LOUISIANA STATE UNIVERSITY AND LOUISIANA AGRICULTURAL CENTER

Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

"CHARTER AND POLICIES"

June 2012 Revision

Office of Environmental Health and Safety
126 Public Safety Building
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APPROVAL SIGNATURES

Director, Office of Environmental Health and Safety — Date: 6/8/2012

Chair, IBRDSC — Date: 6/8/12

LSU Biosafety Manager — Date: 6/8/2012

LSU Vice Chancellor for Research & Economic Development — Date: 6-8-12

LSU AgCenter Vice Chancellor and Director for Ag Experimental Stations — Date: 08 June 2012

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IBRDSC Adopted Policies

1. Introduction

The handling of various biological agents has the potential to result in accidental exposures to University personnel, liability and public relation issues, community outbreaks of disease or damage to natural ecosystems. The Louisiana State University/Louisiana Agriculture Center Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC) is charged with protecting LSU faculty, staff, students, and visitors and has the authority to stop any activity that the committee believes to be unsafe. This document establishes policy for conducting biological research activities and defines responsibilities of principal investigators, lab workers, department heads, the IBRDSC, the Manager of Biological Safety and the Responsible Official. Additionally, it details the procedures to be used by the IBRDSC in the review of biological research and activities. The information provided is based on federal, state, and University regulations and guidelines.

The IBRDSC follows federal guidelines with respect to the review and approval of protocols involving biological materials. All teaching, diagnostic, research and extension activities which involve recombinant DNA or potentially hazardous biological materials and performed by LSU faculty, students, and visitors must be reviewed and approved by the IBRDSC. The requirements apply also to activities on LSU land, facilities (owned, leased, or rented) and sponsored activities. The IBRDSC is comprised of faculty from many academic disciplines at LSU, non-scientific members, and community representatives not affiliated with the University.

2. Institutional Authority under Which the Inter-Institutional Biological and Recombinant DNA Committee (IBRDSC) Operates

The Inter-Institutional Biological and Recombinant DNA Safety Committee is an official university committee that operates under the authority of two Institutional Officials; the Louisiana State University's Vice Chancellor for Research and Economic Development and the Louisiana Agricultural Center Vice Chancellor and Director for Agricultural Experiment Stations.

3. Reason for the IBRDSC's Existence

In order to assure compliance with current federal guidelines and regulations which include the Department of Health and Human Services' and Department of Agriculture's Select Agent rule, the IBRDSC oversees and establishes University policy for the review or approval of all research projects, teaching, diagnostic testing and any other activities involving the use of recombinant DNA and potentially biohazardous materials. Specific guidelines include:

- The National Institute of Health's Guidelines for Research Involving Recombinant DNA Molecules; URL, http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

- DHHS, Centers for Disease Control, Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (BMBL); URL, http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

- DHHS, Possession, Use, and Transfer of Select Agents and Toxins, 42 CFR Parts 72 and 73, URL, http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf

- USDA, Agricultural Bioterrorism Protection Act of 2002, Possession, Use, and Transfer of Biological Agents and Toxins; URL, http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf

The IBRDSC also oversees the use of non-regulated pathogens of humans, animals and plants. Anyone at Louisiana State University who either stores or uses in anyway biohazardous materials must inform the IBRDSC by submitting a registration form; URL, https://sites01.lsu.edu/wp/ehs/biological-safety-registration-of-biohazard-recombinant-dna-research/ through the Biological Safety Manager located within the Office of Environmental Health and Safety.

The LSU IBRDSC maintains all related records for three years after the completion of the activity.

No BSL-4/Risk Group 4 Agents may be used or stored at LSU, URL, http://www.absa.org/riskgroups/index.html

4. Activities which Require Review by the IBRDSC

Potentially biohazardous materials includes all infectious organisms such as fungi, bacteria, parasites, chlamydiae, prions, rickettsiae and viruses which can cause disease in animals, plants and humans or cause environmental or agricultural impact. Also included are human and primate tissues, fluids, cells and cell cultures which may harbor infectious organisms. Examples of materials that require IBRDSC approval prior to the start of research projects are listed here (this list is not inclusive).

- Genetically modified organisms:
  - Animals, plants, invertebrates
  - Transgenic field trials
  - Field testing of plants engineered to produce pharmaceutical and industrial compounds

- Recombinant DNA
- Organisms, agents, or toxins requiring federal permits including APHIS, CDC, EPA, FDA
- Pathogens/infectious agents (human, animal, plant, and other)
- **Select Agents and Toxins** (CDC and USDA). Possession, use, or transfer of Select/Biological Agents and Toxins entails additional requirements and falls under the oversight of the Universities' Responsible Official who is the Director of the Office of Environmental Health and Safety. Contact the LSU Biological Safety Manager for this information.
- Biological toxins
- Human blood, tissues, human fluids, human/primate cell lines
- Use of animals or vectors known or suspected as reservoirs of BL2 or BL3 infectious agents
- Oncogenic viruses used in conjunction with animals

5. Who May Submit Registrations to the IBRDSC?

Any LSU PhD including Post-Doctoral Fellows. Undergraduates, graduate students including doctoral students must be under the supervision of a principal investigator with a PhD who is responsible for the registration. The committee may also agree to review research registrations from other institutions which may not currently have an Institutional Biosafety Committee provided this has been preapproved by the associated Vice Chancellor and Office of Risk Management.

6. Duties and Responsibilities

I. Principal Investigators/Instructors/Laboratory Managers

Principal Investigators (PI's) are responsible for the people and activities in their laboratories. They are responsible for implementing an appropriate biological safety program which includes training of staff and documentation of specific protocols tailored to their specific laboratory in a current Biosafety Manual. They are responsible for performing risk assessments and maintaining an appropriate biological safety level as assigned by the University's Biological Safety Manager and IBRDSC. In order to accomplish this the PI must register any potentially biohazardous agents with IBRDSC using the appropriate registration form.

II. Principal Investigator Responsibilities under NIH

Principal Investigators (PIs) are responsible for full compliance with the *NIH Guidelines* during the conduct of recombinant DNA research. As part of this general responsibility, the PI should:

- Be adequately trained in good microbiological techniques.
- Provide laboratory research staff with protocols describing potential biohazards and necessary precautions.
- Instruct and train laboratory staff in: (i) the practices and techniques required to ensure safety, and (ii) the procedures for dealing with accidents.
- Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection).
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in the release of recombinant DNA materials.
- Ensure the integrity of physical containment (e.g., biological safety cabinets) and biological containment (e.g., purity and genotypic and phenotypic characteristics).
- Comply with permit and shipping requirements for recombinant DNA molecules.
- Adhere to IBRDSC-approved emergency plans for handling accidental spills and personnel contamination.
- Comply with NIH, CDC, USDA, OSHA and State requirements.

Before initiating research subject to the *NIH Guidelines*, the PI must:

- Determine whether the research is subject to Section III-A, III-B, III-C, III-D, or III-E of the *NIH Guidelines*.
- Propose physical and biological containment levels in accordance with the *NIH Guidelines* when registering research with the IBC.
- Propose appropriate microbiological practices and laboratory techniques to be used for the research.
- Submit a research protocol to the IBRDSC for review and approval.
- Seek OBA's determination of containment for experiments that require case-by-case review.
- Petition OBA, with notice to the IBRDSC, for proposed exemptions from the *NIH Guidelines*.

- Obtain IBRDSC approval before initiating research subject to the *NIH Guidelines*.
- Seek NIH approval, in addition to IBC approval, to conduct experiments specified in Sections III-A and III-B of the *NIH Guidelines*.

While conducting research subject to the *NIH Guidelines*, the PI must:

- Determine the need for IBRDSC review before modifying recombinant DNA research already approved by the IBRDSC.
- Submit any subsequent changes (e.g., changes in the source of DNA or host-vector system) to the IBRDSC for review and approval or disapproval.
- Remain in communication with the IBRDSC throughout the duration of the project.

Report any significant problems pertaining to the operation and implementation of containment practices and procedures, violations of the *NIH Guidelines,* or any significant research-related accidents and illnesses to the IBRDSC, OBA, and, as applicable, the Biological Safety Manager, Greenhouse or Animal Facility Director, and other appropriate authorities.

II. Laboratory Workers (Technicians, Technologists, Students, Post Doctorates);

- Laboratory Workers must follow all safety practices and establish good laboratory technique. They must work using the assigned biological safety containment level and use personal protective equipment as recommended by the Principal Investigator.

- Make the Principal Investigator or University Biological Safety Manager aware of any health condition that may be due to their work in the lab or any health condition that may be compromised prior to the initiation of a research project (i.e., pregnancy, immunosuppression).

- Follow all biosafety practices and procedures.

- Report problems, procedural mistakes, spills, etc. as soon as they occur.

- Report to the Biological Safety Manager or IBRDSC violations of biosafety procedures or policies.

III. Department Heads (Chancellors, Vice Chancellors, Deans, and Directors)

Department Heads have the following responsibility:

- Be aware of your responsibility to be in compliance with federal guidelines, recommendations and laws regarding safety, biosafety, and the use of recombinant DNA and select agents. Provide leadership and support in laboratory safety at the management level in the department. Ensure that Lab Workers receive appropriate safety training prior to the initiation of research protocols.

- Support the work and decisions of the Inter-Institutional Biological and Recombinant DNA Safety Committee in its charge to protect University students, staff and faculty and reduce liability for the University.

- Assist the IBRDSC by ensuring that principal investigators prior to initiation of research using pathogens, human blood, tissues, body fluids, human cell lines or recombinant DNA, submit and receive approval from the IBRDSC.

- Determine that facilities are appropriate and safe for the research proposed if the research involves potentially biohazardous agents.

IV. The Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

The IBRDSC is responsible for reviewing and approving practices and protocols for the handling of recombinant DNA and potentially biohazardous materials at all research facilities under the authority of Louisiana State University and the Louisiana AgCenter. The IBRDSC also develops and reviews policy. The IBRDSC is comprised of faculty representatives from many different academic disciplines. This includes researchers, non-scientific members, and community representatives who are not affiliated with the university. The Committee meets monthly to review research and other activities. The IBRDSC can be reached through Gregory V. Hayes, DrPH, University Biological Safety Manager at 225-578-4658 (ghayes@lsu.edu). Meetings of the IBRDSC are open to the public unless discussions of proprietary information (intellectual property) are to take place. Meeting dates, times and locations are posted on the EHS web site under biological safety; URL, https://sites01.lsu.edu/wp/ehs/

V. The Biological Safety Manager (BSM)

The Biological Safety Manager develops, directs and manages a comprehensive biological safety program throughout all laboratories at Louisiana State University. This program must meet NIH, CDC, USDA, OSHA, and State requirements.

