North Carolina A&T State University

Biological and Biohazardous Materials Safety Guide for Researchers

Institutional Biosafety Committee

June 2013

North Carolina Agricultural and Technical State University

Dr. Harold L. Martin, Sr., Chancellor

Dr. Barry L. Burks, Vice Chancellor for Research and Economic Development

Dr. Tonya R. Hargett, Institutional Biosafety Committee Administrator

STATEMENT OF AUTHORITY

Upon publication of these procedures, the Institutional Biosafety Committee (IBC) of North Carolina Agricultural and Technical State University is hereby authorized to act as agent for North Carolina A&T State University in matters of review, control, and mediation arising from the use or proposed use of biohazardous/biological materials, including recombinant DNA, at North Carolina A&T State University.

Furthermore, it is hereby declared that the IBC derives its authority directly from the Chancellor in all matters involving biosafety and/or violations of accepted rules of practiced described herein. The Responsible Official, Alternate Responsible Official, and Biosafety Officer are hereby granted the authority to immediately suspend a project found to be a threat to health, property, or the environment.

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Barry L. Burks, Ph.D.
Vice Chancellor for
Research and Economic Development

Date

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LIST OF ABBREVIATIONS

AAV	Adeno-Associated Virus
ABSA	American Biological Safety Association
AdV	Adenovirus
ALA	Allergy to Laboratory Animals
ANSI	American National Standards Institute
APHIS	Animal and Plant Health Inspection Service (USDA)
ARO	Alternate Responsible Official
BBP	Bloodborne Pathogen
BMBL	Biosafety in Microbiological and Biomedical Laboratories (CDC/NIH Guidelines)
BSC	Biosafety Cabinet
BSO	Biosafety Officer
CDC	Centers for Disease Control and Prevention (U.S.)
cDNA	Complementary DNA
CFR	Code of Federal Regulations (U.S.)
DOC	Department of Commerce (U.S.)
DOT	Department of Transportation (U.S.)
EHS	Office of Environmental Health and Safety (N.C. A&T)
EPA	Environmental Protection Agency (U.S.)
FDA	Food and Drug Administration (U.S.)
IACUC	Institutional Animal Care and Use Committee (N.C. A&T)
IATA	International Air Transport Association
IBC	Institutional Biosafety Committee (N.C. A&T)
ICAO	International Civil Aviation Organization
IRB	Institutional Review Board (N.C. A&T)
LD50	Lethal Dose 50 (i.e. dose of agent required to kill 50% of recipient subjects)
LFH	Laminar Flow Hood
MSDS	Material Safety Data Sheet
NIH	National Institutes of Health (U.S.)
NIOSH	National Institute for Occupational Safety and Health (U.S., CDC)
OBA	Office of Biotechnology Activities (U.S., NIH)
PI	Principal Investigator
PPD	Purified Protein Derivative (a common test for tuberculosis)
OSHA	Occupational Safety and Health Administration (U.S.)
RAC	Recombinant DNA Advisory Committee (to NIH/OBA)
RCL	Replication Competent Lentivirus
RCR	Replication Competent Retrovirus
rDNA	Recombinant DNA
RO	Responsible Official
SAE	Serious Adverse Event
SAT	Select Agents and Toxins
SOP	Standard Operating Procedure
USDA	Department of Agriculture (U.S.)

DEFINITIONS

Biohazards are infectious agents or hazardous biological materials that present a risk or potential risk to the health of humans, animals, or the environment.[1] The risk can be direct through infection or indirect through damage to the environment.

Biohazardous materials include certain types of recombinant DNA: organisms and viruses infectious to humans, animals or plants (e.g. parasites, viruses, bacteria, fungi, prions, rickettsia); and biological agents (e.g. toxins, allergens, venoms) that may cause disease in other living organisms or cause significant impact to the environment or community.

Biological materials are any materials containing genetic information and capable of reproducing itself or being reproduced in a biological system. Biological materials include (but are not limited to):

- Microorganisms
- Recombinant DNA (rDNA) [2]
- Cell lines
- Animals (live or tissues and biological fluids)
- Plants
- Human tissue or biological fluids
- Microbial Toxins

Biohazardous waste is any liquid or solid waste generated through the handling of specimens from humans or animals that may contain infectious agents. Cultures of infectious agents, human anatomical remains, and animal carcasses that may be infectious are also considered biohazardous waste.

