains a sink for hand washing.
3. The laboratory is designed so that it can be easily cleaned. Carpets, rugs and cloth-covered furniture in laboratories are not appropriate.
4. Bench tops are impervious to water and are resistant to moderate heat and the organic solvents, acids, alkalis, and chemicals used to decontaminate work surfaces and equipment.
5. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning.
6. Laboratory windows that open to the exterior are fitted with screens.

Biosafety Level 2 (BSL-2) for Molecular and Microbiological Experiments

Biosafety Level 2 is similar to Biosafety Level 1 and is suitable for work involving agents of moderate potential hazard to personnel and the environment. It differs from BSL-1 in that (1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists with experience in the procedures; (2) access to the laboratory is restricted when work is being conducted; and (3) all procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.

In addition to general laboratory training requirements, all personnel attend Laboratory Biosafety Awareness training.

The following standard and special practices, safety equipment, and facilities apply to agents assigned to Biosafety Level 2.

A. Standard Microbiological Practices for BSL-2

1. Access to the laboratory is restricted when experiments are in progress.
2. Persons wash their hands after removing gloves and just prior to leaving the laboratory.
3. Eating, drinking, smoking, handling contact lenses, applying cosmetics, and storing food for human consumption are not permitted in the work areas. Food and cosmetics for human use are stored outside the laboratory area in cabinets or refrigerators designated for this purpose only.
4. Mouth pipetting is prohibited; mechanical pipetting devices are used.
5. Use of sharps is minimized, and spent sharps are disposed of in red, puncture-resistant containers manufactured for the purpose of sharps disposal.
6. Broken glassware must not be handled directly. Instead, it must be removed using a brush and dustpan, tongs, or forceps. Plastic ware should be substituted for glassware whenever possible. Containers of contaminated needles, sharp equipment, and broken glass are decontaminated by autoclaving or other means prior to contacting EH&S for pick up.
7. All procedures are performed carefully to minimize the creation of splashes or aerosols.
8. Work surfaces are decontaminated on completion of work and at end of day and after any spill or splash of viable material with disinfectants that are effective against the agents of concern.
9. All cultures, stocks, and other regulated wastes are decontaminated before disposal by autoclaving. Methods to demonstrate sterility must be used when disinfecting infectious waste by autoclaving prior to disposal. Materials to be decontaminated outside of the immediate laboratory are transported in a closed, leak-proof secondary container labeled with the biohazard symbol.
10. A sign incorporating the universal biohazard symbol must be posted at the entrance to the laboratory when infectious agents are present. Posted information must include: the laboratory's biosafety level, the investigator's name and contact information and the name and contact information of a second person familiar with the laboratory as an emergency contact, any personal protective equipment that must be worn in the laboratory, the required immunizations, and the procedures required for entering and exiting the laboratory. Agent information (e.g., organism name) is posted according to departmental emergency procedures for safety and security.
11. An effective integrated pest management program is required.
12. The laboratory supervisor must insure that laboratory personnel receive appropriate training regarding their duties, the necessary precautions to prevent exposures, and exposure evaluation procedures. Personnel must receive annual updates or additional training when procedural or policy changes occur. Personal health status may impact an individual's susceptibility to infection, ability to receive immunizations or prophylactic interventions. Therefore, all laboratory personnel and particularly women of childbearing age should be provided with information regarding immune competence and conditions that may predispose them to infection. Individuals having these conditions should be encouraged to self-identify to the institution's healthcare provider for appropriate counseling and guidance.

B. Special Practices for BSL-2

1. All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements. 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. The laboratory director has the final responsibility for assessing each circumstance and determining who may enter or work in the laboratory.
2. The laboratory director establishes and the IBC approves procedures for personnel to receive appropriate immunizations or medical surveillance for the agents handled or potentially present in the laboratory (e.g., hepatitis B vaccine or TB testing).
3. The laboratory director should consider the need for collection and storage of serum samples from at-risk personnel, depending on the agents handled or the function of the facility.
4. This biosafety manual must be adopted as policy, and supplemented with laboratory-specific safety information prepared by the laboratory director. The biosafety manual must be available and accessible. Personnel are required to sign a laboratory-specific safety statement certifying that they have been advised of special hazards and agree to follow instructions on practices and procedures.
5. The laboratory supervisor must ensure that laboratory personnel demonstrate proficiency in standard and special microbiological practices before working with BSL-2 agents. Personnel receive annual updates or additional training as necessary or as procedures change. The laboratory director maintains a record of training for all laboratory personnel, including laboratory-specific training as well as the safety classes. Personnel who have not completed the necessary training are not allowed to work in the laboratory.
6. Cultures, tissues, body fluid specimens, or potentially infectious materials are placed in a durable container with a cover that prevents leakage during collection, handling, processing, storage, or transport within a facility.
7. Laboratory equipment should be decontaminated routinely, as well as after spills, splashes, or other potential contamination.
    a. Spills involving infectious materials must be contained, decontaminated, and cleaned up by staff properly trained and equipped to work with infectious materials.
    b. Equipment must be decontaminated before repair, maintenance, or removal from the laboratory. A record of the decontamination must be prepared and kept for three years. Follow established decommissioning procedures for disposal of large equipment such as refrigerators or incubators regardless of working or non-working condition.
8. Incidents that may result in exposure to infectious materials are immediately evaluated and treated according to the Bloodborne Pathogen Exposure Control Plan. All such incidents are reported to the Laboratory Director and Burrell College Compliance Officer. A physician provides medical evaluation, surveillance, and treatment, and the Human Resources office maintains appropriate records.

9. All procedures involving the manipulation of infectious materials that may generate an aerosol are conducted in a certified biological safety cabinet or other physical containment device.

C. Safety Equipment (Primary Barriers) for BSL-2

1. Properly maintained and certified biological safety cabinets (BSC), preferably Class II, or other appropriate personal protective equipment or physical containment devices are used whenever:
   c. procedures with a potential for creating infectious aerosols or splashes are conducted. These may include pipetting, centrifuging, grinding, blending, shaking, mixing, sonic disruption, opening containers of infectious materials whose internal pressures may be different from ambient pressures, inoculating animals intranasally, and harvesting infected tissues from animals or eggs.
   d. high concentrations or large volumes of infectious agents are used. Such materials may be centrifuged in the open laboratory using sealed rotor heads or centrifuge safety cups.
2. Protective laboratory coats, gowns, smock, or uniforms designated for lab use are worn while in the laboratory. This protective clothing is removed and left in the laboratory before leaving for non-laboratory areas (e.g., administrative offices). All protective clothing is either disposed of in the laboratory or laundered by the institution; personnel do not take laundry home.
3. Eye and face protection (goggles, mask, face shield or other splatter guard) is used for anticipated splashes or sprays of infectious or other hazardous materials when the microorganisms must be handled outside the BSC or containment device. Eye and face protection is disposed of with other contaminated laboratory waste or decontaminated before reuse. Persons who wear contact lenses should wear eye protection in laboratories.
4. Gloves are worn when hands may contact potentially infectious materials, contaminated surfaces or equipment. Glove selection should be based on an appropriate risk assessment. Alternatives to latex gloves should be available. Gloves must not be worn outside the laboratory. In addition, BSL-2 laboratory workers should:
   e. Change gloves when contaminated, glove integrity is compromised or when otherwise necessary.
   f. Remove gloves and wash hands when work with hazardous materials has been completed and before leaving the laboratory.
   g. Disposable gloves are not washed or reused. Dispose of used gloves with other contaminated laboratory waste. Hand washing protocols must be rigorously followed.

D. Laboratory Facilities (Secondary Barriers) for BSL-2

1. Laboratory doors should be self-closing and are locked when personnel are not present.
2. Each laboratory contains a sink for hand washing; hands-free operation is preferred.
3. The laboratory is designed so that it can be easily cleaned and decontaminated. Carpets and rugs are not permitted in laboratories.

4. Laboratory furniture is capable of supporting anticipated loading and uses. Spaces between benches, cabinets, and equipment are accessible for cleaning. Bench tops are impervious to water and are resistant to heat, organic solvents, acids, alkalis, and chemicals used to decontaminate the work surfaces and equipment. Chairs and other furniture used in laboratory work are covered with a non-porous material that can be easily decontaminated with appropriate disinfectant.
5. Laboratory windows that open to the exterior must be fitted with screens.
6. Install biological safety cabinets so that fluctuations of the room supply and exhaust do not interfere with proper operations. Locate biological safety cabinets away from doors, windows that can be opened, heavily traveled laboratory areas, and other possible airflow disruptions to maintain the biological safety cabinets' air flow parameters for containment.
7. Vacuum lines are protected with liquid disinfectant traps.
8. An eyewash station is readily available within 50 feet of the work area.
9. There are no specific ventilation requirements. However, planning of new facilities should consider mechanical ventilation systems that provide an inward flow of air without recirculation to spaces outside of the laboratory.
10. HEPA filtered exhaust air from a Class II BSC can be safely recirculated back into the laboratory environment if the cabinet is tested and certified at least annually and operated according to manufacturer’s recommendations. BSCs can also be connected to the laboratory exhaust system by either a thimble (canopy) connection or directly exhausted to the outside through a hard connection. Provisions to assure proper safety cabinet performance and air system operation must be verified.
11. A method for decontaminating all laboratory wastes is available in the facility (e.g., autoclave, chemical disinfection, incineration, or other validated decontamination method).