- The Biological Safety Manager provides guidance and consultation in assessing risk when working with potentially biohazardous materials.
- The Biological Safety Manager represents and provides support to the members of the IBRDSC.
- The Biological Safety Manager represents the IBRDSC at the LSU and AgCenter Institutional Animal Care and Use Committees (IACUC), and other University committees as well as interacts with the LSU researchers and teaching, diagnostic, and extension community members.
- The Biological Safety Manager ensures compliance with state and federal regulations and recommendations.
- Conducts inspections and follow-up to ensure deficiencies are corrected.

VI. Responsible Official

The "Responsible Official" is the individual designated by the Vice Chancellors with the authority and control to ensure compliance with federal regulations. The Responsible Official has full authority to develop and manage the University's "select agent program". All select agent research must be carried out in accordance with the provisions of the Department of Health and Human Services' 42 CFR parts 72 and 73 and the Department of Agriculture's 9 CFR part 331 and 9 CFR Part 121. All research and support personnel must have authorization granted by the Responsible Official and pass a security risk assessment. For a list of "select agents", see http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html

7. Authority of the IBRDSC

I. Defined Scope of Authority

The LSU IBRDSC has the authority to approve, require modifications in, or disapprove all research, teaching, diagnostic, or extension activities (whether funded or non-funded) that fall within its jurisdiction as specified

by both federal regulations and Institutional policy.

II. Authority to Approve, Require Modification, or Disapprove Studies Based Upon Consideration of Biological Safety Aspects

The LSU IBRDSC approves protocols for three years. After three years the research protocol must be resubmitted. Research that has been reviewed and approved by the LSU IBRDSC may be subject to further review by the Institutional Animal Care and Use Committees.

The LSU IBRDSC functions independently of other committees. The IBRDSC decisions are based on regulations, guidelines, and policies which assure safety. The IBRDSC has jurisdiction over all research involving regulated or potentially hazardous biological materials.

III. Authority to Require Progress Reports from Investigators and Oversee the Conduct of the Study

All approved research is subject to continuing LSU IBRDSC review and is re-evaluated every three years. This re-evaluation can occur more often if specified by the IBRDSC.

IV. Authority to Approve/Disapprove Modifications

All modifications to previously approved research must be reviewed and approved prior to implementation. Modifications are submitted to the Biological Safety Manager (BSM) who may approve or determine that the modification needs to go back before the committee. He may also determine that a new proposal registration needs to be submitted. Modifications only last until the end of original approval period.

Examples of modifications:

- Protocols that increase risks (committee)
- Change in personnel or additional personnel (BSM)
- Change in lab room (BSM)
- New pathogens introduced (new registration)
- Use of a new cell line (BSM)
- Change of contact information (BSM)

V. Authority to Suspend or Terminate Approval of a Study

The LSU IBRDSC has the authority to terminate/suspend research at LSU that has not followed IBRDSC requirements or recommendations or if serious consequences have occurred. The IBRDSC will inform the Vice Chancellor, Principal Investigator and Department within 10 working days of this decision in writing.

VI. Responsibility to report non-compliance to Federal Agencies

The IBRDSC is obliged to report noncompliance to NIH and CDC and other federal agencies. The IBRDSC will assume non-compliance if there

is no response to their recommendations after 30days. The Biological Safety Officer will then send the non-compliant individual an official notification letter requesting compliance. If no response is received within 30 days the committee will notify the individual's supervisor, Department Chair, Dean and Vice-Chancellor that non-compliance is being reported to the Federal Agencies involved.

8. Membership of the IBRDSC

I. Number of Members

According to NIH guidelines the IBRDSC shall have no less than five members. Members will have varying backgrounds to promote complete and adequate review of research, teaching, diagnostic, and extension activities. Consultants are to be used when committee members lack expertise in a particular area and are warranted.

II. Qualification of Members

The IBRDSC will have enough expertise among its members to determine the acceptability of submitted research and activities in terms of institutional commitments, regulations, recognized guidelines, applicable laws, and standards of professional conduct and practice.

III. Diversity of Members

The IBRDSC membership will be adequately qualified through experience, expertise and diversity enough to promote respect for its capability to assess the safety of research involving pathogens and recombinant DNA and to identify risks to people, the community and the environment.

The IBRDSC will include at least two members from the community not associated with LSU. These members shall represent the interests of the community.

The Biological Safety Manager will be a non-voting member which represents the members of the committee.

The Universities' Responsible Official under 42 CFR Parts 72 and 73 and 7 CFR Part 331 and 9 CFR Part 121 will be a voting member of the committee.

The Committee Chair will be a voting member of the committee.

Every effort will be made to include at least one member whose primary expertise is in plant pathology, plant pathogens, and plant pest containment principles.

Every effort will be made to include one member with expertise in animals and animal containment principles.

Every effort will be made to include one member with expertise in molecular biology.

Every effort will be made to include one member with expertise in entomology.

Every effort will be made to include one member with expertise in biology.

Every effort will be made to include one member with expertise in immunology.

Every effort will be made to include one member with expertise in bacteriology and virology.

9. Management of the IBRDSC

I. The Chair

A. Selection and Appointment

The Chair is appointed by popular vote of the IBRDSC members.

The Chair is also a voting member and counts toward quorum.

If the Chair is not available for an IBRDSC meeting the chair may appoint any member as a replacement. If the Chair is unable to participate for more than 4 meetings the committee may appoint a temporary Chair.

B. Duties

The Chair directs the IBRDSC meetings, working closely with the Biological Safety Manager and other committee members. Meetings adhere to federal and institutional recommendations. The Chair helps to ensure that research and all other activities at LSU or any of its extensions which involve potentially biohazardous materials or recombinant DNA are conducted in a safe and appropriate manner in accordance with all federal, state, and Institutional regulations, policies, and procedures.

C. Removal

The Chair may be removed or replaced by the Institutional Officials.

II. The IBRDSC Members

A. Selection and Appointment

IBRDSC members are appointed by the Institutional Officials. LSU faculty members appointed to the IBRDSC will serve a four-year term and may be re-appointed.

Community and/or non-affiliated IBRDSC members will be appointed for 2 year terms and may be reappointed.

There is no limit to the number of terms a member may serve on the IBRDSC.

B. Duties

LSU IBRDSC members are responsible for ensuring that research and all other activities at LSU or any of its extensions which involve potentially biohazardous materials or recombinant DNA are reviewed and approved in a safe and appropriate manner in accordance with all federal, state, and Institutional regulations, policies, and procedures.

C. Removal

IBRDSC members may be removed or replaced by the Institutional Officials.

III. Training of IBRDSC Chair and Members

A. Orientation

When a new member or alternate is appointed to the IBRDSC the Chair and Biological Safety Manager will conduct a new member orientation. This orientation will include a discussion of IBRDSC mandates, procedures, federal regulations, the IBRDSC registration form and other processes. The new member will be provided with appropriate reference materials.

B. Continuing Education

Continuing education is provided as frequently as necessary depending on the budget available. This training may include reference materials, presentations, guest speakers or simply discussions at IBRDSC meetings. The IBRDSC Chair, committee members and Biological Safety Manager may attend professional development conferences throughout the year in order to keep current on related issues.

C. Reference Materials

Each IBRDSC member is provided with a manual which includes the specific LSU IBRDSC Charter and policies as well as other pertinent reference materials to assist their decision making.

IV. Liability Coverage for IBRDSC Members

State law offers protection for state employees and authorized volunteers who are sued for duties and actions performed in the course of their employment and in good faith.

V. Use of Consultants

The LSU IBRDSC can use specialized consultants for advice and information as needed. These consultants may be LSU faculty or staff, or may be unaffiliated with LSU. The consultants may present their assessments in writing or in person.

VI. Biological Safety Manager

Evaluates, recommends, assists with interpretation and provides information regarding compliance with laws, regulations, and safety standards.

Communicates with Principal Investigators the requests of the committee for additional information, revisions, approvals and denials.

Prepares correspondence, reports, agendas, and certifications of approval for the IBRDSC committee.

Reviews and prepares changes to the committee's administrative procedures.

Provides advice to faculty, staff, and students preparing registration documents for IBRDSC review and advises them of proper procedures in handling biological materials including pathogens and recombinant DNA materials.

Inspects and prepares reports of laboratories in compliance with safety rules.

Maintains all records related to IBRDSC activities.

10. Conflict of Interest Policy

There shall be no selection of IBRDSC members as reviewers by Principal Investigators.

IBRDSC members must excuse themselves from review of a proposal that is a conflict of interest. This might be their own proposal or a proposal in which they are a co-investigator or in which they or a family member has a financial interest. IBRDSC members are obligated to report their conflict of interest to the IBRDSC Chair prior to discussion of the protocol in question.

No research at Louisiana State University or the Louisiana Agricultural Center is exempt from oversight or review.

11. Functions of the IBRDSC

I. Review and Approval

The LSU IBRDSC is responsible for the review and approval of all projects (funded or not funded) that involves regulated or potentially biohazardous recombinant DNA or pathogens conducted in association with Louisiana State University and the Louisiana AgCenter umbrella.

II. Reporting of IBRDSC Decisions to the Principle Investigator

The Biological Safety Manager will report the findings and actions of the IBRDSC to the Principal Investigator.

III. Frequency of Protocol Reviews

The IBRDSC requires that all active protocols be resubmitted every three years, unless the IBRDSC has determined the nature and/or risk of the research requires more frequent renewal.

IV. Review and Approval of Changes/Modifications

All modifications to currently approved research/activities are required to have approval prior to implementation.

An approved proposal modification is only good until the end of the original approval period. If for example, the original proposal approval was issued on January 1, 2006 it will have an expiration date of December 31, 2008. A proposal modification only lasts until December 31, 2008.