Hazardous waste is any hazardous material that is to be abandoned, discarded, or recycled.

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[1] The CDC, NIH, and other government agencies and professional organizations provide listings and information on organisms and viruses considered to be biohazardous or infectious agents. Any organism or virus listed in Risk Group (RG) two, three, four or that requires Biosafety Level (BL) two, three or four containment is considered biohazardous.

[2] The NIH Guidelines provide a list of covered experimental uses of recombinant DNA that are considered biohazardous and a separate list of exempt experimental uses of recombinant DNA that are not considered biohazardous. These lists are found in Section III of the NIH Guidelines.

Infectious agent is any microorganism, bacteria, mold, parasite, or virus that normally causes or significantly contributes to increased human mortality. Infectious agents have also been defined as any materials that contains an organism capable of being communicated by invading and multiplying in body tissues (40 CFR 259.10)

Select agents and toxins are agents and toxins listed by the Secretary of the U.S. Department of Health and Human Services as having potential to pose a severe threat to public health and safety, in accordance with section 351A(a)(1) of the Public Health Service Act.

Sharp waste includes devices or objects capable of cutting or piercing, such as hypodermic needles, razor blades, and broken glass.

Transgenic materials include microorganisms, plants, and animals that have been genetically engineered or modified. Recombinant DNA techniques create new genetic combinations by changing, adding, or subtracting DNA genes, but this methodology does not necessarily mean that new organisms are created. With the exception of transgenic bacteria that could be infectious (considered biohazardous waste), transgenic materials generally do not pose a threat to public health or the environment.

FOREWARD

This Biological/Biohazardous Safety Guide has been developed to accomplish these goals:

- To protect against exposures of personnel (N.C. A&T employees and students, community members, and visitors) to biological agents;
- To prevent environmental contamination;
- To provide an environment for high quality research while maintaining a safe workplace;
- To comply with applicable federal, state, and local regulations and guidelines;
- To comply with guidelines implemented by federal funding agencies and accepted by N.C. A&T as a condition of funding eligibility; and
- To create a secure laboratory environment to prevent unauthorized utilization of a biological agent

This guide provides university-wide safety guidelines, policies and procedures for the use, possession, manipulation, and transport of biological materials. Although the implementation of these procedures is primarily the responsibility of the Principal Investigator (PI), its success depends largely on the cooperative efforts of laboratory supervisors, employees, and students. Please read the section on responsibilities for additional information. Planning for and implementation of biological safety must be part of every laboratory activity in which potentially biohazardous material is used.

Recommendations in this Biosafety Guide define a "standard of practice" that laboratories should follow.

In general, guidelines on the possession, handling, manipulation, and transport of biological agents cover:

- Recombinant DNA molecules;
- Infectious or potentially infectious agents, including human- or non-human primate-derived material, cultures, and genetically modified cells;
- Microbial agents (i.e. viruses, bacteria, mycobacteria, rickettsia, yeast, fungi, prions, parasites) or specimens that may be exposed to microbial agents; and
- Toxins of biological origin.

They also require the use of various precautionary measures depending on the material(s), facilities, personnel and their experience, and procedures involved.

This guide provides assistance in the evaluation, containment and control of these biohazards. All parties involved and/or working with these materials are required to be familiar with the contents of this guide, complete the required training, and that they seek additional advice when necessary. The IBC Chair, IBC members, and the Biosafety Officer (BSO) are available to assist in this endeavor.

This guide focuses on Biosafety Level (BSL) 1 and 2. A separate guide will be developed for BSL3 labs. However, BSL3 work is subject to the Biosafety Registration requirements of this document. **No work with BSL4 agents may be conducted at N.C. A&T.**

We urge you to use the guide as a road map to compliance within your laboratory. Consult the sections relevant to your research and apply the appropriate safety procedures. The IBC Administrator is available for consultation if you have any questions or concerns with any aspect of the Biosafety Program at N.C. A&T. The credos "*Think before you act*" and "*If you don't know, ask*" are relevant to the use of this guide. If you are unsure of a requirement or biosafety practice, please contact the IBC Administrator at 285-3184 or the Office of Environmental Health and Safety at 334-7992 for assistance. We also would appreciate any feedback or comments that you may have about the use of this guide and will incorporate suggestions in future versions.