Table 1. Summary of Recommended Biosafety Levels for Infectious Agents

Source: BMBL, 5th Ed., Section IV

BSL	Agents	Practices	Primary Barriers and Safety Equipment	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	• No primary barriers required. • PPE: lab coats, gloves, eye and/or face protection as needed	Laboratory bench and sink required
2	Associated with human disease • Routes of transmission include percutaneous injury, ingestion, mucous membrane exposure	BSL-1 practice plus: • Limited access • Biohazard warning signs • "Sharps" precautions • Biosafety manual defining any needed waste decontaminati on or medical surveillance policies	Primary barriers: • Biosafety cabinet (BSC) or other physical containment devices are used for all manipulations of agents that cause splashes or aerosols of infectious materials • PPE: Lab coats, gloves, face and eye protection as needed.	BSL-1 plus: • Autoclave available
3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure	BSL-2 practice plus: • Controlled access • Decontamination of all waste • Decontamination of laboratory clothing before laundering	Primary barriers: • Biosafety cabinet (BSC) or other physical devices used for all open manipulations of agents • PPE: Protective lab clothing, gloves, face, eye and respiratory protection as needed.	BSL-2 plus: • Physical separation from access corridors • Self-closing, double-door access • Exhausted air is not recirculated • Negative airflow into lab • Entry through airlock or anteroom • Hand washing sink near lab exit

VIII. OVERVIEW OF SELECTED BIOSAFETY PROCEDURES AND TASKS

This section presents basic information about equipment and procedures that are commonly used in laboratories for cell biology, tissue culture, molecular biology, and microbiology activities.

AUTOCLAVES AND STEAM STERILIZATION

Principle

Supersaturated steam (water heated above 212° F) under pressure is an efficient and cost effective means of:

1) Sterilization of liquids and heat-stable solids and
2) Decontaminating viable organisms cultured on solid media and related biohazardous waste.

Overview

At start-up, an autoclave produces steam (superheated water) inside an airtight "jacket" that surrounds the chamber of the autoclave. The chamber door is fitted with a gasket to ensure an airtight seal when the door is closed and the cycle engaged. Sterilization is achieved by applying heat to at least 250° F (121ºC) and pressure to15 psi and maintaining these conditions for at least 15 minutes.

The nature and quantity of the materials being autoclaved affects the total cycle run time. For instance, a half hour timed cycle for twenty 500 ml bottles or ten 1.0-liter flasks may take 90 minutes to heat up, run for 30 minutes at temperature and pressure, and exhaust. Alternatively, the total time for twenty boxes of µl pipette tips (a dry load) to complete the sterilization cycle will be close to the 30 minutes scheduled for the cycle.

The state Environmental Department regulates decontamination of laboratory waste under the New Mexico Administrative Code (NMAC), *Special Waste Requirements* (NMAC Title 20, Chapter 9, Part 8). Sterilization of lab ware, media, and supplies before use is not regulated. Burrell College does not currently use an autoclave to decontaminate biohazardous waste. Instead, Burrell College utilizes an outside entity to dispose of biohazardous waste.

Definitions

Autoclave: a steel chamber with an integral jacket constructed to withstand internal pressurization when charged with super-saturated steam; a "pressure cooker".

Sterilize: to make free from living bacteria, virus, and other microorganisms; the complete destruction of all forms of microbial life, including bacterial and fungal spores.

Decontaminate: a process to reduce the number of viable organisms so that the risk of disease transmission is eliminated.

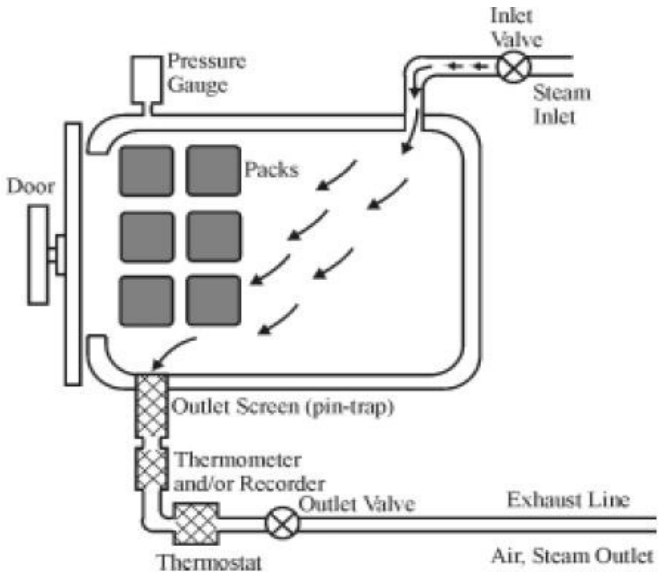

Figure 3. Autoclave diagram.

Autoclave Operating Parameters

Cycle settings: Review the autoclave manufacturer's instruction manual to select the proper cycle conditions for the solid or liquid materials to be sterilized. Autoclave users must be trained to operate the equipment and to understand the methods to verify the effectiveness of the decontamination treatment. Contact the laboratory manager for more information about the cycle settings, or if you observe problems related to the autoclave pressure, exhaust, or sterility of materials.

Cycles can be programmed to differ in the rate that the chamber is exhausted at the completion of the cycle. Typically, materials run on the "gravity" cycle are exhausted more rapidly than a "liquids" cycle. It is essential that vessels containing liquids are loosely capped during autoclaving to permit off-gassing during the exhaust cycle. Tightly capped vessels may explode or implode in the autoclave during the exhaust cycle or after the container is removed from the autoclave due to pressure or vacuum created in the vessel head-space (the space between the cap and liquid surface) as the container cools.

Temperature: Temperature is routinely set to 250° F (121ºC).

Pressure: The autoclave is set to provide 17 psi to the interior chamber.

Time: The cycle time is dependent on the load. Total run time depends on the load (liquid or solid) that in turn determines the appropriate exhaust setting (rapid or slow). Generally, a rapid exhaust is selected for sterilization of dry goods, and a slow exhaust is selected for liquids.

Monitoring Autoclave Operating Parameters

Burrell College does not currently utilize an autoclave to decontaminate hazardous waste but does autoclave liquids and heat-stable solids for sterile laboratory use. Refer to the Burrell College Autoclave Use SOP for further information on regular validation of autoclave performance.

Operators must monitor autoclave operation in order to validate that contents were exposed to adequate steam under pressure for a sufficient time to achieve sterilization. A biological or a chemical indicator is used to validate the sterilization process as described in the Burrell College Autoclave Standard Operating Procedure.

Typically, a **biological indicator (BI)** uses spores of a thermophilic bacterium to demonstrate a microbiological kill at the end of the autoclave decontamination cycle. A typical BI contains spores of a challenge organism suspended in an appropriate media that contains a pH-sensitive dye. Prior to autoclaving, the BI is placed inside the waste bag (integrated into the load). Use an "alligator" clip and a length of string, wire or small gauge chain to assist with post-cycle recovery of the strip or vial from the bag. After the decontamination cycle is complete, the BI is recovered from the load and incubated usually for 24 hours (sometime as long as 72 hours) and visually inspected for a color change. No color change indicates the spores were killed. A color change indicates the spores were not killed and bacterial growth has caused the pH indicator to change color.

Since Burrell College does not decontaminate solid or liquid waste by autoclaving, a BI may only be used to confirm sterilization.

A typical **chemical indicator (CI)** is a strip of foil-backed bonded paper (approximately 4 inches by 0.5 inches) embedded with a chemical that migrates across a "window" when exposed to steam under pressure at 250 degrees F (121 degrees C) for the requisite 15 minutes (See figure 4). The chemical integrator reacts to steam under pressure for the duration of the autoclave cycle in a manner considered equivalent to a microbiological kill. It can be used in solid and liquid loads, and with gravity or vacuum cycles. Prior to autoclaving an indicator strip is placed inside of each bag or container of laboratory waste. Use an "alligator" clip and a length of string, wire or small gauge chain to assist with post-cycle recovery of the strip from the bag.

Figure 4. Chemical indicator strip display

If the indicator chemical fails to migrate the entire length of the strip, the decontamination cycle is considered unsatisfactory. The autoclave cycle is repeated with a new CI strip to confirm the result. A second event resulting in the indicator chemical failing to migrate across the entire length of the strip means the autoclave must be taken out of service and is not used until it is repaired and re-tested. The unit should be posted with an "out of service" or similar warning notice. Laboratory waste cannot be released for disposal to a landfill unless it has been decontaminated as part of a validated autoclave cycle.

Note: Autoclave indicator tape and biohazard bags with chemically embedded stripes or words (e.g., "AUTOCLAVED") that appear after exposure to 250 °F are not equivalent to a chemical integrator. Autoclave tape is useful for marking and labeling the exterior of items to be autoclaved, but the use of autoclave tape alone is not sufficient to demonstrate decontamination of the contents of the package. Autoclave tape may be used together with a chemical indicator strip but may not be used instead of a chemical indicator strip. Further, biohazard bags and containers that are red or orange indicate regulated waste, and if used cannot be disposed in the regular trash. Any item labeled with the biohazard symbol (except sharps containers and regulated medical waste) that has been treated by heat or chemicals to render the contents non-infectious must have the biohazard symbol defaced and be marked to indicate the method of sterilization before release to the general waste stream.