V. Ensuring Prompt Reporting to the IBRDSC of Unanticipated Problems

The Biological Safety Manager will report in writing within 10 working days to the IBRDSC Chair, Vice Chancellors and relevant Department Heads any report of adverse events as mandated in the Federal Regulations. Select Agents and Toxins require immediate notification of the Responsible Official (Director of Environmental Health and Safety) and the relevant agency (CDC or APHIS).

12. Operations of the IBRDSC

I. Scheduling of Meetings

The IBRDSC will convene monthly unless there is no business to be conducted, in which case a meeting will not be held. Monthly meetings will be arranged by the Biological Safety Manager. IBRDSC meetings are open to the public unless proprietary information is up for discussion. Meeting dates, locations and meeting times are posted on the Office of Environmental Health and Safety's website under biological safety; URL, https://sites01.lsu.edu/wp/ehs/biological-safety-registration-of-biohazard-recombinant-dna-research/

II. Pre-meeting Distribution of IBRDSC Review Materials to Members

Prior to a meeting, the Biological Safety Manager will send to each committee member

- Agenda for the meeting
- Location and time of the meeting
- Minutes from the previous meeting
- New protocols to be reviewed
- Modification Requests
- Renewal Requests
- Continuing Education Materials that may be available

III. The Review Process

Description of the Review Process

The LSU IBRDSC is responsible for the review and approval of all research or activities that involve regulated biological or biohazardous materials at Louisiana State University, Louisiana AgCenter or any of its extensions whether funded or not funded. Additional information may be requested in addition to the registration document if anything is unclear.

A. Pre-Review

When a protocol is received the Biological Safety Manager will review the registration document for completion and signature. If anything is missing or unclear the Biological Safety Manager will contact the Principal Investigator for additional information.

B. Committee Review

The IBRDSC Chair will assign two reviewers to each submitted proposal. The Biological Safety Manager will then distribute the proposal to the reviewers as well as the entire committee. Reviewers may contact the Principal Investigator prior to the committee meeting to answer questions or provide additional information needed to make an informed decision. All committee members are expected to read and review all proposals prior to a committee meeting. At the committee meeting each proposal will be discussed in detail and voted upon. Conclusions, additional questions, etc. will be communicated back to the Principal Investigator by the Biological Safety Manager. Determinations made by the IBRDSC can include the following:

1. **Approved:** The IBRDSC may make a motion and vote to approve the protocol as submitted. The PI will then receive an approval letter with a certificate.

2. **Approved Pending Inspection:** The IBRDSC may request the Biological Safety Manager to inspect the laboratory prior to being sent an approval letter with a certificate.

3. **Approved Pending Receipt of Federal Permits**: The IBRDSC will always defer approval pending receipt of federal permits (i.e., APHIS, EPA, etc.) if applicable.

4. **Approved Pending Receipt of Additional Information/or Minor Modifications:** The IBRDSC frequently may request that additional information be provided for the record. The Biological Safety Officer will assure this information has been received prior to providing final approval.

5. **On Hold Pending Modifications**: When the IBRDSC feels that major modifications or additional information is needed to make a decision, they may place the proposal on hold. Modifications and additional Information must come back to the IBRDSC for approval at the next face-to-face meeting.

6. **Not Approved:** When proposed activities are considered too hazardous to the Principle Investigator, personnel, the environment, the community or to the University due to lack of expertise or facilities the IBRDSC may vote to disapprove the research proposal.

C. Expedited Review

The IBRDSC does not conduct expedited reviews. Expedited reviews are not allowed by NIH under the NIH Guidelines.

IV. Voting requirements

A. Quorum required

A quorum of half of the voting membership is required to conduct business.

B. Voting rights of all reviewing members

Each member has one vote.

C. No proxy votes

No proxy votes are allowed.

D. No conflict-of-interest voting

IBRDSC members must not vote on a protocol if they are investigators on the protocol or have any other conflict of interest with any person or entity connected to a protocol.

E. Alternates

Each IBRDSC member may have designated alternates. Alternates may attend all meetings, however, they vote only when the primary member is absent. Alternates attending meetings (when the primary member is present) do not count toward quorum and may not vote. Alternates are encouraged to review all protocols and participate in

all discussions.

V. Communication from the IBRDSC

A. Conveying IBRDSC Decisions to the Investigator

IBRDSC actions that occur during meetings are promptly conveyed (usually within 5 days) to the Principal Investigator in writing by the Biological Safety Manager. Communications include approval or for deferred protocols all requirements that must be met for the committee to grant approval.

B. Criteria for appeal

If a registration application is not approved, the IBRDSC will provide reasons for disapproval and this will be provided through the Biological Safety Manager in writing. Principal Investigators may respond in writing and may appear before the IBRDSC to plead their case for approval.

13. IBRDSC Record Requirements

I. IBRDSC Membership Roster

Annually the Biological Safety Manager must submit a copy of the membership roster including each member's curriculum vitae demonstrating qualifications to the Office of Biotechnology Activities (OBA), NIH.

II. Written Charter and Policies

The IBRDSC Charter and policies are is posted on the EHS website under Biological Safety:
https://sites01.lsu.edu/wp/ehs/biological-safety-inter-institutional-biological-and-recombinant-dna-safety-committee-ibrdsc/

III. Minutes of Meetings

The Biological Safety Manager will take minutes at each meeting of the IBRDSC. The minutes will contain:

- Members present
- Others present (guests/consultants/researchers)
- Summary of discussions
- Motions made and seconded

Meeting minutes are available to the public upon request.
If a member of the public requests copies of the IBRDSC minutes

the Office of Environmental Health & Safety will review the minutes and redact all proprietary and select agent information contained within. Additionally, the minutes will be sent to the Office of University Relations to review and redact personal information prior to release. If a federal agency requests copies of the IBRDSC minutes no redacting will occur.

If public comments are received by the committee they will be discussed at a face-to-face meeting containing a quorum of members. The minutes of this discussion will be forwarded to NIH OBA.

IV. Retention of Records

Research registration documents, inspection sheets and related materials will remain on file in the Office of Environmental Health and Safety (EHS) for 3 years following the conclusion of the research project.

Meeting minutes and IBRDSC rosters will remain on file at the Office of Environmental Health and Safety as a record of the committee's activities.

14. Information the Principal Investigator Provides to the IBRDSC

I. Registration Form

Principal Investigators must submit a Registration form to the Biological Safety Manager (ghayes@lsu.edu) located in the Office of Occupational Health and Environmental Safety (EHS). The form must be submitted electronically. The URL for the registration form: https://sites01.lsu.edu/wp/ehs/biological-safety-registration-of-biohazard- recombinant-dna-research/

AgCenter registration forms should be signed by the department chair where the research will take place. Additionally, copies of federal permits, appendices or any supporting material should also be submitted.

II. Reports of Unexpected Adverse Events

Principal Investigators are required to report any adverse events to the IBRDSC through the Biological Safety Manager. The Principal Investigator should indicate what happened, what was done to correct the problem and what will be done so that the adverse events do not happen again.

III. Three Year Renewal/Project Expiration

Approximately 2 months prior to the expiration of an approved protocol, the Principal Investigator will receive an e-mail from the database notifying them that their approved registration is about to expire. Investigators desiring to continue their research are responsible for completing a new registration form and returning it to the IBRDSC through the Biological Safety Manager before the expiration date.

15. Laboratory Inspections and Safety Manuals

I. Biosafety Laboratory Inspection

The LSU Biological Safety Manager and/or the LSU Biological Safety Coordinator inspects BSL-2 and BSL-3 laboratories and BSL-1 laboratories using checklists. Problems are reported to the Principal Investigator for remedy and the inspection report is maintained on file in the Office of Environmental Health and Safety Environmental Safety. Laboratories are inspected annually. Problems are reported to the IBRDSC.

II. Biosafety Manuals

The Biological Safety Manager reviews biosafety protocols when laboratories are inspected. The collection of safety protocols and procedures (safety manual) must exist in every laboratory.

III. Assessment of University Facilities contemplating Biohazardous and/or Recombinant DNA Research

The LSU Biological Safety Manager and/or the LSU Biological Safety Coordinator will be informed in advance of laboratory moves, laboratory renovations, establishment of new laboratories and plans for new laboratory construction. They will review these plans, consult with the PIs involved and report this information back to Environmental Health & Safety and IBRDSC for comment.

16. Activities Requiring Additional Permits or Approvals

Many biological materials and activities require additional permits. These permits may be necessary for a wide range of activities. In general any biological material that requires a federal or other permit should be registered with the IBRDSC through the Registration form (EPA, APHIS, CDC, NIH, DEQ, ATCC, etc.)

I. American Type Culture Collection (ATCC)

Researchers ordering pathogens or human or primate cell lines from ATCC should complete a new registration form for review by the Biological Safety Manager. The ATCC account application should have the signature of the Biological Safety Manager prior to submission.

II. Field Trials of Genetically Modified Organisms (APHIS)

Field trials of genetically modified organisms generally require APHIS permits. An additional area of field trials that includes increased requirements is the area of bio-pharming. There are specific regulations and requirements for the "Field Testing of Plants Engineered to Produce Pharmaceutical and Industrial Compounds" (7 CFR Part 340). Additional information can be found on the APHIS website, URL, http://www.aphis.usda.gov/biotechnology/submissions.shtml
All permits and field testing of plants designed to produce pharmaceuticals must be signed by the AgCenter's Institutional Official (the Vice Chancellor and Director for Agricultural Experimental Stations).

17. Bloodborne Pathogens

Research activities utilizing blood or other potentially infectious bodily fluids must comply with Federal and State requirements. Blood and other bodily fluids are always considered to be infectious agents.

I. Bloodborne Pathogens Program and Training

The LSU Bloodborne Pathogens Program: Exposure Control Plan can be found at URL, https://sites01.lsu.edu/wp/ehs/biological-safety-bloodborne-pathogens-and-universal-precautions-at-lsu/

Seeing that staff receives the required annual training is the responsibility of the unit administrator and individual supervisors. A written record of staff training must be maintained to meet federal regulations and will be reviewed by the Biological Safety Manager.

Training is available through the Office Environmental Health and Safety (225-578-5640).
https://sites01.lsu.edu/wp/ehs/biological-safety-bloodborne-pathogens-and-universal-precautions-at-lsu/

II. Biosafety Level

In general research activities with blood and other bodily fluids must be performed in a BL2 laboratory.