IMPORTANT CONTACT NUMBERS

1.1 Emergency Phone Numbers

Ambulance/Fire/Police (N.C. A&T)	336 334-7675
Prime Care (Greensboro)	336 852-7530
Cabarrus Family Medicine (Kannapolis)	704 786-6521
Carolina Medical Center Northeast Emergency Department (Kannapolis – after hours)	704 403-1275
Sebastian Health Center (students)	336 334-7880
Biological/Chemical/Radiological emergencies	336 334-7675
N.C. A&T Human Resources & Benefits	336 334-7747

1.2 Office of Environmental Health and Safety (EHS)

EHS Main Office	336 334-7992
Louisa Thomas, Responsible Official	336 334-7992
Jarwin (JD) Hester, Alternate Responsible Official, RSO	336 334-7992
Dan Rodriguez, Environmental & Occupational Health Officer, BSO	336 334-7992

1.3 Research Support and Compliance

IBC Administrator, LaKesha Reid	336 285-4281
Export Control, Dr. Tonya Hargett	336 285-3184
Office of Sponsored Programs	336 334-7995
Office of Technology Transfer and Economic Development	336 334-7995
Office of Legal Affairs	336 334-7592
24-hour Compliance Hotline (for confidential reporting of compliance concerns)	1 877 507-7313

2. ROLES AND RESPONSIBILITIES

2.1 Department Chairs

The Department Chair bears overall responsibility for the implementation and maintenance of safe practices and procedures in the department. Department Chairs have these responsibilities:

- To ensure that before the initiation of work, each Principal Investigator (PI) of a research laboratory within the department that may expose A&T personnel, students, animals, the environment, or public to biological materials files a Biosafety Application for review by the Institutional Biosafety Committee (IBC) and that approval has been granted before the initiation of the research.
- To ensure that students, staff, and faculty within the department have instruction in safety procedures in research and teaching laboratories or field situations where biological agents are used or collected.

2.2 Principal Investigators

The Principal Investigator using biological materials bears the ultimate responsibility and authority for assessing risks, establishing policies and procedures, training personnel, and maintaining the facility and equipment.

- **Registering with the IBC:** PIs are required to register research work involving biological materials, rDNA, and potential animal, human or plant pathogens with the IBC by completing the IBC Protocol for Research Involving Biohazardous Materials (IBC Application). The application and instructions can be retrieved from the link http://www.ncat.edu/research/dored/compliance-ethics/ibc/index.html, the Division of Research and Economic Development/IBC website, the IBC Administrator, or EHS. Changes to approved research must be submitted as amendments to the IBC and approved before the initiation of the changes to the research.
- **Completing the Risk Assessment:** Performing risk assessment of research projects should be completed by the PI before work is conducted and should be reassessed periodically as new data is obtained. The assessment should include an analysis of the risks posed by the particular organism under investigation and of any specific research, clinical or teaching methods that affect the risk (i.e. procedures requiring highly concentrated amounts of microorganisms or inoculation of animals). No human or animal pathogen should be studied without prior written approval of the N.C. A&T Institutional Biosafety Committee (IBC). The procedures for handling unclassified agents must also be reviewed by the N.C. A&T IBC, Environmental Health and Safety (EHS), as well as the Institutional Animal Care and Use Committee when work with animals is anticipated. The agents must be registered, and information about these agents must be provided to EHS.