The laboratory manager is responsible for providing and documenting training for autoclave users. A general explanation of autoclave principles, sterilization and recordkeeping is provided in person to anyone wishing to operate the Burrell College autoclave. In addition to this general awareness training, a Standard Operating Procedure will be available for all laboratory waste handlers. See Appendix D for the Burrell College Autoclave Standard Operating Procedure.

The Laboratory Director and Laboratory Manager conduct periodic reviews of log details and training records in order to certify that Burrell College's sterilization processes are effective.

BIOLOGICAL SAFETY CABINETS (BSCS)

Background

The design concept for what we now refer to as a biological safety cabinet originated at the National Institutes of Health and resulted in the development of a product specification that remains in use to this day. Colloquial terms such as "hood" and phrases like "tissue culture hood" and "laminar flow hood" are often used (incorrectly) to refer to biological safety cabinets. In a laboratory setting, the term "hood" may mean chemical fume exhaust hood, or it may refer to a component of a respiratory protection device. Similarly, the phrase "tissue culture hood" is inaccurate because it implies that the BSC may be restricted to use for tissue culture. And the generic phrase "laminar flow hood" is not specific because it refers to any device that moves air at a constant velocity in a uniform pattern and direction. Use of non-specific phrases may cause confusion between biological safety cabinets and clean air benches. There are two ways to clearly refer to biological safety cabinets; the term biosafety cabinet is a contraction of the proper name, and the other is the acronym BSC. The CDC/NIH publication "*Primary Containment for Biohazards: Selection, Installation, and Use of Biological Safety Cabinets"* is a good source of information on the operation, use, and certification of BSCs. This document is available in *Biosafety in Microbiological and Medical Laboratories* (BMBL), Appendix A, and can be accessed online at http://www.cdc.gov/biosafety/publications/index.htm.

Biological safety cabinets (BSCs) are primary containment devices designed to protect the product being manipulated, the operator, the environment, or all three. BSCs use high efficiency particulate air (HEPA) filters to remove airborne particles, bacteria, spores, and viruses from laboratory work areas. Equipment manufacturers may have more than one design for each type of BSC in their product line. The original NIH design evolved into the three classes of BSCs in use today, known as Class I, Class II and Class III. Class II BSCs are the most widely used in clinical, biomedical, and microbiological research and manufacturing applications.

Table 2 summarizes the differences in face velocity, airflow patterns and the acceptable biosafety level for each class and type of BSC.

Class II Type A1 & A2 BSCs are designed to exhaust the HEPA-filtered air from the BSC either into the laboratory or via a canopy exhaust connection to the building exhaust duct. A BSC canopy exhaust connection resembles the canopy used to capture the steam plume released when opening an autoclave door or a kitchen range hood. There are three benefits to installing a canopy exhaust: 1) The canopy connection assists with maintaining the negative pressurization of the BSL-2 laboratory; 2) the canopy will exhaust contaminated air in the event of a BSC exhaust HEPA filter failure; and 3) the canopy connection reduces the noise from the BSC blower motor.

Table 2. Summary of Biological Safety Cabinet Classes

Source: BMBL 5th Ed., Appendix A

Type	Face Velocity (Linear feet/minute)	Airflow Pattern	Lab Biosafety Level
Class I	75 lfm	Air flows in at front (not HEPA-filtered); exhaust through a HEPA filter into the room or to the outside through a canopy unit.	BSL 1, 2, 3
Class II A1	75 lfm	70% of HEPA-filtered supply air is re-circulated within the BSC and 30% is exhausted through a HEPA filter into the room or to the outside through a canopy unit.	BSL 1, 2, 3
Class II A2	100 lfm	70% of HEPA filtered supply air is re-circulated within the BSC and 30% is exhausted through a HEPA filter into the room or to the building exhaust through a canopy unit. Plenums are under negative pressure to the room.	BSL 1, 2, 3
Class II B1	100 lfm	30% of internal air is re-circulated within the BSC and 70% of HEPA filter-air is exhausted through a dedicated duct to the outside	BSL 1, 2, 3
Class II B2	100 lfm	No recirculation; total exhaust to the outside through a HEPA filter and dedicated duct	BSL 1, 2, 3
Class III	N/A	Supply air is HEPA filtered. Exhaust air passes through two HEPA filters in series and is exhausted to the outside via a hard connection to building exhaust system.	BSL 3 & 4

Testing and Certification of Biological Safety Cabinets

Every BSC used for work at BSL-2 must be tested and certified prior to initial use, at least annually thereafter, whenever a BSC is relocated, and after repairs that require accessing a contaminated plenum (blower motor and HEPA filter replacement are the most common events).

In 2012, the National Sanitation Foundation International in conjunction with the American National Standards Institute issued a revised NSF/ANSI Standard 49 on Class II (laminar flow) biosafety cabinetry. The NSF/ANSI Standard 49 applies only to Class II biological safety cabinets, as designed to minimize the hazards inherent in working with agents assigned to biosafety levels 1, 2, or 3.

An NSF-accredited field certifier performs a battery of primary and secondary tests to measure the performance of a BSC in meeting the manufacturer's operating specifications. BSC containment is assessed by testing HEPA filters for leakage, the internal airflow pattern, measuring the down flow velocity of the HEPA filtered air, the in-flow velocity, and when appropriate, a cabinet leak test. Each of these parameters must meet the original equipment manufacturer (OEM) specifications in order for the unit to be certified.

Secondary tests include measurements of noise output, light intensity, electrical voltage supply, and ground resistance. The electrical connections are checked to ensure the proper polarity, the ground fault interrupter circuit, and any alarm is checked as well. At the conclusion of the testing, a report is issued to the laboratory director indicating that the BSC passed certification or failed certification. The certifier often applies a decal listing the BSC serial number, the date of the test, the certification expiration date, and the certifier's name. If the BSC fails certification testing, the report will provide recommended corrective actions (usually HEPA filter replacement) needed to pass certification. The Laboratory Director will maintain a copy of test reports.

UV Lights and Biological Safety Cabinets

In a controlled environment and using a validated procedure, constantly emitted UV light of the appropriate wavelength and intensity is effective at decontaminating non-porous surfaces and in denaturing DNA. UV light does not decontaminate some organisms (non-replicating bacteria, some molds, and yeasts). Variables that adversely affect the efficacy of UV include failure to routinely wipe dust off of the UV lamp and a failure to routinely monitor the UV lamp to ensure output is of the appropriate wavelength and intensity. The tendency to store equipment and supplies results in at least a portion of the BSC work surface area being "shaded" from exposure to UV light, and there are areas that are inherently shielded from UV light by the design of the cabinet. Note that the lamp will emit a blue light long after the output has ceased to meet the requisite intensity and wavelength. And, even if the intensity and wavelength are appropriate, UV light does not penetrate surfaces and cannot penetrate covered surfaces like the underside of fittings (petcocks and outlets) and other places where potential contaminants may "hide".

Hazards associated with exposure to UV light include retinal irritation (prolonged exposure can lead to permanent retinal damage) and mild irritation of unprotected skin. These hazards are somewhat mitigated by an interlock incorporated into the design of newer models that requires the view screen to be fully closed in order for the UV light to work. Reflected UV light is also hazardous and UV protective eyewear must be used to mitigate hazard from reflective UV light.

The cost of operating a UV light over the serviceable lifetime of a BSC can be substantial and is not often considered. The cost of installing a UV lamp fixture in a new BSC (~$200.00) pales in comparison to the cost of UV lamp replacement ($15.00 - $40.00 each, depending on part number and vendor) and fees for disposal of the mercury-containing spent lamps as hazardous waste as required by EPA regulations. This is a significant expense over the life of a BSC. The CDC, NIH, and the American Biological Safety Association do not recommend the use of UV as the primary sterilizing procedure in BSCs.

Finally, it is critical to note that experimental manipulations occur in the absence of UV radiation, because the lamp is turned off during culture work. That means success in experiments is entirely dependent on the operator's aseptic technique and not the use of UV light. The IBC requires users to follow the chemical decontamination procedure and ensure that every user follows the procedure at start up and shut down of the BSC.

Proper Use of Biological Safety Cabinets

Proper use of a biological safety cabinet is based on the user's training and understanding of the operating parameters of the BSC, the experimental procedures to be performed, and most importantly, activities and events that reduce the effective functioning of a BSC. The following description of the proper use of a BSC at BSL-2 is based on the laboratory door being closed, the unit having been certified within the past year, and the unit being located away from high traffic areas and away from any potential source of disruption to the internal BSC air curtain (primarily doors and room air supply ducts).