III. Human Cell Lines

Human and primate cell lines are commonly used in biomedical research, yet appropriate biosafety requirements for handling these cell lines are often subject to debate within the scientific community. In order to clarify the University's position on this matter, the Institutional Biological and Recombinant DNA Safety Committee has adopted the following policy.

LSU Policy; All cell and organ cultures of human origin, including well established cell lines as well as primate cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL2) containment. All University personnel working with these cultures shall maintain a written record of their annual training as required under the OSHA Bloodborne Pathogens Standard.

18. Biosecurity

The security of biological materials is very important on this campus and at extension campuses and is taken very seriously by university administration. The Principal Investigator and all associated personnel must be very conscientious in controlling these materials and being held accountable for them. Access to biological materials should be limited to the greatest extent; URL, http://www.nap.edu/catalog/10827.html#toc .

Principal Investigators depending on the risk the biological agent may pose should perform a vulnerability assessment and develop a plan to protect the security of the material in question. Solutions might include:

- Additional locks on laboratory doors, freezers, etc. where biological agents are used or stored.
- Chain-of-custody forms within laboratories to track materials.
- Inventories of biological materials.
- Logs of access to areas where biological materials are in use.

For more information consider the document entitled “Laboratory Security and Emergency Response Guidance for Laboratories Working with Select Agents” URL: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5119a1.htm .

Shipping of Biological Materials

Shipping of biological specimens and agents create security vulnerabilities, as well as safety concerns for the public. For this reason, PIs must include in their research protocols adequate instructions and/or procedures for proper shipping of these materials, if such is envisioned or planned in the research project.

19. Institutional Animal Care and Use Committee (IACUC) – IBRDSC Coordination (LSU Campus)

The following procedure is intended to ensure appropriate review by both committees for proposals involving recombinant DNA and / or pathogens or toxins in animal studies. ***The IACUC will not grant full approval to any animal use protocol involving pathogens or recombinant DNA until the project has been reviewed by the IBRDSC***.

I. Investigators preparing animal use proposals that involve any of the following must register their projects with the IBRDSC:

   A. recombinant DNA in animals, including transgenic animals (the purchase and use of transgenic/knockout rodents from commercial vendors is exempt)

   B. recombinant DNA in microorganisms or viral vectors which are subsequently introduced into animals

   C. animal studies using bacteria, viruses, fungi, protozoa, helminthes, or other microbes or prions that are known or suspected pathogens of humans or livestock animals

   D. the introduction of toxins of biological origin into animals

II. For projects that involve pathogens or potentially infectious rDNA in animals, investigators are also required to fill out the SVM, Division of Laboratory Animal Medicine's (DLAM) IACUC form; "*Biosafety Precautions in Animal Rooms,*" sign the form, and forward it to the biological safety manager along with the registration document(s). The Biological Safety Manager reviews the precautions and signs the form returning it to the investigator for submission to the IACUC. This form can be obtained from the DLAM office or from the EHS web site.

III. Once a registration has been received, reviewed and approved by the IBRDSC, the investigator is issued a Certificate of Registration for the project, which is valid for three (3) years from the date of issuance. The certificate of registration states the required containment level and any other requirements to ensure safe conduct of the research. In some cases, recommendations are also included.

IV. The Biological Safety Manager sits on the IACUC as a non-voting advisory member and provides biosafety input into animal studies as appropriate.

20. IBRDSC – LSU School of Veterinary Medicine BSL-3 Biological Safety Committee

This committee approves use of the School of Veterinary Medicine's BSL-3 laboratory based on space/availability. It exercises oversight for scheduling, management, maintenance, and regulatory compliance of the BSL-3 laboratory within the School of Veterinary Medicine. This committee communicates its Charter and policies to the IBRDSC and the Veterinary School's IACUC regarding the use of the BSL-3. It also has the authority to remove BSL-3 privileges from Investigators not following its policies or Standard Operating Procedures.

- The School of Veterinary Medicine's BSL-3 Biological Safety Committee reports to the Dean of the Veterinary School
- The following are ad hoc members of the committee
    - Associate Dean for Research and Graduate Studies
    - The LSU Biological Safety Manager (EHS)
    - Representative of Hansen's disease Center
- The Committee Chair is the BSL-3 laboratory director
- The voting members of the committee are the approved Principal Investigators who use the BSL-3.

21. IBRDSC Coordination with the AgCenter's IACUC

The Biological Safety Manager and/or Biological Safety Coordinator sit as a non-voting members of the AgCenter's IACUC.

22. Federal Regulations and Guidelines

Animal and Plant Health Inspection Service, Department of Agriculture, 7 CFR Part 331 and 9 CFR Part 121, Agricultural Bioterrorism Protection Act of 2002; Possession, Use, and Transfer of Biological Agents and Toxins; Final Rule. 03/18/2005. URL: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf

Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th edition, Centers for Disease Control (CDC) and the National Institutes of Health (NIH). URL: http://www.cdc.gov/biosafety/publications/bmbl5/index.htm

NIH Guidelines for Research Involving Recombinant DNA Molecules, NIH, 04/2002. URL: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

Office of Inspector General, Department of Health and Human Services, 42 CFR Parts 72 and 73, Possession, Use, and Transfer of Select Agents and Toxins; Final Rule. 03/18/2005. URL: http://www.selectagents.gov/resources/42_cfr_73_final_rule.pdf

USDA/APHIS 7 CFR Part 340, Introduction of Organisms and Products Altered or Produced through Genetic Engineering and all APHIS Permit regulations/guidelines. URL: http://www.aphis.usda.gov/brs/pdf/7cfr340.pdf

USDA/ARS Facilities Design Standards, Chapter 9. Biohazard Containment Design URL: http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf

23. References

American Type Culture Collection Frequently Asked Questions, URL: http://www.atcc.org/

Health & Safety Office, UNC at Chapel Hill, Biological Safety Manual. March 2010. URL: http://ehs.unc.edu/manuals/biological/

OSHA Letter of Interpretation, URL: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519

University of Montana, IBC, Overview/Mission Statement. URL: http://www.umt.edu/research/complianceinfo/IBC/

University of Virginia, Institutional Biosafety Committee (IBC). Policy on the Use of Human Cell Lines for Laboratory Personnel. December 2003. URL: http://ehs.virginia.edu/biosafety/bio.hdm.html

WSU Institutional Biosafety Committee Manual, September 12, 2005 URL: http://www.bio-safety.wsu.edu/

IBRDSC ADOPTED POLICIES

APPENDIX I

IBRDSC Policy on the Use of Human and Primate Cell Lines for Laboratory Personnel

Adopted August 15, 2006

Introduction

Human and primate cell lines are commonly used in biomedical research, yet appropriate biosafety requirements for handling these cell lines are often subject to debate within the scientific community. In order to clarify the University's position on this matter, the Inter-Institutional Biological and Recombinant DNA Safety Committee has created the following policy.

Background

In 1991, the Occupational Safety and Health Administration (OSHA) issued the Bloodborne Pathogens (BBP) Standard to protect employees who have occupational exposure to human blood or other potentially infectious materials. While human blood, most body fluids, unfixed human tissues and organs were clearly included within the scope and application of the standard, the inclusion of human and primate cell lines was ambiguous.

In 1994, OSHA issued an interpretation of the applicability of the BBP Standard towards human cell lines. According to the interpretation, human cell lines are considered to be potentially infectious and within the scope of the BBP Standard unless the specific cell line has been characterized to be free of hepatitis viruses, HIV, Epstein-Barr virus, papilloma viruses and other recognized bloodborne pathogens. In alignment with this interpretation, the American Type Culture Collection (ATCC) recommends that all human cell lines be accorded the same level of biosafety consideration as a line known to carry HIV. Moreover, the Fourth Edition of the CDC publication, *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), recommends that human and other primate cells should be handled using Biosafety Level 2 (BSL2) practices and containment.

In consideration of the aforementioned regulatory interpretation and consensus guidelines and other factors, the LSU/LSU AgCenter Inter-

Institutional Biological and Recombinant DNA Safety Committee has adopted the following policy in regards to the use of human and primate cell lines.

Policy

All cell and organ cultures of human origin, including well established cell lines as well as primate cell lines, shall be handled in accordance with the OSHA Bloodborne Pathogens Standard and under Biosafety Level 2 (BSL2) containment. All University personnel working with these cultures shall maintain a written record of their annual training as required under the OSHA Bloodborne Pathogens Standard.

References

American Type Culture Collection Frequently Asked Questions, URL: http://www.atcc.org/TechnicalInfo/faqCellBiology.cfm#Q53

Biosafety in Microbiological and Biomedical Laboratories, 4th Edition, URL: http://www.bmbl.od.nih.gov/

Health & Safety Office, UNC at Chapel Hill, Biological Safety Manual: Chapter 11; Hazards of Cell and Tissue Culture Systems. August 2000. URL: http://ehs.unc.edu/manuals/bsm/BSM11.pdf

OSHA Letter of Interpretation, URL: http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=INTERPRETATIONS&p_id=21519

Rapport, J. Letter from the Institutional Biosafety Committee on the Subject of the OSHA Bloodborne Pathogen Standard. Temple University. 2001 URL: http://www.research.temple.edu/ehrs/docs/IBCOSHA.pdf

University of Montana, IBC, Overview/Mission Statement. URL: http://www.umt.edu/research/ibc/ibcoverview.htm

LSU/LSU AgCenter thanks UV for permission to use this document along with UCI and UC Santa Cruz

APPENDIX II

IBRDSC Guidance for Acquisition/Use/Disposal of Recognizable Anatomical Materials (Human Body Parts) for Research Purposes

Adopted November 2009

LSU OFFICE OF ENVIRONMENTAL HEALTH & SAFETY

The LSU Office of Environmental Health & Safety may advise you in this process but does not have an acceptable method for disposal. If you are planning on obtaining human body parts you should register with the Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC). Once you have obtained anatomical materials from a reputable source you must make arrangements with that source to dispose of the materials when you have finished. Additionally, anatomical parts cannot be removed from their primary storage location or area of intended use without permission (especially not off campus).