- **Developing and Implementing Policies and Procedures:** Developing, establishing, and implementing appropriate safety practices and procedures within the laboratories must be completed before bringing biological agents to campus and/or before initiating any new research project (independent of funding status) to ensure safe operation and instructing students of potential hazards is a vital responsibility. This involves:
    - Being knowledgeable in good laboratory practices and maintaining current knowledge of new safety practices and/or equipment that may improve safety within the laboratory.
    - Demonstrating a positive safety attitude.
    - Making available to the laboratory staff copies of the written procedures that describe potential biohazards, precautions, and actions to be taken in response to spills and accidents, including decontamination procedures and emergency procedures. These procedures and other information will be constructed into a standard operating procedure (SOP) and posted in the laboratory.
    - Maintaining up-to-date knowledge to changes in international, federal, state, and local regulations and guidelines pertaining to biological materials, in consultation with the Biosafety Officer (BSO), and modifying laboratory procedures to meet compliance.
- **Approving Laboratory Personnel:** PIs are responsible for approving research personnel to work in the laboratory and documenting that personnel are competent to conduct the work. They are also responsible for the safety of personnel listed on their IBC application and their actions. This includes:
    - Providing laboratory staff with documented formal and informal instruction and training in the practices and techniques required to ensure safety and in the procedures for dealing with accidental spills, personnel contamination, and other laboratory accidents or emergencies.
    - Informing the laboratory staff of the risks involved with the biological agents in the laboratory and the reasons and provisions for any precautionary medical practices (i.e. physical exams, serum collection, and vaccinations).
    - Making provisions for any precautionary medical practices, including occupational health physical exams, vaccinations, and/or medical surveillance of personnel when required by the agents and nature of the experiments.
    - Supervising and monitoring the performance of the staff to ensure that required safety practices and techniques are employed.
    - Ensuring the authorized staff completes the appropriate IBC training modules and keeping these training records up-to-date.
- **Maintaining Compliance:** PIs must maintain compliance with all federal, state, and/or local regulations on possession, use, transfer, and/or disposal of biohazardous materials. The PI is also responsible for ensuring that the terms and conditions of the NIH Grants

Policy Statement are maintained within the laboratory for all research projects (independent of funding status or sponsor). This includes compliance with the NIH Guidelines for Research with Recombinant DNA Molecules, the Occupational Health and Safety Administration (OSHA) standards included in 29 CFR Part 1910, and other applicable safety guidelines, including those in the CDC/NIH publication Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition.

2.3 Laboratory Personnel and Students

Laboratory personnel and students are responsible for completing requirements for approval to work in the laboratory and ensuring that work is conducted in compliance with N.C. A&T, NIH, CDC, state labor and waste management laws, DOT and other guidelines and regulations.

- Standard Operating Procedures (SOPs): All personnel working in the lab are responsible for learning the SOPs , the potential hazards of infectious agents in use, emergency procedures, and maintaining compliance with the laboratory protocol and SOPs.
- Medical Surveillance: All personnel are responsible for completing any medical surveillance requirements as mandated by the IBC on the PI's IBC protocol agreement with the IBC before initiation of work with biological materials. Any medical restriction, reportable illness, and/or any event that may result from an exposure or result in the creation of a potential hazard, as well as any irregular conditions, must be reported to the PI.
- Laboratory Practices: Any practice in the laboratory SOPs that make it impossible or impractical to maintain operations within the laboratory should be brought to the attention of the PI so the SOPs and/or IBC protocol can be amended.

2.4 Biosafety Officer (BSO)

N.C. A&T's Biosafety Officer has responsibility for the daily administration of standards set by the IBC and acts as the agent of the committee in the implementation of their standards. In addition, the BSO serves as a resource to researchers, administration, and compliance officers. Responsibilities of the BSO include:

- Providing information and consultation on the operation of the laboratory to ensure compliance with CDC, NIH, USDA, DOT, EPA, state and local requirements to researchers, administrators, and other institutional compliance and facilities departments.
- Evaluation and inspection of laboratory facilities for work with infectious agents, recombinant DNA, and other potentially hazardous biological agents. This includes advising on safety measures and equipment for new procedures that may be utilized to mitigate risks associated with working with potentially hazardous materials.
- Providing general biosafety training related to proper handling of biological materials and maintenance of training records.

- Providing advice and assistance in the event of large, high-hazard, or public biological material spills.
- Investigating laboratory incidents, accidents, exposures, potential exposures, and illnesses that may have resulted from potential exposures to biological materials in the laboratory.

2.5 N.C. A&T Institutional Biosafety Committee (IBC)

The N.C. A&T Institutional Biosafety Committee (IBC) serves to maintain institutional compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines); the Center for Disease Control and Prevention (CDC); Biosafety in Microbiological and Biomedical Laboratories (BMBL), current edition; and international, federal, state, and local regulations on the handling of biological materials. The IBC serves as an advisory committee to the Vice Chancellor for Research and Economic Development. The IBC's composition, roles, and responsibilities adhere to those dictated in NIH Guidelines. The membership can be viewed at http://www.ncat.edu/research/dored/compliance-ethics/ibc-members.html.