Using the BSC properly includes these steps:

1. If the BSC blower is off, turn on the blower motor and let the unit run for 5-10 minutes to allow the cabinet to purge ambient air and establish an internal equilibrium. Check the airflow gauge or display to ensure the BSC is operating correctly.
2. After the unit has equilibrated, wipe down the interior (work surface, side and back walls, and interior of the view screen) with an appropriate chemical solution (for example, Cavicide or 70% ethyl alcohol) prior to placing equipment or supplies into the BSC. Decontaminating solutions intended for use inside a BSC should be made using sterile water.
3. Similarly, wipe down each piece of equipment (automatic pipettors, power supplies, racks, etc.) as it is brought into the BSC.
4. Consider the tasks to be performed and place only necessary equipment and supplies inside the BSC. This will minimize the number of times the operator's hands will need to "enter" and "exit" the BSC and subsequently minimize the opportunity for contaminants to "draft" into the work area.
5. Place equipment and supplies toward the back wall of the BSC. Be aware that the laminar flow within the BSC "splits", meaning that half of the HEPA filtered air flows to a slot in the back wall of the cabinet and half flows toward the front intake grill. Keep the front and rear grills clear.
6. Biological safety cabinets are designed for continuous operation. Although energy conservation may suggest BSC operation only when needed, especially if the cabinet is not used routinely, room air balance is an overriding consideration in the decision to operate the BSC 24 hours a day or to shut down the blower when not in use.

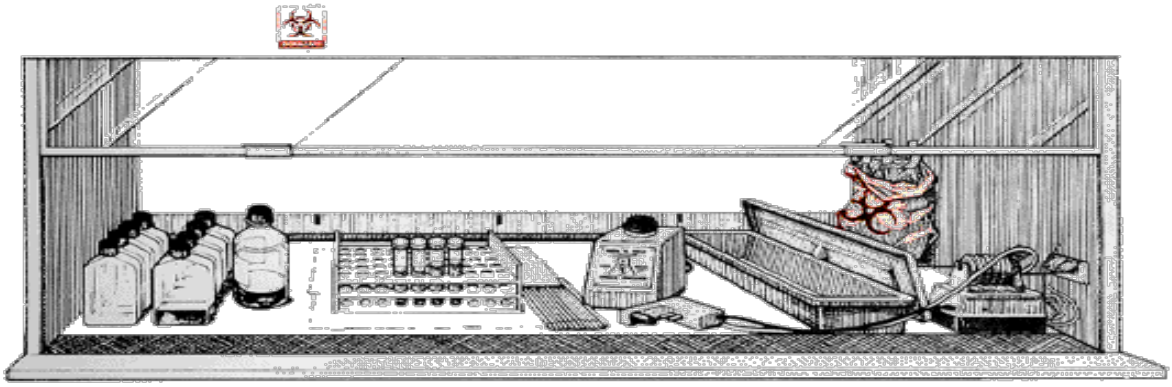

Figure 1. Arrangement of materials in a BSC, with "clean" items separated from "dirty" materials. Source: *BMBL, 5th Edition*

The use of flammable or explosive materials within BSCs is prohibited. Most BSC manufacturers apply a decal on the front of each unit warning against use of flammables and explosive materials. Since HEPA filters remove only particulates from the air that is recirculated inside the BSC, flammable and volatile vapors may build up inside the cabinet creating a fire or explosion hazard. Furthermore, the use of chemicals in a BSC that is vented to the laboratory may create an inhalation hazard for other people in the room or building area.

In the past, the two most common flammables used in BSCs were an alcohol burner and a Bunsen burner. Flames disrupt the airflow and contribute to the heat load inside the BSC. Flames have burned holes through HEPA filters and have caused explosions in BSCs.

Disposable plastic lab ware (pipettes, & loops for streaking agar plates) should be used instead of metal implements. If there is no alternative to re-useable implements, a "Bacti Cinerator"® (a portable, electric furnace) may be used to sterilize loops, needles, and scalpels instead of alcohol or Bunsen burners.

Figure 2. Bacticinerator®

BSCs are precision-engineered primary containment devices and should be serviced only by NSF-accredited technicians (or by someone supervised by an NSF-accredited technician) qualified to perform testing and repair of BSCs. **Under no circumstances should laboratory users attempt electrical repair or part replacement of a BSC.** For units less than three years old, improper use or maintenance by anyone other than a qualified service provider is likely to invalidate the warranty. The Laboratory Director is responsible for ensuring annual inspections and certifications of Burrell College BSCs.

Improper Use of Biological Safety Cabinets

Consider the following examples to avoid improper use of a BSC:

- Avoid keeping excess supplies like pipette tips, paper towels, and other lab ware in the BSC. Clutter inside the BSC may affect proper airflow and the level of protection provided.
- Do not place equipment or supplies on the air intake grill. Any obstruction to the supply air volume will adversely affect the function of the BSC.
- Do not work in a BSC while a warning light or alarm is signaling.
- The UV lamp should never be on while an operator is working in the cabinet.
- Avoid drafts from doors, air conditioning, and excess movement around the BSC operator.
- Avoid keeping loose paper towels and Kim Wipes™ on the BSC work surface while the blower motor is running. Paper towels can be entrained in the interior exhaust through the slot in the back of the cabinet and will lodge against the exhaust HEPA filter, creating an annoying fluttering noise, and reducing the surface area of the HEPA filter. Paper towels may or may not "fall off" of the HEPA and be recovered from the rear exhaust slot when the blower motor is turned off, but this is not routinely successful. Usually, the BSC must be decontaminated and the exhaust plenum accessed by a trained technician in order to remove the paper towel.
- Drilling, grinding or cutting into an internal or external surface of the cabinet for any reason is prohibited. BSC design and performance is rigorously tested to meet NSF International "listing" criteria. Any change to the physical structure of a BSC is considered an adulteration of the original equipment manufacturer specification and invalidates the NSF listing of the adulterated unit. BSC certification technicians are taught to evaluate each BSC for intentional and unintentional damage and note these observations on the test report document. The reason for prohibiting drilling and grinding is that holes will affect the internal air balance by creating a leak of potentially contaminated air from the pressurized plenum. There is also a risk of damaging electrical wiring. For newer BSCs, any user changes to the physical structure or internal electronic systems of a BSC will void the manufacturer's warranty.

Do not attempt to access the motor or HEPA filter areas of the BSC. The internal housing is considered contaminated with infectious material trapped in the HEPA filters. The BSC must be chemically sterilized before filter changes, maintenance and repair.

- Using a biosafety cabinet as a chemical fume exhaust hood when manipulating large quantities (above 250 ml) of volatiles, acids or bases is prohibited. Only the relatively small volume of chemicals typically used in molecular and microbiological protocols is permitted. As mentioned previously, HEPA filters act on particulate matter only and do not capture chemical fumes. The electrical systems and front sash of biosafety cabinets are not designed to provide protection from sparks or chemical explosions, and Class II BSCs are not constructed to be gas-tight. The airflow of many biosafety cabinets is exhausted back into the laboratory. Flammable, combustible, or toxic vapors and gas should be handled only in a chemical fume hood.
- Do not place boxes or other objects on top of the BSC that exhausts into the room, as this will block the exhaust airflow, and will damage the exterior surface of the HEPA filter.

BIOHAZARD SPILL CLEAN UP

Overview

This section refers to spills involving biohazardous liquids. For information on general spill response and clean up refer to Burrell College Spill Response Standard Operating Procedure.

Spills will occur with any task involving liquids. This section describes the proper way to clean up cell or tissue culture spills in a BSL-1 and BSL-2 laboratory. The PI must identify and provide a safe and effective compound for decontamination. For many BSL-1 organisms, a solution of commercial anionic or non-ionic detergent (household dish soap) is an appropriate decontaminating agent. For BSL-2 organisms, a 10% (v/v) dilution of 6.0% sodium hypochlorite (household bleach) is an appropriate decontaminating agent. A routine formula is 100 mls of bleach per 900 mls of distilled or de-ionized water. The solution is discarded and replaced by a fresh-made solution at least every other day.

Typically cell and tissue culture procedures involve anywhere between 10 ml and 500 ml of liquid, or higher volumes for pilot plant or scale up projects. Propagation of agents on semi-solid media involve upwards of 10^6 colony forming units (cfu). Persons cleaning up spills must always wear gloves and a lab coat for protection during the clean-up procedure.

Spill Risk Assessment

Assess all spills before beginning the clean-up. Lab users must be trained to recognize the hazards, and must be able to obtain the appropriate personal protective equipment and spill kit materials. Consider these items i for spill clean-up in research laboratories:

1. Is the agent known to be infectious via exposure to aerosols and if so what is the infectious dose? This consideration is significant for deciding if the laboratory (or other affected area) should be vacated after the spill for a period of time to permit aerosols to settle out of the atmosphere.
2. What is the largest volume of liquid culture manipulated and what is the highest titer of the organism per vessel (or colony population per plate) attained in your protocol?
    a. A large volume spill must be contained from uncontrolled spread throughout the laboratory. It is essential to have sufficient paper towels or other absorbent material on hand to contain a large volume spill.
    b. Large volume cultures (>10 L) of recombinant organisms (even if non-infectious) are currently not allowed at Burrell College.
    c. A high titer of organisms in a culture may enhance the risk of exposure if the vessel or plate(s) hits the floor. This is not usually a concern for work at BSL-1 but must be considered for cultures of BSL-2 organisms, particularly for spills outside of a BSC.
3. For spills inside of the biosafety cabinet: while laboratory occupants should be notified, a spill contained within a BSC represents less of a risk to uninvolved laboratory occupants since the BSC will contain aerosols generated within the unit. However, the operator must take care to avoid panic that will likely result in rapid hand movements into and out of the BSC. Rapid motions will affect the airflow and permit aerosols to escape from the BSC.