Contact: Gregory V. Hayes, DrPH
Biological Safety Manager
Office of Environmental Health & Safety
Public Safety Bldg., Suite 126
225-578-4658
ghayes@lsu.edu

The federal government and most states do not regulate body donation through licensure and inspection. Currently body donation is governed by the Uniform Anatomical Gift Act, (http://www.law.upenn.edu/bll/archives/ulc/fnact99/uaga87.htm), which has been largely adopted by most states. There are varying laws from state to state relating to the transportation and disposition of human bodies. Problems with disposition of body parts have been the cause of large legal settlements and therefore you must be careful where you obtain human cadaveric specimens and how they are disposed of. Make sure you are dealing with a reputable source. You must have the proper paperwork available to document the source, etc. You must provide proper security to insure that there is no unauthorized access to the specimen and that it is properly maintained [depends on whether it is embalmed or fresh (unfixed) material] and that it is used solely for the purpose intended. If the specimen is unfixed you must abide by the OSHA bloodborne pathogen standard.

LSU DEPARTMENT OF KINESIOLOGY

The Department of Kinesiology here on the LSU Baton Rouge campus regularly uses human body parts for research and may be able to answer some of your questions also.

Contact: Dr. Wanda Hargroder
Assistant Professor of Professional Practice
Department of Kinesiology
103 Long Fieldhouse
225-578-7178
whargro@lsu.edu

RECOMMENDED SOURCE OF HUMAN MATERIALS:

The LA State University Health Science Center, Department of Cell Biology and Anatomy receive human specimens through donations from the Bureau of Anatomical Specimens for the purpose of research and teaching of human anatomy. All information regarding the donor is private and confidential. Institutions or agencies may request the use of cadaveric specimens for research and/or teaching purposes by contacting the department. Use of such will require reimbursement to the department for costs associated with maintenance, transportation, harvesting, and cremation of cadaveric specimens. All specimens are cremated by the department and either returned to family members or buried in a cemetery. Thus, if specimens are transported to a location outside of the LSUHSC campus, such specimens are returned to the LSUHSC campus for cremation.

They do NOT and will NOT cremate specimens that are received from other organizations. The above reimbursement for specimens is a cost recovery and would require a contract with LSUHSC upon request of the specimens and prior to delivery. If you have any further questions please contact the following individuals:

Contact: Dr. Richard Whitworth
President, Bureau of Anatomical Services
Department of Cell Biology and Anatomy
Louisiana State University School of Medicine
1901 Perdido Street
New Orleans, LA 70112-1393
Phone: (504) 568-4032

Fax: (504) 568-4392
rwhitw@lsuhsc.edu

OR: Melissa M. Hebert, R.N., B.S.N.
Assistant Director
LA State University Health Science Center
Dept. of Cell Biology & Anatomy
1901 Perdido Street
New Orleans, LA 70112
Phone: (504) 568-4435
Fax: (504) 568-2169
mmoral@lsuhsc.edu

APPENDIX III

IBRDSC Policy - Autoclave Use and Validation

Adopted April 26, 2012

Requires operator training, written SOPs, and use of PPE

Efficiency dependent on

- Density of material to be autoclaved
- Steam penetration/internal steam generation
- Load configuration
- Verification of established run parameters (*Time/Temperature/Pressure)*

Autoclaves can pose physical hazards (e.g. heat, steam and pressure) and biological hazards. (e.g. inadequately sterilized infectious materials). All PIs at LSU are required to train their personal on the proper use, validation and maintenance of autoclaves they will use in your department.

Different varieties of autoclaves may have their own unique characteristics for loading, load sizes, cycle types and cycle settings. The materials to be sterilized will determine the sterilization cycle that will be used. For this reason it is important to read and understand the user's manual for the specific model of autoclave that is being used. Be certain that the user's manual is readily available incase questions or concerns arise during the operation of the autoclave.

An autoclave is suitable for the treatment of certain types of waste but not all types. The <u>following items of waste should not be autoclaved</u>:

1. Items of waste which are mixed with volatile chemical solvents or radioactive materials (this waste must be handled as either chemical waste or radioactive waste).

2. Pathological waste (pathological waste is handled as follows: animal carcasses are taken to the pathological waste freezers in the Research Animal Facility)

The following are the responsibility of the PI or Supervisor

A. Training:

The supervisor for each laboratory needs to develop and implement an autoclave safety training program. All users shall be trained before operating an autoclave; the supervisor is responsible for insuring that each person in the lab is appropriately trained. All training must be documented and the records maintained in the lab with other safety training materials. These records will be reviewed during during an Environmental Health and Safety Inspection.

B. Maintenance:

Autoclave maintenance is essential for a safe and properly functioning autoclave. The manufacturer's recommendations should be followed for preventative maintenance. All contractors hired to perform regular maintenance and repairs should be approved by the manufacturer. Each autoclave user is responsible for ensuring the autoclave is monitored as follows:

Heat Sensitive Tape Monitoring — All operators shall use heat sensitive sterilization indicator tape for each load.

- Tape will only indicate that the proper temperature for the cycle has been reached. Tape will not indicate that the load was heated at the proper pressure or for the appropriate length of time.

- Be certain that the heat sensitive tape does not contain a lead base indicator. This type of tape must be collected and managed as hazardous waste.

Biological Indicators — All operators that autoclave infectious/biohazardous waste must do the following:

- At least once a month use a biological indicator such as Geobacillus stearotherophilus placed at the center of a load processed to confirm adequate sterilization conditions. Remember for the autoclave to sterilize the steam must penetrate what you are autoclaving. Maintain these validation records.

C. Recordkeeping:

Documentation records of any autoclave preventative maintenance/repairs and validations shall be maintained. These records will be reviewed during your next inspection. The records should indicate who performed the work, the type of maintenance or repairs conducted and the date the autoclave was serviced. Biological indicator validation records and test results shall also be maintained. Records should be kept in the room with the autoclave or there should be a sign indicating where the records are located.

Autoclave Safety Practices:

Do not autoclave items containing corrosives, solvents, volatiles or radioactive materials.

I. Prior to loading

1. Before using the autoclave, check inside the autoclave chamber for any items left by the previous user that could pose a hazard.

2. Ensure that the drain strainer is clean before loading the autoclave.

3. Ensure that the door gaskets have not deteriorated, but are still intact and pliable.

II. Loading

4. Load the autoclave as per the manufacturer's recommendation. DO NOT overload the autoclave.

5. Liquids should be within a heat resistant plastic tray containing an inch of water.

   a. Bottles should not be filled more than 2/3.

   b. Keep 1-2 inches of space between bottles.

6. Individual glassware pieces should be within a heat resistant plastic tray on a shelf or rack and never placed directly on

the autoclave chamber bottom or floor.

7. Make sure that the door of the autoclave is fully closed and latched and ensure that the correct cycle for the items being autoclaved has been selected before starting the cycle.

III. Opening

8. Wear the proper PPE, including heat resistant gloves, lab coat, eye protection and close toed shoes when opening the autoclave door after a cycle. If there is a sharps hazard (e.g. biological waste), wear heat and cut resistant gloves.

9. When the cycle is complete, open the door slowly. Keep your head, face and hands away from the opening.

Additional Practices for Autoclaving Liquids:

1. When running an autoclave cycle with liquids, the cycle time is longer but uses lower temperatures to minimize evaporation of the liquids. Liquid cycles also have a longer depressurization time to avoid "boil-over" of liquids.

2. To prevent bottles from shattering during the pressurization, the caps of containers with liquids must be loosened before loading.

3. Use only borosilicate glass (Pyrex™ or Kimax™) which can withstand the high autoclave temperatures.

4. Use a heat resistant "autoclave" tray with a solid bottom and walls to contain the contents and catch spills.

5. Wait 10 minutes after the cycle ends before removing autoclaved liquid load items.

6. Let the liquids stand for at least a full hour before touching with ungloved hands. Be sure to let others in the area know that a heat hazard is present.

Additional Practices for Autoclaving Dry Loads:

1. Add ¼ to ½ inch of water to the tray so that the bottles will

heat evenly.

2. Check plastic materials to ensure that they are compatible with being autoclaved.

3. Before removing autoclaved items, wait 5 minutes after the cycle ends for loads containing only dry glassware.

4. For dry loads, let the glassware cool for a minimum of 15 minutes before touching it with ungloved hands.

Autoclave Failure:

Discontinue use immediately if an autoclave is not working properly. Post a sign alerting others not to use the autoclave. Include the date and your contact information. Mechanical failures need to be attended to by a trained technician. Contact the service company responsible for the maintenance of your autoclave or your department's safety representative for further guidance.

Burn Emergency:

If you are burned, you should seek medical treatment immediately. Burns to the face, third-degree burns or burns over large areas of the body should be treated as emergencies. (Call 911). Minor burns should be treated by using first aid procedures, including immersing the burn in cool water immediately, removing clothing from the burn area and keeping the injured area cool for at least 5 minutes. Regardless of the severity, notify your supervisor. For non-life threatening burns call or proceed to the Student Health Center.

Report any accidents: https://sites01.lsu.edu/wp/ehs/accident-report/

General Cycle Parameters:

121°C, 15 psi, for 30 minutes (variable – depends on load)

For prions: (per CDC) 132°C, 30 psi for 4.5 hours

Many industries have strict rules about monthly biological indicators on high organic loads and are required to profile generic waste loads such as sharps containers full of pipettes, etc., since many types of materials, such as

plastics, do not conduct heat well. Each decon autoclave has a specific cycle time for a certain type of load. Most universities go by state law, or just specify a "safe" time, with overkill built in. Some Universities are required to test decon autoclaves weekly. The Louisiana Sanitary Code, Title 51, Part XXVII. Management of Refuse, Infectious Waste, Medical Waste, and Potentially Infectious Biomedical Waste, Chapter 11, Treatment; states "autoclaving at a temperature of at least 120°C., (248°F.), and a pressure of at least 15 pounds per square inch for at least 30 minutes".

APPENDIX IV

IBRDSC Policy - Recombinant DNA and Biohazard Incident Reporting

Adopted April 26, 2012

All University personnel (Louisiana State University A&M and the Louisiana AgCenter) are required to report incidents (spills) and exposures (inhalation, inoculation, ingestion or skin contact) involving recombinant DNA (rDNA) or biohazards to the LSU Office of Environmental Health and Safety (EHS). The EHS after review by the LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC) must report these incidents to the National Institutes of Health, Office of Biotechnology Activities (NIH OBA). This policy describes this requirement and the appropriate process.