The IBC is required to review applications form research involving recombinant DNA (rDNA) and biological materials to determine whether the facilities, procedures, and practices meet the standards required by the university and the NIH. In addition, it has the responsibility to certify annually to the NIH that such facilities, procedures, and practices, and the training and expertise of personnel meet NIH standards. Additional IBC responsibilities include:

- Reviewing applications and performing comprehensive risk assessments to determine the appropriateness and adequacy of containment levels and safety measures proposed and/or used in research and teaching. The IBC may down-grade or up-grade containment levels as appropriate to address risks associated with proposed activities.
- Assessing the adequacy of facilities, procedures, practices, training, and expertise of personnel involved in research or instructional activities.
- Ensuring that approval to use select agents is granted only to individuals who meet the access requirements stated in federal regulations on the possession, use, and transfer of select agents and toxins as described in 7 CFR 331, 9 CFR 121, and 42 CFR 73 and other applicable federal regulations.
- Recommending to the Vice Chancellor for Research and Economic Development appropriate sanctions for noncompliance with biological safety standards, guidelines, or regulations.
- Ensuring that no activities involving rDNA in humans are approved through the IBC until approval has been obtained from the NIH OBA rDNA Assurance Committee and compliance with Appendix J of the NIH Guidelines can be ensured.

3. BIOSAFETY REQUIREMENTS

The following information describes the requirements for N.C. A&T researchers as defined by N.C. A&T Institutional Biosafety Committee (IBC) and Office of Environmental Health and Safety (EHS). It is the responsibility of each PI to ensure compliance in the workplace.

3.1 Registration for the Use of Biological/Biohazardous Materials

All PIs working with biological/biohazardous materials are required to complete and submit the IBC Application before initiating research (independent of its funding status) and/or bringing new biological/biohazardous materials to campus. **Work at the BSL2 and BSL3 levels cannot begin until approval has been granted by the IBC.** The IBC Application must be kept current to accurately reflect the materials and their manipulations, personnel handling the material, and the location in which the material may be handled or stored. A copy of the IBC Application form can be accessed online at http://www.ncat.edu/research/dored/compliance-ethics/ibc/index.html.

Submit the Biosafety Application Form for these materials and operations:

- Biohazardous Materials as defined in the Definitions Section of this guide;
- Non-exempt recombinant DNA (as defined by the NIH Guidelines for Research with Recombinant DNA), mammalian cells, tissues, organs or fluids requiring BSL2 or higher containment;
- Risk Group 2 or higher microbial agents (as defined in the Biosafety in Microbiological and Biomedical Laboratories current edition);
- Large-scale (more than 10 liters) cultures of biological materials;
- Biological materials delivered into animal and human subjects;
- Toxins of biological origin;
- Select agents and toxins; and
- Shipping of biological materials, toxins of biological origin, materials on dry ice or liquid nitrogen, or genetically modified organisms.

Once the application is completed, an electronic copy can be submitted to the IBC administrator.

Please note that all Biosafety Applications and amendments are reviewed for compliance with the annual training requirements, NIH Guidelines, CDC, state, and local laws, and university environmental health and safety guidelines.

Annual Affirmation of Biosafety Protocol Information

The Office of Environmental Health and Safety must maintain accurate information regarding the use of biological materials (e.g., microorganisms, cell lines, human materials, animals, and toxins) by N.C. A&T personnel. Approvals of biosafety applications issued by the IBC are for a three-year period. During the three-year period, the IBC requires all PIs to submit an annual renewal, one month before the anniversary date of approval, to ensure that the information provided on the approved biosafety application continues to reflect accurately the current situation in their laboratories. Annual Renewal Forms can be found on the DORED website at: http://www.ncat.edu/research/dored/compliance-ethics/ibc/index.html.

Amendments to Approved Biosafety Protocols

Amendments must be submitted to the IBC Administrator (trharget@ncat.edu) and approved before implementing any change(s) to IBC-approved biosafety protocols. Amendments are made for any of the following:

- Additions or deletions of biological materials and/or non-exempt rDNA;
- Changing the design, operations, scope or location of existing work, including alterations in:
    - Any non-exempt rDNA, including new vectors, inserts; or operations;
    - Administration or exposures of new target cells, organs, organisms; and/or animals;
    - Employing new techniques that may increase risk of exposure of personnel;
    - Creation of a new transgenic strain of animal;
    - Changes in locations; or
    - Changes in major equipment used (e.g. biosafety cabinet, centrifuge).
- Addition or deletion of any personnel to the list of authorized users who may handle biological materials;
- Providing infectious agents to another investigator on or off campus; or
- Arranging for visiting researchers and/or volunteers to work in the laboratory.