Under no circumstances should an operator put their head inside of a BSC while cleaning up a spill. The risk is obvious. Once the work surface is decontaminated and cleaned, it should be lifted up carefully to inspect the underside and cleaned if necessary. Do not remove the work tray from the BSC until it is properly decontaminated.

4. For spills outside of biological safety cabinet: liquid spills outside of the BSC should be contained to a minimum area and not permitted to spread. Plates may or may not open when dropped or they may shatter spreading cultures and shards of plastic across the floor. The surrounding floor and work surface areas where splashes or larger aerosols may have settled around the spill should be included in the clean-up.
5. Major spills of chemicals must be immediately reported to the Laboratory Director.
6. Major spills, incidents, or illnesses involving BSL-2 materials must be immediately reported to the IBC Chair. After the crises, send an email with details of the incident to the IBC Chair.
7. Spills or accidents occurring in BSL-2 laboratories with recombinant materials resulting in an overt exposure must be immediately reported to the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA). Contact the IBC Chair for assistance. The NIH template for reporting incidents can be accessed online from ORSP or the NIH OBA website.

Liquid Spill Clean Up Procedure

1. Alert other persons in the vicinity that a spill has occurred, especially for large volume spills, so that others do not walk through the contaminated area. Based on hazard of the materials and the Emergency Action Plan, determine if evacuation is necessary.
2. Don necessary protective equipment: gloves, eye protection and lab coat at a minimum; a face shield may be needed.
3. Cover the spill with paper towels or other absorbent material to confine the spill to as small an area as possible and absorb the liquid.
4. Apply decontaminating solution (usually a bleach solution of 10% or higher, to reach a final concentration of at least 0.5-0.6% sodium hypochlorite) to the absorbent material. Let stand for 10 minutes or the recommended contact time for the chemical disinfectant.
5. Discard the disinfectant-soaked materials into the wastebasket. The resulting waste, paper towels, and other materials do not require autoclaving for most BSL-2 biohazards. Consult with the IBC Chair or Laboratory Manager for disposal of mixed wastes or other special hazards.
6. Repeat the application of disinfectant solution to the work surface (step 4 and step 5).

- **Do not autoclave materials containing bleach or toxic chemicals**, as this will result in the release of vapors into the room and can corrode the interior of the autoclave.

Note: For information on chemical spill clean-up, see the chemical Safety Data Sheets and Hazard Communication Plan.

BLENDING, MIXING, SONICATING AND CELL DISRUPTION

Overview

This section identifies risks associated with blending, mixing, sonicating, and disrupting cells and tissue. Potentially hazardous aerosols are likely to be generated by blending, grinding, mixing, stirring, shaking, or disrupting cells, tissues, blood, and environmental samples. Each of these actions applies force (mechanical or sound waves) to manipulate the material of interest. When available, use laboratory-grade equipment designed to contain aerosols of potentially infectious or pathogenic cells, tissues, or similar materials. Overall, laboratory-grade equipment is designed to contain liquids, and any aerosol likely to be generated during its use. For example, the Warring Blender can withstand autoclaving, the motor bearings are made of Teflon®, the agitator is fabricated into the lid, and the screw-cap lid is fitted with an O-ring. Additionally, the blender has built in access ports that allow adding or removing materials without opening the blender. As a group, magnetic stirrers, incubator shakers, and water baths impart a less vigorous action on the materials but are not without risk of aerosol generation.

In the absence of a laboratory-grade device, use of an engineering control such as a biological safety cabinet, or fume hood is recommended to contain or ventilate aerosols generated during manipulations of these materials.

Finally, it is important to disassemble and thoroughly clean these devices between uses to prevent cross-contamination of subsequent processes.

Personal Protective Equipment

Lab coat and eye protection are required. A risk assessment of the procedures must be done to evaluate the need for additional precautions, such as a full-face shield, particulate facemask respirator, and/or hearing protection.

Hazard Assessment

Aerosol generation is a constant by-product of these activities. Failure to contain the aerosol will lead to dispersal throughout the workplace.

Electric shock hazard is possible when using electric-powered equipment with liquids.

CENTRIFUGATION

Overview

Centrifugation is a common step in a multitude of laboratory procedures. Centrifugal force applied to a solution will result in separation of solution components according to their respective mass. A number of different centrifuge and rotor designs have evolved for specific applications, but the principle of operation remains constant. Older tabletop centrifuges (and some super speed) models are not fitted with an airtight seal and will not contain aerosols. The nature and volume of the material to be recovered influences the type of rotor and velocity chosen for a particular run. There are four classifications of centrifuges loosely based on the range of operating speeds.

Low speed centrifuges typically operate in the range of 100 rpm to ~1000 rpm.

High-speed centrifuges typically operate from 1000 rpm to ~5000 rpm.

Super speed centrifuges typically operate from 5000 rpm to ~20,000 rpm.

Ultra-centrifuges typically operate up to ~100,000 rpm.

The user is responsible for cleaning, decontamination and visual inspection of centrifuges on an as-needed basis. Due to the increased risk inherent in their operation, high-speed and ultra-centrifuges (along with their rotors) must be routinely inspected and maintained by manufacturer-qualified service persons. Rotors are subject to the cumulative effects of metal fatigue and corrosion experienced over prolonged use. Based on a visual inspection, and the total run time, the maximum operating velocity of a rotor is reduced, or "de-rated". Information recorded in the centrifuge logbook is used in making this determination.

Bottles and tubes intended to be re-used should be monitored over multiple runs, and inspected for leaks. These observations provide the basis for assigning a maximum number of uses after which these tubes and bottles should be replaced. It is essential that bottles and tubes are properly capped or sealed prior to being centrifuged. If available, caps fitted with O-rings are preferable to plastic or rubber-lined caps. Generally, bottles and tubes threaded on the outside and fitted with a screw cap provide a more reliable seal than non-threaded stoppers or plugs. Aluminum foil or "parafilm" should not be used to seal bottles or tubes, especially for cell cultures.

Definitions

Centrifuge safety cups are containers that fit around rotor buckets and provide containment of tubes or bottles holding potentially infectious agents while transporting the bucket from the biosafety cabinet to the centrifuge, during the centrifuge run, and while transporting the materials to the biosafety cabinet for further processing.

Rotor is a container or container-holder that rotates about the drive shaft of a centrifuge.

Over-speed occurs when a rotor accelerates beyond its maximum rated velocity.

Trunnion is a cup that holds bottles or tubes and is placed on opposing arms of a centrifuge rotor, and "swings" outward during the centrifuge run. Some types are fitted with caps.

Personal Protective Equipment for Centrifuge Operations

- Use gloves when handling potentially hazardous materials.
- Use eye protection when there is a potential for a splash.
- Wear close-toed shoes.

Hazard Assessment

Aerosol release may result when tubes or bottles fail during centrifugation or if integral tubes and bottles are handled in an unsafe manner, i.e., not observing good laboratory practices.

Drive shaft failure can result in catastrophic consequences, especially if the centrifuge is operating near maximum velocity at the time of failure.

Oil leak from the vacuum pump or motor that escapes from the centrifuge will result in a slip-hazard, and if not promptly wiped up, will damage the floor surface or finish.

Rotor imbalance can damage the centrifuge drive shaft, and if allowed to accelerate uninterrupted, may result in the centrifuge "walking" across the room.

Rotor failure has several causes. For example, an improperly maintained and inspected rotor can disintegrate during a run, or if an improperly balanced rotor is permitted to accelerate beyond a certain speed, or if a rotor (properly maintained and balanced) accelerates beyond its rated maximum velocity. Depending on the speed at the time of failure, a disintegrating rotor can destroy the protective chamber and "spray" fragments around the room.

Loading the Centrifuge

Check the rotor or buckets to ensure absence of residue or debris. Check the tubes, caps, bottles, O-rings, and chamber seals for damage. Use a biosafety cabinet to contain aerosols when loading tubes or bottles with potentially infectious cultures. Over-filling the tube or bottle will contaminate the tube closure. Ensure that tubes and bottles are balanced and that balanced pairs are inserted at opposing positions in the rotor or trunnion. Confirm that the run speed does not exceed the rating of the rotor, bottles or tubes. Exercise care in placing the rotor on the drive shaft to ensure the unit is properly seated on the spindle. For ultra-centrifugation, ensure that the proper over-speed decal is installed. Record the run data; rotor number, speed setting, date, material description, operator initials. Start the centrifuge.

Unloading the Centrifuge

Allow the rotor to stop completely before opening the centrifuge lid or door. Practically, this requires waiting at least ten minutes (longer for higher run speeds) after the run timer has expired before opening the centrifuge. After opening, check the chamber for leaks or other abnormalities. Remove the rotor (or rotor content) containing potentially infectious cultures and place it in a biosafety cabinet. Do not open vessels containing potentially infectious cultures on the open bench. Once the centrifuge is empty, decontaminate any liquid that leaked inside the chamber. Decontaminate the entire centrifuge chamber with a dilute bleach, iodophor or quaternary ammonium compound, ensuring the exposed surfaces experience a 10-minute contact time with the solution.