Responsibilities

(1) University personnel involved in the incident will immediately report the incident to their Principal Investigator and the Office of Environmental Health and Safety (*immediately means by the end of the work shift at the latest):*

Office of Environmental Health & Safety (EHS)
Copy & Mail Center
Corner of South Stadium Drive and CEBA Lane
225-578-5640 OR

Gregory Hayes, DrPH
Biological Safety Manager
Phone: 225-578-4658
Fax: 225-578-7489
ghayes@lsu.edu

Quinesha Morgan, PhD
Biological Safety Coordinator
Phone: 225-578-4235
Fax: 225-578-7489
qperry2@lsu.edu

(2) University personnel will also complete the LSU/NIH incident Reporting Form located on the EHS web site at: https://sites01.lsu.edu/wp/ehs/biological-safety/

(3) The report will be provided to the Institutional Biosafety Committee (IBRDSC) for review.

(4) Following review by the IBRDSC the biosafety manager will submit the report to NIH on behalf of the University. Copies of

the incident report will be provided to the LSU A&M Vice Chancellor of Research and Economic Development, AgCenter Vice Chancellor & Director Louisiana Agricultural Experimental Stations, and the Chair of the Department involved.

Reportable Incidents

(1) Spills or accidents in a BSL2 laboratory resulting in an overt exposure, injury or illness of personnel, including bites/exposures to animals intentionally infected with RG2 agents or potential zoonotic diseases.

(2) Spills or accidents in a BSL3 laboratory resulting in an overt potential exposure, injury or illness of personnel, including bites/exposures to animals intentionally infected with RG3 agents or potential zoonotic diseases.

(3) Release of a Risk Group 2 or 3 agent / genetic material from a primary containment device (e.g., biological safety cabinet, centrifuge, or primary container into the laboratory)

(4) Spills or accidents that lead to personal injury or illness or breach of containment (e.g., aerosols released outside of containment, skin punctures with needles containing Risk Group 2 or 3 agents or genetic material from these agents).

(5) Failure to adhere to the containment and biosafety practices described in the NIH Guidelines.

TimeLines and Authority:

Institutional incident reporting to NIH

Section IV-B-2-b-(7). Reporting any significant problems with or violations of the NIH Guidelines and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the Institutional Biosafety Committee determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the Office of Biotechnology Activities, National Institutes of Health, 6705 Rockledge Drive, Suite 750, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), 301-496-9838, 301-496-9839 (fax).

Appendix G-II-B-2-k. Spills and accidents which result in overt exposures to organisms containing recombinant DNA molecules are immediately reported to the Institutional Biosafety Committee and NIH/OBA.

Form Attached:

Submit by Email | Print Form

rDNA Incident Reporting Form

Return to:
LSU Office of Environmental Health & Safety
Room 212, Copy & Mail Center
Phone: 225-578-5640
Fax: 225-578-7489
E-mail: ghayes@lsu.edu

The *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) states that "...any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses" must be reported to NIH OBA within 30 days. Certain types of incidents must be reported on a more expedited basis. Spills or accidents in BL2 laboratories resulting in an overt exposure must be immediately reported to NIH OBA. Spills or accidents occurring in high containment (BL3 or BL4) laboratories resulting in an overt or potential exposure must be immediately reported to NIH OBA.

This form is intended to facilitate the reporting of incidents that occur during the conduct of research subject to the *NIH Guidelines*.

Does this incident involve research subject to the NIH Guidelines?	Yes ☐ No ☐
	If no, this incident does not have to be reported to OBA
Department Name	
Date of Report	
Name & Position of Person Reporting	
Telephone Number	
E-mail Address	
Date of Incident	
Name of Principal Investigator	
Is this an NIH funded project?	Yes ☐ No ☐
If yes, please provide:	NIH grant or contract number:
	NIH funding institute or center:
	NIH program officer contact information (name, e-mail, etc.)

What was the nature of the incident?	☐ Personnel exposure ☐ Spill ☐ Loss of containment ☐ Loss of transgenic animal ☐ Failure to obtain IBC approval ☐ Failure to follow approved containment conditions ☐ Other - please describe
Did the Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC) approve this research?	Yes ☐ No ☐ If yes, on what date?
If yes, please provide:	Approval date: Approved biosafety level for the research: Additional approval requirements:
What section(s) of the NIH Guidelines is the research subject to?	
Has a report of this incident been made to other federal or local agencies? If so please indicate by checking the appropriate box.	☐ CDC ☐ USDA ☐ FDA ☐ EPA ☐ OSHA ☐ Research Funding Agency/Sponsor ☐ (name) _____ ☐ State/Local Public Health ☐ Federal/State/Local Law Enforcement ☐ Other, Please describe

Please provide a narrative of the incident including a timeline of events. The incident should be described in sufficient detail to allow for an understanding of the nature and consequences of the incident.
Include the following information as applicable.

A description of:
• The recombinant agent or material involved.
• The incident/violation location (e.g. laboratory biosafety level, vivarium, non-laboratory space).
• Who was involved in the incident/violation, including others present at the incident location? Note – please do not identify individuals by name. Provide only position titles (e.g., graduate student, post doc, animal care worker, facility maintenance worker).
• Actions taken immediately following the incident/violation, and by whom, to limit any health or environmental consequences of the event.
• The training received by the individual(s) involved and the date(s) the training was conducted.
• The institutional or laboratory standard operating procedures (SOPs) for the research and whether there was any deviation from these SOPS at the time of the incident/violation.
• Any deviation from the IBC approved containment level or other IBC approval conditions at the time of the incident/violation.
• The personal protective equipment in use at the time of the incident/violation.
• The occupational health requirements for laboratory personnel involved in the research.
• Any medical advice/treatment/surveillance provided or recommended after the incident.
• Any injury or illness associated with the incident.
• Medical surveillance results (if not available at the time of initial report please indicate when results will be available).
• Equipment failures.

DESCRIPTION OF INCIDENT: (use additional space as necessary)

DESCRIPTION OF INCIDENT (continued)

Has a root cause for this incident been identified?	Yes ☐ No ☐
	If yes please describe:
Describe measures taken by the Principal Investigator to mitigate any problems identified. For measures identified but not yet taken, please include a timeline for their implementation: (use additional space as necessary)	

APPENDIX V

LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: Maintenance of Laboratory Equipment

Adopted April 26, 2012

Properly functioning laboratory equipment is a critical component of good laboratory practice and safety. Each laboratory should have equipment management policies which include regular inspections and comprehensive equipment maintenance strategies. Many of the accidents that occur in the laboratory can be attributed to improper use or maintenance of laboratory equipment. (Autoclave use and validation is a separate policy.)

Equipment Examples: Microplate Reader, Microplate Washer, pH Meter, Balances, Water Bath, Water Distiller, Dilutor, Dispenser, Spectrophotometer, Autoclave, Drying Oven, Incubator, Microscope, Pipettes, Stirring Heating Plate, Refrigerators, Freezers, Chemistry Analyzers, Colorimeters, Biological Safety Cabinets, Chemical Fume Hoods, Centrifuges,

Biological Safety Cabinets

Biological safety cabinets must be certified at least annually (BSL-3 laboratories bi-annually) according to the National Sanitation Foundation Standard/American National Standard 49 (NSF/ANSI 49), which is the accepted standard for the biological safety cabinet industry. Testing must be performed to verify air flows, HEPA filter integrity, containment of contaminated cabinet air, and that the cabinet is safe to operate regarding other cabinet operational features. Whenever biological safety cabinets are moved, internal repairs are to be made, or when filters are to be replaced, the cabinet must be gaseous decontaminated. It also must be recertified before use. LSU requires that certification be done by third party firms and is the responsibility of the user.

Types of Biological Safety Cabinets
http://www.cdc.gov/biosafety/publications/bmbl5/BMBL5_appendixA.pdf

Class I: Protection for the operator, but no product protection. Air flow, at a minimum inward face velocity of 75 linear feet per minute (lfpm), directed through the front opening, across the work area and out through the HEPA filter on top. This cabinet is used with a full width open front, or can be used with an attached armhole front panel with or without attached rubber gloves. These cabinets do not protect your materials from contaminants introduced from the environment or the operator.

Class II: Class II cabinets afford protection for the operator and the work performed. The capacity to protect materials within the cabinet is provided by the flow of HEPA-filtered air over the work surface. These cabinets can be used to manipulate low to moderate risk agents.

Class III: Class III Biological Safety Cabinets are totally enclosed and offer the highest degree of personnel and environmental protection from infectious aerosols, as well as protection of research materials from microbiological contaminants.

Other "Cabinets"

Clean Benches: Clean Benches direct HEPA-filtered air horizontally over the work area to protect research materials from contamination. Applications for clean benches include media plate preparation, electronics inspection, medical device assembly and pharmacy drug preparation. Since these cabinets do not provide protection to the user, they must not be used in with biohazardous material, hazardous chemicals, or radionuclides.

Cage Change Stations: Some rooms in animal housing facilities have cage change stations that are used for protecting the animals from pathogens and limiting exposure of personnel to allergens. They should not be

used when working with hazardous chemicals or infectious biological agents.

Ultraviolet Lights in Biological Safety Cabinets

Ultraviolet lights are a common in many Biological Safety Cabinets. These lights are intended as biocidal devices. Unfortunately, the actual effectiveness of UV light in providing this "sterile" environment is doubtful. Also, there are potential occupational hazards that carry significant risks (e.g., serious eye and skin injury) with the use of these lamps. Ultraviolet lamps must be periodically tested to ensure that the energy output is adequate to kill microorganisms. The radiation output should be at least 40 microwatts/ cm2 at 254 nm when measured.

The CDC, NIH, National Sanitation Foundation and the American Biological Safety Association all state that UV lamps are neither required nor recommended for use in a biological safety cabinet. ***Therefore, the LSU Office of Environmental Health and Safety does not recommend the installation of these lights or their use.***

http://www.ehs.umass.edu/ABSA%20UV%20light%20paper.pdf

Gas Flames in Biological Safety Cabinets

The LSU Office of Environmental Health and Safety prohibits the use of gas and flames in a biological safety cabinet.

http://www.bakerco.com/lib/pdf/bulletins/UseOfFlames.pdf

Chemical Fume Hoods

Louisiana State University has approximately 800 chemical fume hoods located on the main campus and various auxiliary sites.