Amendments must comprehensively describe the new proposed changes and document any new risk assessment(s) and proposed risk management methods, as appropriate. Amendments can be submitted by completing an amendment form found on the DORED webpage at: http://www.ncat.edu/research/dored/compliance-ethics/ibc/index.html. Any amendment that involves an alteration in risk relative to the previously approved biosafety protocol will be submitted to the IBC for review and approval. Simple amendments involving no alterations in risk (e.g. personnel changes, additions of grants) will be handled administratively by the IBC Administrator. All questions can be addressed to the IBC Administrator, trharget@ncat.edu or 336 285-3184.

3.2 Training Requirements

Successful completion of a range of biosafety training programs may be required before the initiation of your work at N.C. A&T. Relevant training and/or experience to topic of proposed research must be documented in the IBC Biosafety Application.

In accordance with the Laboratory Standard, information regarding the Laboratory Safety Manual, Laboratory Safety Plan, and Material Safety Data Sheets must be communicated to employees and all those working in the lab.

3.3 Laboratory Establishment, Close-outs, and Moves

To ensure appropriate containment is maintained, safety measures are implemented and compliance with all federal, state, and local regulations and guidelines for all biological materials at N.C. A&T have been met, documentation must be provided, reviewed, and approved by the IBC before moving any biological agents into any new facility (which may be brought to campus by incoming new faculty or materials that may be moved to new locations not previously authorized as part of the PI's IBC approved protocol). In addition, to ensure that the biological materials are properly removed and facilities are decontaminated before the closing of a lab, PIs must contact EHS to move biological agents when closing out a lab that housed biological agents.

4. RISK MANAGEMENT: BIOSAFETY LEVELS

Management of the risks associated with research involving biological materials is accomplished via a combination of Practices, Safety Equipment, and Facilities. Biosafety Levels (BSLs) refer to the level of containment required and appropriate to contain risk as assessed. The CDC, WHO, and NIH have established standards for four biosafety containment levels for work with all biohazardous materials in the publication Biosafety in Microbiological and Biomedical Laboratories (BMBL). These standards provide general descriptions of the combination of microbiological practices, laboratory facilities, and safety equipment as well as their recommended uses to contain biological agents that may be infectious to humans, or impact the environment.

Because working with hazardous materials in animals creates additional risks to the laboratory worker or the environment and laboratory logistics, there are also standards for four biocontainment levels for research with biohazardous materials and animals or ABSLs (Section V of the BMBL).

The biosafety containment level standards are intended as a guideline for management of the risks as determined during the risk assessment. However, this is not a prescriptive, formulaic process. Mitigation and management methods should always provide prudent measures to contain the materials and protect exposure of the users to the materials based on the risks assessed. Therefore, since the risks in each laboratory are unique to the laboratory, the Standard Operating Procedures (SOPs) should be specific for the laboratory, agents, operations, and practices within the lab. Protective measures to block the routes of transmission, based on the operations involved and locations must be reviewed. Keep in mind that on occasion, a risk may be present that may require an additional or alternative protective measure (e.g. development of a special practice or procedure, use of special equipment or restriction to a facility) to protect personnel and the environment from the biological agents proposed for use. These may go beyond those explicitly stated in the BMBL or NIH Guideline standard, however, it is the IBC's responsibility (as per NIH Guidelines) to ensure the assessed risks involved in a proposed experiment have been reduced to an acceptable level based on the mandated comprehensive risk assessment. Therefore, the IBC may stipulate special containment measures as a condition of receiving approval.

The following table summarizes practices, equipment, and facility requirements for agents assigned to basic biosafety level 1 – 4 (BSL1 – 4) (Table 1). Additional information on biosafety levels may be found in the BMBL or NIH Guidelines.