DISPOSAL PROCEDURES FOR BIOLOGICAL LABORATORY WASTES

In accordance with the state regulations for special waste in New Mexico Administrative Code (NMAC), materials identified as infectious waste must be handled with special consideration. For laboratory-generated biological waste, the BSRL Laboratory Director is responsible for preparing a written procedure for the safe handling and disposal of infectious wastes, and for training laboratory personnel in those procedures.

Biohazard (Infectious) Waste

1. Segregate biohazard waste from ordinary trash. Biohazard waste includes microorganisms that are infectious to humans, animals, or plants; blood, blood products and internal body fluids from humans and animals; cells and unfixed tissues; and recombinant materials that are non-exempt from the *NIH Guidelines*.

2. Sharps (razors, glass, scalpels, needles, etc.) should not be placed in bags of other waste. Provide rigid, puncture-proof sharps containers that are clearly marked according to biohazard or chemical contamination.

3. Solid laboratory waste must be placed inside a biohazard labeled container that is puncture-resistant, leak proof, and closed when not in use. Reusable rigid containers can be lined with an autoclave safe bag.

4. All solid waste must be collected in the central biohazard disposal container. Solid waste disposal at Burrell College is performed via contract by MediWaste Corp. Contact the Laboratory Manager when the central biohazard disposal container reaches 50% capacity.

5. Many liquid cultures can be chemically treated by adding household bleach to a final concentration of 10% (v/v). Let stand for at least 30 minutes, then pour down the sanitary drain with running water. Contact the Laboratory Director if information is needed.

Non-Infectious Waste

Ordinary non-sharp waste can be disposed of in the general trash.

Broken glass that is not contaminated with biohazards or chemicals should be placed in a rigid container that is clearly marked with the word “GLASS”, such as a cardboard box lined with a plastic bag. When full, the box should be taped closed and disposed of in the dumpster.

Sharps

- Glass or plastic supplies that have the potential to break or puncture, such as microscope slides, serological pipettes, test tubes, culture plates or thin-walled vials should be placed in a rigid container lined with a plastic bag for autoclaving before disposal.

- Never discard sharps into ordinary trash or bags of biological waste.

- Place sharps containers within arm's reach of the location where sharps will be used. Immediately after use, discard the entire sharps device (whether contaminated or not) into puncture resistant sharps containers. Do not attempt to recap, bend, or remove the needle.
- Separate sharps that are contaminated with chemicals from other biologically-contaminated sharps. Chemically-contaminated sharps must be placed in rigid, non-biohazard sharps containers (thick plastic, metal).

- Biologically-contaminated medical sharps (i.e., syringes, needles, scalpels) must be placed in a rigid, puncture proof container manufactured for use in sharps disposal (i.e., red sharps container labeled with the biohazard symbol).

- Do not overfill sharps containers. Close completely when 3/4 full. Never place red sharps containers in ordinary trash, even if the sharps and/or containers have been autoclaved.

- In the event of a needle stick or other injury from sharps or glass, wash the area thoroughly with soap and water. Notify your supervisor and go to the designated Burrell College-affiliated occupational health clinic immediately for evaluation.

INTEGRATED PEST MANAGEMENT AT THE BURRELL COLLEGE RESEARCH LABORATORIES

Integrated Pest Management (IPM) is a decision-making process that uses all available pest management strategies to prevent economically damaging pest outbreaks while reducing risks to human health and the environment. IPM is a continuum along which there are many levels of treatments. The IPM program takes advantage of all pest management options including but not limited to the judicious use of pesticides. Pest control ranges from simple monitoring to properly timed pesticide use, or even bio-intensive IPM in which there is total elimination of synthetic pesticides. Pests are managed in order to reduce any potential human health hazard, to protect against a significant threat to public safety, to prevent loss of or damage to college property and to enhance the quality of life for faculty, students, staff, and visitors.

IPM is an important part of managing a research facility. Many pests, such as flies and cockroaches, can mechanically transmit disease pathogens and compromise the research environment.

BSRL occupants should report pest infestations to the Laboratory Director. Indoor applications are routinely scheduled when the building or room is unoccupied. Personnel should be notified in advance and may vacate the building or room depending on the pesticide used for treatment.

Many pest problems can be prevented or corrected by ensuring proper sanitation, reducing clutter and pest habitat, and by performing repairs that exclude pests. Laboratory records should be maintained to track repairs and interventions, and determine if corrective actions were effective. Monitor for pests using traps, visual inspections, and staff interviews. Record the results of monitoring in a logbook to support quality control assessments for the research operations and submit recommendations for improvement if needed.

SHIPPING RESEARCH MATERIALS

Contact the BSRL Laboratory Manager for current guidance and assistance with shipping biological materials from the laboratory.

A condensed version of the shipping requirements for infectious substances can be found in the CDC/NIH publication *Biosafety in Microbiological and Biomedical Laboratories*. **The information provided here is introductory, and is not intended to substitute for the comprehensive training requirements specified in the regulations.**

Overview

The efficient and safe transport of research materials requires good coordination between the sender, the carrier and the receiver. From a research perspective, there are several preliminary determinations that must be made prior to shipping research materials. Review the following considerations for responsible and successful transportation:

- Do any proprietary restrictions apply to the material, e.g., do you own the rights to the material or do you have written permission from the owner to transfer the material? For example, the ATCC material transfer agreement (MTA) explicitly prohibits subsequent transfer of cell cultures and other purchased materials without the company's written permission. Review the purchase documents or contact the source's Intellectual Property office for details. Conversely, if the material to be shipped is proprietary to Burrell College or a Burrell College PI, the Office of Research & Sponsored Programs should be consulted to determine if an MTA is necessary prior to shipping the material.

- Are permits needed to transfer, transport, or possess the material? Many permits restrict the possession and use of the material to the permit holder and prohibit subsequent transfer to a third party (who may or may not hold a permit for the material). In any case, the applicable permit conditions must be accounted for prior to shipping any permitted material.

- Materials exported to a destination outside the United States may require an export license or reporting to the U.S. Department of Commerce, using the Export Classification and Control Number (ECCN). This practice prevents export to restricted countries and controls the export of "dual use" materials so that research items are not used for unintended purposes. Contact the office of the Assistant Dean for Research for information and guidance.

- Many research materials are considered hazardous materials, defined by the U.S. Department of Transportation (DOT) as a substance or material which is "**capable of posing an unreasonable risk to health, safety, and property when transported in commerce**". This definition is found in the requirements for transporting hazardous materials known as the ***Hazardous Materials Regulations*** (HMR), issued by DOT's Pipeline and Hazardous Materials Safety Administration (PHMSA). The HMR are published in Title 49, Code of Federal Regulations (49 CFR), Parts 171-180.

- In addition to DOT requirements, shipping research materials via air is guided by the International Air Transport Association (IATA) ***Dangerous Goods Regulations*** (DGRs).

- Commercial carriers are likely to have additional requirements for transporting packages containing research materials. Not all shipping entities accept every type of package, and the requirements for shipping documentation may vary by carrier.

- The DOT and Federal Aviation Administration regularly review the records of shipping companies such as FedEx, and have the authority to perform unannounced inspections of facilities (including research laboratories) that ship dangerous goods. Regulatory inspections can assign civil and criminal liability to the organization and the shipper and result in substantial fines for violations.

- Ensure adequate communication between the sender, the contracted carrier service (e.g., FedEx), and the receiver.

  The shipper (sender, consignor)

  - Makes advance arrangements with the receiver, including investigating the need for import/export permits, letters of authorization, or other documents;
  - Makes advance arrangements with the carrier to ensure that the shipment will be accepted for transport and delivery, and be shipped by the most direct routing;
  - Prepares necessary documentation according to the proper classification of the material, IATA packing instructions, carrier requirements and applicable permits;
  - Notifies the receiver of transportation arrangements and the expected arrival time.

  The carrier provides advice to the sender about correct packaging, shipping documents and instructions, and confirms the routing and delivery.

  The receiver (consignee)

  - Obtains the necessary authorizations to receive the material (i.e., import permit, institutional approval) and provides these to the sender in advance if needed;
  - Should inform the sender upon receipt of the material.

Classification Process

For packaging and shipping purposes, research materials are classified according to the DOT *Hazardous Materials Regulations* and IATA *Dangerous Goods Regulations.* Dangerous goods classification is a mandatory three-step process.

Dangerous goods are assigned **UN numbers** and **proper shipping names** according to their hazard classification and their composition. Proper shipping names are used to clearly identify the dangerous article or substance. Classification allows the shipper to select the proper IATA **packing instructions** and directions to use, and provides information necessary to complete **documentation** (i.e., the Shipper's Declaration).

Classification step 1: Determine the IATA-specified Class of dangerous goods (see Table 5).

Table 5: IATA-defined Classes of Dangerous Goods *Source: 49 CFR 173.2*		
Class	Substance	49 CFR reference
1	Explosives	173.50
2	Gasses	173.115
3	Flammable liquids	173.120
4	Flammable solids	173.124
5	Oxidizing Substances and organic peroxides	173.127, 173.128
6	Division 6.1 (poisonous material) Division 6.2 (infectious substance)	173.132 173.134
7	Radioactive material	173.403
8	Corrosive material	173.136
9	Miscellaneous hazardous material (e.g., dry ice)	173.140

Classification step 2: Determine the Division within the IATA-specified Class

- Biological research materials typically are classified as Class 6.2 (infectious substances).