Fume hoods are critical to the safety of researchers, faculty, and students, as they provide the primary means of preventing exposure to airborne hazardous materials on campus. Therefore, it is extremely important that the hoods be maintained in good working order.

All laboratory fume hoods are inspected annually by the Office of Environmental Health and Safety (EHS) according to requirements of

National Fire Protection Association (NFPA) "45 Standard on Fire Protection for Laboratories Using Chemicals"; and University Policy Statement 19. The Louisiana State Fire Marshall's office also routinely inspects laboratory hoods to insure that annual inspection requirements have been met.

Hoods failing to meet EHS guidelines are posted with warning signs to limit or prohibit usage until repaired. Work requests are submitted to Facility Services to repair fume hood deficiencies. When the repairs are complete, EHS re-inspects the hood to insure that all requirements are met.

Contact Tom Walsh | LSU Office of Environmental, Health & Safety | 225-578-5645 | twalsh@lsu.edu

Centrifuges

Operational guidelines

1. The work surface must be level and firm. Do not use the centrifuge on an uneven or slanted work surface.

2. Balance the tubes in the rotor. If you want to run a tube with 10 mL of liquid, put another tube with 10 mL of water in the opposing hole on the rotor. If the liquid has a higher or lower density than water, you must balance the tubes by mass, not volume.

3. Do not open the lid while the rotor is moving.

4. Wear a face shield and / or safety goggles if you have to work anywhere near a centrifuge that's in use.

5. Do not bump, jar, or move the centrifuge while the rotor is spinning. Make sure you don't have the cord dangling from a table edge where someone could catch their foot in it and pull down the centrifuge.

6. Examine tubes and bottles for cracks or stress marks before using them. Discard any centrifuge tubes that have cracks in them.

7. When working with biohazardous materials, wipe outside of tubes with disinfectant prior to removal from the

biological safety cabinet and before placing in safety cups or rotors.

8. Place all tubes in safety buckets or sealed rotors when centrifuging infectious materials. Inspect the "O" ring seal of the safety bucket and the inside of safety buckets or rotors.

9. Open safety buckets or rotors in a biological safety cabinet. If any spills or leakage are apparent in the centrifuge rotor should be cleaned with a mild detergent, rinsed thoroughly with distilled water, and allowed to air dry completely (while in biosafety cabinet).

10. Clean the rotor and centrifuge well after each use.

    Beckman Coulter Centrifugation Laboratory Resources: http://www.beckman.com/resourcecenter/labresources/resource_centrif.asp

    Sorvall Centrifuge Information: http://www.kendro.com
    AIHA Laboratory Health and Safety Committee Centrifuge information:
    http://www2.umdnj.edu/eohssweb/aiha/accidents/explosion.htm#Centrifuge
    http://www2.umdnj.edu/eohssweb/aiha/technical/labequipment.htm#Centrifuges

Maintenance Manual for Laboratory Equipment. 2nd Edition. 2008. World Health Organization ISBN 978 92 4 159635 0
http://www.who.int/diagnostics_laboratory/documents/guidance/guidance2/en/index.html

APPENDIX VI

LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: Food and Drink in Rooms and Laboratories that contain Biological Materials, rDNA

Adopted April 26, 2012

This policy applies to all staff, faculty, students and University guests.

Do not drink, eat, store food or beverages, chew gum, apply cosmetics or use tobacco products (smoke, chew, dip) in rooms where chemicals, biohazardous or radioactive materials, or other potentially hazardous materials are present. Food or beverage containers may not be stored in the laboratory and washed drinking cups, food containers or eating utensils may not be dried on laboratory drying racks. Refrigerators used for storing food or beverages should be dedicated to food only and should be located outside of the laboratory.

Each school, department, or division is responsible for identifying laboratories where eating, drinking, and similar activities are prohibited, and for notifying individuals of appropriate areas for such activities.

APPENDIX VII

LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: Occupational Health & Safety Program for Individuals working under BSL-3 containment with animals containing viable recombinant DNA organisms at LSU or the LSU AgCenter

Adopted April 26, 2012

Purpose: To maintain a preventive health program for personnel involved in the care and handling of animals: to insure that an accurate assessment is made of the health status of each staff member at the time of hire, to ensure that staff are safeguarded against occupation-related disorders, and to ensure that emerging occupation-related health disorders are promptly diagnosed and corrected.

Responsibility: DLAM Administration

Procedure: DLAM has arranged for an Occupational Health Program (OHP) for all persons at risk of illness or injury as a result of working with animals or their wastes. This includes anyone whose job responsibilities bring them in contact with animals used in teaching and/or research. Investigators using animals are expected to assess the potential hazards of their proposed studies and recommend participation in the OHP to any employee determined to be at risk of illness or injury. This could include the scientific staff, student workers, and facility support personnel. The program is conducted by the Louisiana State University Student Health Center. Participation in Parts 1 and 2 of this program is confidential and voluntary with the following exception. Parts 1 and 2 are mandatory for all individuals working in the presence of viable recombinant DNA (rDNA) at BSL-3. Participation in Part 3 of this program is mandatory for personnel involved in the care and handling of animals. The Program consists of the following:

1. New Employees

Each participating new employee will complete a health questionnaire and present it to the Student Health Center physician at the time of the physical examination. Each new employee will receive a complete physical examination. Based on review of the health questionnaire and the physical examination, the Student Health Center physician will request appropriate diagnostic tests and/or immunizations.

For new employees who will be working with viable BSL-3 rDNA, a baseline serum sample will be provided for storage when applicable. The Student Health Center will establish and maintain a medical record for each employee, and will include in that record, a copy of the health questionnaire.

The Student Health Center physician will notify DLAM in writing of any precautions needed in the work assignments of each employee, based on findings from the health questionnaire, physical examination, or diagnostic tests. DLAM will notify the Principal Investigator responsible for the employee.

All information received from the Student Health Service will be considered confidential and will be secured in the individual employee's personnel file.

2. Continuing Employees

On a yearly basis, each participating employee will complete a health questionnaire and will mail it, in the envelope provided, to the LSU Student Health Center. The Student Health Center physician will review the health questionnaire and will determine which, if any, diagnostic tests, vaccinations, etc., are needed. The Student Health Center will notify the employee that such actions are needed.

A health questionnaire and physician review of the questionnaire must be completed before employees are allowed to work with viable rDNA at BSL-3. A baseline serum sample will be provided for storage when applicable.

For employees identified as working with viable rDNA at BSL-3 in the previous year, special attention will be devoted to factors and conditions of the BSL-3 biological agents in use in the previous year. A serum sample will be provided for surveillance purposes when applicable. The employee will schedule an appointment with the

Student Health Center for the recommended procedures. The Student Heath Center will perform needed procedures and the physician will notify DLAM in writing of any changes or precautions needed in the work assignments of each employee: based on findings from the health questionnaire, physical examination, or diagnostic tests.

3. All Employees

Any medical condition, including injuries, sustained while on the job will be reported to the employee's direct supervisor. The supervisor will determine whether the employee should report to the student health center for evaluation and treatment. Reporting to the student health center for evaluation is mandatory for individuals identified as working with viable BSL-3 rDNA. Severe injuries may be referred to other nearby hospitals.

For further information regarding this Occupational Health Program, please contact: Mrs. Dawn Best-Desjardins, Department of Laboratory Animal Medicine, 502 Veterinary Medicine Building, 225-578-9643, dbest@vetmed.lsu.edu.

APPENDIX VIII

IBRDSC Policy - Non-Compliance with the NIH guidelines or other regulations - Procedure for Reporting Concerns

Adopted May 29, 2012

The IBRDSC investigates all concerns brought to its attention. Reports of suspected non-compliance with NIH Guidelines, Select Agent Regulations, or any other regulatory agency concerns can be made to any IBRDSC member or the Office of Environmental Health and Safety. Indicate times, dates, place and procedures of concern. The more specific information provided, the more effective will be the IBRDSC evaluations.

Initial Evaluation and Actions:

Whoever receives an allegation of non-compliance or other concern will immediately notify the Biosafety Manager or the IBRDSC Chair. The Biosafety Manager will conduct the initial review and submit a report to the IBRDSC Chair. The Chair will promptly initiate an investigation of the circumstances underlying the concern.

Investigation:

A subcommittee appointed by the Chair should conduct the investigation of the circumstances underlying the concern and report findings to the IBRDSC. It is important to avoid actual or perceived conflicts of interest in this process and to protect the identity of the complainant. The IBRDSC should charge the subcommittee to gather information and should impose a deadline for reporting to the IBRDSC. The time allowed will depend on the initial determination of whether immediate action may be required. The nature and sources of the information required will vary depending on the circumstances, but may involve:

- Interviewing complainants (if known), any persons against whom allegations were directed, and program officials;
- Observing the environment
- Reviewing any pertinent records, (e.g. protocol and other documents).

Report:

The subcommittee investigator(s) should provide a report to the IBRDSC that summarizes:

- The concern(s) as reported to the IBRDSC,
- The results of interviews,
- The condition of the environment,
- The results of records and other document reviews,
- Any supporting documentation such as correspondence, reports, and animal records,
- Conclusions regarding the substance of the concerns and requirements of the NIH, institutional policies, procedures, and protocols; and recommended corrective actions and deadlines, if appropriate,
- The report of the subcommittee investigation should be provided to all IBRDSC members,
- The IBRDSC may vote to accept the recommendations of the investigating subcommittee, offer further suggestions or comments, or request convening a meeting to discuss the concern,
- Based upon the report of investigation the IBRDSC will determine required actions, if any.

IBRDSC determinations may include, but are not limited to:

- Investigation did not reveal an issue of non-compliance,
- Investigation revealed non-compliance,
- Related aspects of the program require further review; and
- Other related institutional programs may require review.
- For any noncompliance with standards accepted by the IBRDSC, the IBRDSC must prescribe corrective actions

along with appropriate deadlines and reporting requirements.