Table 1: Summary of Recommended Biosafety Levels

BSL	Agents	Practices	Safety Equipment (Primary Barriers)	Facilities (Secondary Barriers)
1	Not known to consistently cause disease in healthy adults	Standard microbiological practices	None required	Open bench top sink required
2	Associated with human disease or hazard: percutaneous injury, ingestion, mucous membrane exposure	**BSL-1 practices plus**: • Limited access • Biohazard warning signs • "Sharps" precautions Biosafety manual defining policies on any needed waste decontamination or medical surveillance	**Primary barriers**: Class I or II BSCs or other physical containment devices used for all manipulations of agents that cause splashes or aerosols of infectious materials. **Personal Protective Equipment (PPE)**: Lab coats, gloves, face protection as needed	**BSL-1 plus:** Autoclave available
3	Indigenous or exotic agents with potential for aerosol transmission; disease may have serious or lethal consequences	**BSL-2 practices plus**: • Controlled access • Decontamination of all waste • Decontamination of lab clothing before laundering • Baseline serum	**Primary barriers**: Class I or II BSCs or other physical containment devices used for all open manipulations of agents; **PPE:** Protective lab clothing, gloves, respiratory protection as needed	**BSL-2 plus:** • Physical separation from access corridors. • Self-closing, double-door access. • Exhausted air not recirculated. Negative airflow into laboratory
4	Dangerous/exotic agents that pose high risk of life-threatening disease, aerosol-transmitted lab infections, or related agents with unknown risk of transmission	**BSL-3 practices plus**: • Clothing change before entering • Shower on exit • All material decontaminated on exit from facility	**Primary barriers:** All procedures conducted in Class III BSCs or Class I or II BSCs in combination with full-body, air-supplied, positive pressure personnel suit	**BSL-3 plus**: • Separate building or isolated zone • Dedicated supply and exhaust, vacuum, and decon systems. • Other requirements outlined in BMBL.
	Work at BSL4 level is NOT permitted at N.C. A&T.			

5. ACCIDENTS, EXPOSURES, AND SPILL RESPONSE

Laboratory-specific SOPs should address any emergency response procedures, including those required if an accident, exposure, potential exposure, potential exposure, an illness that may have resulted from a possible laboratory exposure, release from primary containment or environmental contamination of any biologically hazardous material.

5.1 Emergency Procedures for Exposure Incidents

An "exposure incident" is a specific eye, mouth, other mucous membrane, non-intact skin or parenteral contact with blood or potentially infectious materials (OPIM) that results from the performance of an employee's duties or commission of the person's responsibilities in conjunction with the research or educational mission of N.C. A&T. A person who sustains a known or potential exposure incident must remove their gloves and treat the affected area immediately by following the appropriate exposure incident response below:

Percutaneous Injury

- Wash the affected area with antiseptic soap and warm water for 15 minutes

Splash to face

- Flush affected area in eyewash continuously for 15 minutes

Aerosol Exposure

- Do not inhale; immediately leave the room. Remove PPE carefully. When removing PPE make sure to turn the exposed areas inward. Wash hands well with soap and water. Post a spill sign on the laboratory entry door to prevent others from entering. The laboratory should remain evacuated for at least 30 minutes to allow for the droplets to settle and/or aerosols to be purged by the air exchange rate within the laboratory.
- The PI must clear the laboratory before re-entry and spill clean-up can begin. For extensive contamination (e.g. an incident involving a centrifuge) or incident involving BSL3 agent, the Responsible Official (EHS Director) must be notified immediately (334-7992) and will assume responsibility, in conjunction with the PI, to clear the laboratory for re-entry.

5.2 Reporting Incidents

The employee must report incidents to his/her supervisor. Because the health and safety issues of injured personnel is of primary importance, if the injury is emergent, the supervisor should take

the injured person to the nearest emergency room (or make arrangements for the injured person to be taken) and reporting requirements should be completed post-hoc.

The supervisor should take measures to ensure that additional personnel are restricted from areas to prevent inadvertent exposures. Any incident, accident, exposure, possible exposure, illness that may have resulted from exposures, releases from primary containment or environmental contamination involving biological materials that occurred in the course of accomplishing the research and/or educational missions of the university should be reported as soon as possible to EHS (334-7992).

6. BIOHAZARDOUS WASTE PICK-UP

The Office of Environmental Health and Safety (EHS) is responsible for removal of any full authorized biohazardous waste container. If laboratory staff notices that containers are full and require removal, please contact EHS at 334-7992.

For additional information or answers to questions that are not addressed in this Guide, contact:

- *The IBC Administrator, Dr. Tonya Hargett, trharget@ncat.edu, 336 285-3184, or*
- *The EHS Director, Ms. Louisa Thomas, lvthomas@ncat.edu, 336 334-7992.*