Classification step 3: Determine the IATA-specified Type of infectious substance.

- Class 6.2 Infectious substances are assigned a proper shipping name and corresponding UN number: UN 2814, UN 2900, UN 3291 or UN 3373. See 49 CFR 173.199 for details of these classifications. You can refer to the *Transporting Infectious Substances* brochure online at www.phmsa.dot.gov for a summary of the classification process, guidance list of infectious substances, and packing and marking requirements.

  Category A: the material is known or reasonably expected to contain a pathogen that is capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals. Specialized training is required before packaging and shipping Category A infectious substances. Contact ORSP for assistance.

  PROPER SHIPPING NAME AND IDENTIFICATION NUMBERS:

  Infectious substances, affecting humans, UN 2814

  Infectious substances, affecting animals *only*, UN 2900

  Category B: the material is known or reasonably expected to contain an infectious substance not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals.

  PROPER SHIPPING NAME AND IDENTIFICATION NUMBER:

  Biological substance, Category B, UN 3373

  Regulated Medical Waste, UN 3291

  Note: RMW that contains or is suspected to contain Category A substance must be identified as a Category A infectious substance UN 2814 or UN 2900.

There are differences in the packaging, paperwork, and container requirements for each respective material to ensure the package arrives at its destination on time and without breakage or leaks. The following information assumes the package contains non-infectious biological materials (i.e., cDNAs with less than ~50% of the genome) or Category B infectious material. The following briefly describes the components that make up the UN standard **triple packaging** system for infectious substances, and is appropriate for any package of biological research materials:

- Leak-proof primary receptacle and secondary packaging, that prevents any loss of contents that might be caused in transportation by vibration, changes in temperature, humidity, or pressure , AND
- with absorbent material sufficient to absorb the entire contents of all primary receptacles that are packaged together, AND
- An outer container (usually a box) manufactured according to regulatory specification (i.e., capable of passing a 1.2-meter (~4 feet) drop test), AND
- Is properly marked (with orientation arrows: ↑ ↑, and the code of manufacturing specifications "i.e., 4G/X 8/S/04" or other as appropriate, screened onto the box) AND
- Is labeled with the proper shipping name for the material (e.g., Biological substance, Category B), AND
- Is labeled with the correct markings containing the UN identification number of the materials (e.g., a diamond-shaped marking containing the number, "UN 3373"), AND
- Is free of extraneous markings, labels, stains or discoloration AND
- Clearly identifies the sender/consignor, AND
- Clearly identifies the receiver/consignee, AND
- Is accompanied by the correct paperwork (i.e., air waybill) that contains the name, address, and telephone number of a person knowledgeable about the material.

Hazardous materials transported by Burrell College employees in approved vehicles

Small quantities of hazardous materials transported by a Burrell College employee for official business are often exempt from the HMR, as long as requirements are met for the DOT Materials of Trade (MOT) exemption. An example would be a Burrell College researcher transporting a package from campus to a research location or to a shipping center for assistance. Although formal DOT training is not required in this situation, specific packaging and marking requirements must be followed. Note: the MOT exemption does not apply to Biological Substance, Category A materials.

Shipping Materials on Dry Ice

While the use of dry ice to preserve the integrity of research materials in transit is necessary, it's use is not without risk. There are three hazards when using dry ice, 1) packing dry ice in an air tight container may cause the container to explode, 2) sublimation of dry ice in poorly ventilated or confined areas (like aircraft cargo holds and courier vehicles) may generate a suffocating concentration of CO2 in the atmosphere, and 3) dry ice can burn exposed skin. Both DOT and

IATA have specific packaging requirements for packages containing dry ice. When dry ice is the only hazardous material in the package (e.g., no infectious agents) the package must be labeled with a Class 9 decal that lists the quantity of dry ice contained in the package. Note: Between 5 and 10 lbs of dry ice will preserve temperature for 24 hours.

Dry ice is a hazardous material and is regulated under the DOT. Federal law requires appropriate training for anyone wanting to ship dry ice. Contact ORSP to review the training guidance and specific procedures that must be followed. The CITI training enables lab personnel to be certified to ship dry ice as long as no other hazardous materials are involved.

Shipping Guidance

In summary, there are specific requirements for determining what forms are necessary for a particular package, how to complete the form(s), and the record keeping requirement for these forms.

All persons who offer a package for shipment must be trained in the regulations within 90 days of being assigned to perform shipping duties, and training must be repeated every 2 years under IATA, and every 3 years under DOT. The supervisor is responsible for arranging the required training, or working directly with ORSP to ensure the package conforms to carrier-specific requirements for the material being shipped.

Websites for Shipping Guidance

1. CDC Office of Safety, Health, and Environment; http://www.cdc.gov/od/ohs/biosfty/shipdir.htm
2. CDC Etiologic Agent Import Permit Program; http://www.cdc.gov/od/eaipp/
3. DOT Hazardous Materials Regulations: http://www.myregs.com/dotrspa
4. FedEx Hazardous Materials Shipments: http://www.fedex.com/us/service-guide/our-services/dangerous-goods- hazmat/index.html
5. International Air Transport Association http://www.iata.org/ps/publications/dgr/Pages/index.aspx
6. United Parcel Service Hazardous Materials Guide: http://www.ups.com/content/us/en/resources/ship/hazardous/index.html?srch_pos=5&srch_phr=hazardous
7. U.S. Postal Service Hazardous, Restricted, and Perishable Mail: http://pe.usps.com/text/pub52/welcome.htm
8. WHO Transport of Infectious Substances http://www.who.int/ihr/infectious_substances/en/ http://www.who.int/ihr/publications/who_hse_ihr_20100801_en.pdf
9. ASM 2012. Sentinel Level Clinical Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases. Packing and Shipping Infectious Substances. Accessed on 4/4/2013 from www.asm.org/index.php/guidelines/sentinel- guidelines

APPENDIX A. THE IBC APPLICATION

Available at: http://bcomnm.org/wp-content/uploads/2019/03/IBC_2018_Application.docx

APPENDIX B. THE IBC ACTIVITY MODIFICATION REPORT

Available at: https://bcomnm.org/research/ibc/

APPENDIX C. ANNUAL BIOSCIENCE RESEARCH LAB SURVEY FORM

Lab Director:		Ph. Office:		Ph. Lab:	
Lab Location: BSL-		Prior Survey Date:			
Secondary Location:		Facility: BSL-	Practices: BSL-		
Biohazardous Material	___ Arthropod (e.g., mosquitoes, ticks) ___ Bacteria_____BSL- ___ Virus: Plant____or Animal _____ (exotic____or endemic_____to NM) Cells or tissues (Animal source) ___ Cells or tissues (Human or non-human primate source), blood or internal body fluids ___ External body fluids (Human or non-human primate source), including urine, saliva, fecal matter ___		___ Fungi, mold or yeast ___ Parasite (e.g., Plasmodium spp.) ___ Toxin (biological product) ___ Recombinant DNA ___ Expression vectors(plasmid, cosmid, phage, viral, other) ___ Other, list material below (e.g. *dura mater* from human, non-human primate, livestock, rickettsia, etc.) _____		

PERSONNEL	BIOSAFETY AWARENESS	HAZ COMM	HAZ WASTE	LAB STANDARD	BBP
Training dates will be filled in by ORSP.	Recommended for BSL-1 Required for BSL-2	Required for all personnel	Required of one person per lab	Required for all personnel	Required for use of human and non-human primate cells/blood

Y/N	SURVEY ITEM	COMMENTS
	ADMINISTRATIVE CONTROLS AND DOCUMENTATION	
	Are Laboratory Safety Plans <u>updated</u> and <u>available</u>? a. Emergency Response/Action Plan b. Biosafety Manual & lab-specific info (e.g., risk assessments, specialized training) c. Chemical Hygiene Plan and MSDS d. Bloodborne pathogen exposure control plan, for labs using human-derived materials (annual requirement for update and refresher training)	
	Biohazard sign posted at the entrance to BSL-2 lab a. Includes emergency contacts: PI & an alternate b. Notice of potential hazards and entry requirements	
	Controlled access (door closes and locks, authorized personnel only)	
	Refrigerators in lab are marked "No Food or Drink". Food that is stored as lab materials is marked "Not for human use"	
	Other Documentation (list location or contact person): a. Decontamination of equipment before repair, disposal, or transport b. Shipping of biohazardous materials c. Inventory of biohazardous materials d. Reports of injury or exposures	
Y/N	**STANDARD MICROBIOLOGICAL PRACTICES**	**COMMENTS**
	Policies: Are the following PROHIBITED in the lab? - Open-toed shoes or sandals - Food or drink (for eating or for storage) - Handling contact lenses and applying cosmetics - Mouth pipetting	
	PPE is available - Lab coats, gowns or other coverings - Gloves (appropriate to hazard) - Safety glasses, goggles, face shield	
	Glove use (observed) - Gloves are removed prior to exiting the laboratory and when handling "common" items like doorknobs, telephones, and computer keyboards. - Personnel wash their hands after handling viable materials, after removing gloves, and before leaving the lab.	

Y/N	SURVEY ITEM	COMMENTS
	Sharps - Are rigid containers used for storing supplies (razor blades, syringes)? - Are sharps containers available for disposal of biohazardous sharps? - Are rigid containers available for disposal of broken glass? - Is broken glass decontaminated before disposal?	
	Decontamination practices - Work surfaces are cleaned at least after completion of work and after spills **Identify disinfectant used, frequency:** - Other items (door handles, telephones, pens) - Floors - Laundering of lab coats - Small equipment (pipetters, spatulas) - Large equipment (centrifuges, freezers)	
	Sterilization/disposal of used materials (identify method) - Liquids - Solids	
Y/N	**LABORATORY FACILITIES & SAFETY EQUIPMENT**	**COMMENTS**
	Hand washing sink, hand soap, paper towels available?	
	Eye wash station is located within 50 ft of lab benches?	
	BSL2 lab is negative pressure to corridor	
	Vacuum lines are protected with liquid traps and/or HEPA filters.	
	Lab is designed for easy cleaning (e.g. appropriate bench tops, no carpets or cloth furniture)?	
	Windows that open to the outside are screened	
Y/N	**SPECIAL PRACTICES**	**COMMENTS**
	Biological safety cabinets - primary reason for use: - properly located & certified annually (requirement for BL2 labs) **Location, ID, and Test date**:	
	Centrifuges use sealed rotors or safety cups, and capped tubes?	
	Liquid nitrogen used in lab? - SOPs include use of thermal gloves and face shield?	
	Autoclave - Location and ID: - Is operating procedure posted? - Who trains personnel in autoclave use? - Has printer that records sterilization cycle parameters? - Is Log book maintained?	
	Validation of waste sterilization - Method: steam integrator strip, spore vial - Frequency: - Records kept by:	
	Are biohazardous materials transported between locations? (e.g., Infectious cultures, Human/primate cells, Recombinant DNA) - Are durable, leak-proof containers available as secondary containment?	
	Pest Management - Is the lab free of insects/rodents?	
	Good housekeeping and sanitation practices are evident.	
	The areas surveyed are free of imminent hazards to life and property.	
	Other:	

ACTION ITEMS:

Action items identified during this survey:

-

APPENDIX D. AUTOCLAVE STANDARD OPERATING PROCEDURE

Available at: https://bcomnm.org/research/research-laboratories/forms-sops/

APPENDIX E. BURRELL COLLEGE BIOSAFETY POLICY

Available at: https://bcomnm.org/wp-content/uploads/2019/12/B8520_Biosafety_.pdf

APPENDIX F. BURRELL COLLEGE EXPOSURE CONTROL PLAN

Available at: http://bcomnm.org/wp-content/uploads/2019/03/Bloodborne-Pathogen-Exposure-Control-Plan_Final-Draft.pdf

APPENDIX G. BURRELL COLLEGE IBC BYLAWS CHARTER

Burrell College Institutional Biosafety Committee

1. Composition and terms: The committee shall have no fewer than five members appointed by the Dean of the College in consultation with the Assistant Dean of Research. Members shall be selected such that they collectively have experience and expertise in the handling and safe conduct of activities that involve the use of hazardous chemicals, biohazardous agents and recombinant or synthetic nucleic acid molecules. The following shall be ex officio members with voting rights: the Assistant Dean of Research, the Director of the Anatomy Laboratory, and the Bioscience Research Laboratory Manager. Two at-large members shall be selected from the faculty on the basis of their experience and expertise with hazardous and biohazardous agents to serve staggered three-year terms. Two public members shall be selected who are not affiliated with the college and represent the interests of the surrounding community with respect to health and protection of the environment. Public members shall be appointed to renewable one-year terms.
    a) The Institutional Compliance Officer and the Assistant Vice-President for Administration shall serve as ex officio non-voting members.
    b) The Dean may appoint additional voting or non-voting members to the committee, including alternate members, as needed in order to fulfill the obligations of the institution upon consultation with the Chair of the committee.
2. Responsibilities: This committee shall have the responsibility for making recommendations to the dean regarding the handling and safe conduct of activities that involve the use of hazardous chemicals, biohazardous agents and recombinant or synthetic nucleic acid molecules in the college's owned or operated facilities. Such procedures as developed shall be in compliance with NIH and OSHA guidelines.
    a) The committee shall assume such additional authority as may be required by regulatory agencies holding oversight of the college's research activities.

Extracted from the College Bylaws available at: https://bcomnm.org/wp-content/uploads/2020/06/BCOM-Bylaws-as-Amended-3.9.2020-Final.pdf

APPENDIX H. REFERENCES

1. NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules. http://osp.od.nih.gov/office-biotechnology-activities/rdna/nih_guidelines_oba.html

2. Laboratory Safety Monograph: A Supplement to the NIH Guidelines for Recombinant DNA Research (1979). http://orf.od.nih.gov/PoliciesAndGuidelines/Pages/safety+standards+and+operating+procedures+_28+ssops_29.aspx

3. Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition (December 2009). http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

4. Primary Containment for Biohazards: Selection, Installation and Use of Biosafety Cabinets. In BMBL 5th Edition, Appendix A. www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf

5. NSF/ANSI 49 – 2012. Biosafety Cabinetry: Design, Construction, Performance, and Field Certification. NSF International, 11/27/2012. This standard is available in the NMSU Library at http://libcat.nmsu.edu/vwebv/holdingsInfo?bibId=1585881

6. National Select Agent Registry: www.selectagents.gov

7. USDA Animal and Plant Health Inspection Service Permits and Certifications: http://www.aphis.usda.gov/wps/portal/aphis/resources/permits

8. CDC Permit to Import or Transport Etiologic Agents, Hosts, or Vectors of Human Disease: http://www.cdc.gov/od/eaipp/

9. New Mexico Administrative Code Title 20, Environmental Protection, Chapter 9 Solid Waste. http://www.nmcpr.state.nm.us/nmac/_title20/title20.htm

10. Department of Transportation Hazardous Materials Regulations (49 CFR Parts 171-180). Accessed from www.ecfr.gov/. Educational Materials are available from http://www.phmsa.dot.gov/hazmat/training-outreach.

11. WHO "Guidance on Regulations for the Transport of Infectious Substances," Jan 2009, http://www.who.int/csr/resources/publications/biosafety/WHO_HSE_EPR_2008_10/en/

APPENDIX I. SELECT AGENTS AND TOXINS LIST (2/11/2019)

7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. The list of excluded agents and toxins can be found at: http://www.selectagents.gov

* Denotes Tier 1 Agent

HHS SELECT AGENTS AND TOXINS

1. Abrin
2. *Bacillus cereus* Biovar *anthracis**
3. Botulinum neurotoxins*
4. Botulinum neurotoxin producing species of *Clostridium**
5. Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$)[1]
6. *Coxiella burnetii*
7. Crimean-Congo haemorrhagic fever virus
8. Diacetoxyscirpenol
9. Eastern Equine Encephalitis virus[3]
10. Ebola virus*
11. *Francisella tularensis**
12. Lassa fever virus
13. Lujo virus
14. Marburg virus*
15. Monkeypox virus[3]
16. Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
17. Ricin
18. *Rickettsia prowazekii*
19. SARS-associated coronavirus (SARS-CoV)
20. Saxitoxin

South American Haemorrhagic Fever viruses:

21. Chapare
22. Guanarito
23. Junin
24. Machupo
25. Sabia

26. Staphylococcal enterotoxins A,B,C,D,E subtypes
27. T-2 toxin
28. Tetrodotoxin

Tick-borne encephalitis complex (flavi) viruses:

29. Far Eastern subtype
30. Siberian subtype

31. Kyasanur Forest disease virus
32. Omsk hemorrhagic fever virus
33. Variola major virus (Smallpox virus)*
34. Variola minor virus (Alastrim)*
35. *Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

36. *Bacillus anthracis**
37. *Bacillus anthracis* Pasteur strain
38. *Brucella abortus*
39. *Brucella melitensis*
40. *Brucella suis*
41. *Burkholderia mallei**
42. *Burkholderia pseudomallei**
43. Hendra virus
44. Nipah virus
45. Rift Valley fever virus
46. Venezuelan equine encephalitis virus[3]

USDA SELECT AGENTS AND TOXINS

47. African horse sickness virus
48. African swine fever virus
49. Avian influenza virus[3]
50. Classical swine fever virus
51. Foot-and-mouth disease virus*
52. Goat pox virus
53. Lumpy skin disease virus
54. *Mycoplasma capricolum*[3]
55. *Mycoplasma mycoides*[3]
56. Newcastle disease virus[2,3]
57. Peste des petits ruminants virus
58. Rinderpest virus*
59. Sheep pox virus
60. Swine vesicular disease virus

USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS

61. *Coniothyrium glycines* (formerly *Phoma glycinicola*and *Pyrenochaeta glycines*)
62. *Peronosclerospora philippinensis (Peronosclerospora sacchari)*
63. *Ralstonia solanacearum*
64. *Rathayibacter toxicus*
65. *Sclerophthora rayssiae*
66. *Synchytrium endobioticum*
67. *Xanthomonas oryzae*