The IBRDSC must also determine whether the noncompliance meets the criteria "serious or continuing noncompliance" or "serious deviation" so as to require reporting to NIH.

Notification in Writing:

The Biological Safety Manager will communicate, in writing, the results of the IBRDSC evaluation of a reported concern to:

- The person(s) responsible for the situation reported,
- The appropriate Vice Chancellor,
- And the person reporting the concern if they wish to be notified of the outcome.

The communication will contain a summary of the concern, the findings of the investigation, determinations of the IBRDSC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) responsible for the situation reported of their option to appeal the decision by writing the IBRDSC Chair/Biosafety Manager within 10 days of the receipt of the letter and request a meeting with the IBRDSC.

Examples of IBRDSC actions that may be appropriate in response to situations that constitute non-compliance are:

- Terminate approval of the respective research study,
- Suspend approval of the respective research study pending submission by the principal investigator responsible for the situation of a written plan for the correction and/or prevention of the problem,
- Take such other action as the IBRDSC deems appropriate.

Reporting to NIH:

The IBRDSC is obligated to report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH's Office of Biotechnology Activities within 30 days of the original notification.

APPENDIX IX

LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: SPILL/EXPOSURE for Recombinant DNA (rDNA) and Biohazardous Materials

Adopted April 26, 2012

DUE TO FEDERAL REPORTING REQUIREMENTS ALL SPILLS INVOLVING rDNA MUST BE REPORTED TO ENVIRONMENTAL HEALTH AND SAFETY WHETHER AN EXPOSURE HAS OCCURRED OR NOT.

Office of Environmental Health & Safety (EHS)
Copy & Mail Center
Corner of South Stadium Drive and CEBA Lane
Phone: 225-578-5640 OR

Gregory Hayes, DrPH
Biological Safety Manager
Phone: 225-578-4658
Fax: 225-578-7489
ghayes@lsu.edu

Quinesha Morgan, PhD
Biological Safety Coordinator
Phone: 225-578-4235
Fax: 225-578-7489
qperry2@lsu.edu

For Spills involving <250 mL of agents at 2 containment

SPILL IN BIOLOGICAL SAFETY CABINET

1. Lower sash and wait 5 minutes to allow BSC to contain aerosols.

2. Put on a lab coat, gloves, and face shield (if not already wearing).

3. Place paper towels over spill.

4. Slowly pour a freshly prepared 10% bleach solution on the paper towels and let sit for at least 30 minutes.

5. Dispose of paper towels in biohazardous waste container.

6. Repeat steps 3-5.

7. Disinfect all surfaces of the Biosafety Cabinet with a freshly prepared, 10% bleach solution and let sit for at least 30 minutes.

8. Wipe all surfaces of the Biological Safety Cabinet with 70% ethanol to reduce corrosion.

9. Allow Biological Safety Cabinet to run for at least 10 minutes before resuming work or turning it off.

10. Dispose of paper towels and PPE in biohazardous waste container.

SPILL IN LABORATORY OUTSIDE OF BIOLOGICAL SAFETY CABINET OR IN TRANSPORT

1. Notify Principal Investigator and others in the area that a spill has occurred.

2. Remove contaminated clothing and place in a biohazard bag if applicable for decontamination.

3. Wash any area of your skin that has contacted spilled material with soap and water for at least 5 minutes. If exposed to eyes, flush in eyewash station for at least 15 minutes.

4. Leave area for 30 minutes to let aerosols settle.

5. Put on lab coat, gloves and face shield (if not already wearing).

6. Use forceps to remove any visibly contaminated items that can be autoclaved and reused and place in autoclave bag.

7. Place paper towels over spill.

8. Slowly pour a freshly prepared 10% bleach solution on the paper towels and let sit for at least 30 minutes.

9. Dispose of paper towels in biohazardous waste container.

10. Repeat steps 6-8.
11. Disinfect all other contaminated surfaces with a freshly prepared, 10% bleach solution and let sit for at least 30 minutes.

12. Dispose of paper towels and PPE in biohazardous waste container.

SPILL INSIDE A CENTRIFUGE

1. Clear area of all personnel.

2. Wait 30 minutes for aerosol to settle before attempting to cleanup spill.

3. If a spill is identified after the centrifuge lid is opened, carefully close the lid, evacuate the area and close the laboratory door. Remain out of the area for at least 30 minutes. Notify personnel of spill and not to enter.

4. Wear a laboratory coat, safety glasses and gloves during cleanup.

5. Remove rotors and buckets to nearest BSC for cleanup.

6. Thoroughly disinfect inside of centrifuge.

7. Discard contaminated disposable materials using appropriate biohazardous waste disposal procedures.

BIOLOGICAL SPILL ON A PERSON

If a biological material is spilled on a person, emergency response is based on the hazard of the biological agent spilled, the amount of material spilled, and whether significant aerosols were generated. If aerosol formation is believed to have been associated with the spill, a contaminated person shall leave the contaminated area immediately. Contaminated clothing should be removed and placed in red or orange biohazard bags for disinfecting. Contaminated skin should be flushed with water and thoroughly washed with a disinfectant soap. Showering

may be appropriate, depending on the extent of the spill.

For Spills Involving >250 mL of BSL-2

Notify Environmental Health and Safety at 225-578-5640 for assistance and documentation.

APPENDIX X

IBRDSC Policy - Shipment of Biological Materials

Adopted May 29, 2012

Before you begin, in order to conserve your efforts, notify/contact Don Michael Hooks, Office of Environmental Health & Safety (EHS), 225-578-8498.

Table of Contents

Introduction

The Office of Environmental Health and Safety (EHS) developed this manual to assist in the shipment of biological materials and dry ice. This document includes information about how to properly classify, package, mark and label your shipment. This manual also describes the training requirements necessary to ship biological materials and dry ice.

Shipped biological specimens, infectious agents and other biological materials are regulated by governmental and non-governmental, consensus development organizations. Penalties for noncompliance with the rules are significant and could result in the following fines:

- Up to $250,000 and up to a year jail sentence for individuals.
- Up to $500,000 per incident for organizations.

Several agencies regulate the shipment of biological materials including:

- International Air Transport Association (IATA).
- US Department of Transportation (DOT).
- US Public Health Service (PHS).
- Occupational Health and Safety Administration (OSHA).
- United States Postal Service (USPS).

Infectious substances and other dangerous goods must always be transported according to the appropriate regulations. Carrying dangerous goods by hand, for example in a vial in your pocket or in luggage, is strictly prohibited. IATA and DOT regulations cover your checked luggage, materials you carry on, or materials you carry in your pockets when you board an airplane. Persons who violate regulations are subject to fines and criminal prosecution. IATA regulations are commonly encountered since they regulate materials transported by air and are generally the most restrictive. For these reasons, this guide pays special attention to IATA protocols.

I. Training Requirements

Federal rules require that anyone wishing to ship biological materials or dry ice must first have shipping training.

If you intend to package biological materials or dry ice for shipment or fill out a Shipper's Declaration for Dangerous Goods you must follow the training requirements as set forth by
the regulating agencies.

Please contact EHS if you require training.

II. Shipping Overview

Follow these steps when shipping biological materials and dry ice.

1. Classify your materials for shipment.

2. Package, mark, and label your material(s) appropriately.

3. Fill out the Shipper's Declaration for Dangerous Goods form. Consult Section V.

4. If you are shipping Select Agents, special regulations apply. Consult Section VI.

5. If you plan on importing or exporting biological materials, permits may be required. Consult Sections IX and X.

III. Shipment Type

For shipment purposes, biological material will fit into one of the following categories:

1. Unregulated biological material;
2. Category A infectious substances;
3. Category B infectious substances;
4. Patient specimens;
5. Biological Products;
6. Genetically modified organisms and microorganisms.

Read each material section carefully to determine how to classify a material. If you are shipping a biological material that *cannot cause disease*, infectious substance regulations do not apply, unless sent by mail (see Section XI). Refer to the classification guide to assist with classification of materials.

Note: All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (see Other Packaging Requirements). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must be shipped appropriately.

1. Unregulated Biological Material

The materials listed below are not subject to IATA or DOT infectious substance shipping regulations. However, these materials may require a permit for shipment abroad. All shipments of blood and blood products **must** be labeled with a biohazard symbol.

- Substances which do not contain infectious substances or which are unlikely to cause disease in humans or animals;
- Non-infectious biological materials from humans, animals or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA, or other genetic elements;
- Substances containing microorganisms, which are non-pathogenic to humans or animals;
- Substances that have been neutralized or inactivated such that they no longer pose a health risk;
- Environmental samples which are not considered to pose a significant risk of infection;
- Dried blood spots*;
- Fecal occult blood screening tests*;

- An infectious substance, other than a Category A infectious substance, contained in a patient sample being transported for research, diagnosis, investigational activities, or disease treatment and prevention, or a biological product, when such materials are being transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials;

- Blood or blood components which have been collected for the purpose of transfusion or the preparation of blood products to be used for transfusion or transplantation*;

- Tissues or organs intended for use in transplantation*;

- A material with a low probability of containing an infectious disease or where the concentration of the infectious substance is at a level naturally occurring in the environment so it cannot cause disease when exposure to it occurs. Examples of these materials include foodstuffs and environmental samples (such as water or a sample of dust or mold);

- A biological product, including an experimental or investigational product or component of a product, subject to federal approval, permit, review or licensing requirements such as those required by the Food and Drug Administration or the US Department of Agriculture*.

* When mailing these items with the USPS, follow packaging guidelines for non-regulated items. See Section XI.

Infectious Substances

Infectious substances are materials known to be, or are reasonably suspected to contain, an animal or human pathogen. A pathogen is a virus, microorganism (including bacteria, plasmids, or other genetic elements), proteinaceous infectious particle (prion) or recombinant microorganism (hybrid or mutant) that is known or reasonably expected to cause disease in humans or animals. Microorganisms that are unlikely to cause human or animal disease are not subject to biological shipping regulations.

2. Category A Infectious Substances

Category A infectious substances are capable of causing permanent disability, life threatening or fatal disease in humans or animals when exposure to them occurs. Category A infectious substances are shipped as infectious substances, affecting humans (UN2814), or infectious substances affecting animals (UN2900). Indicative examples of Category A infectious substances are listed in Appendix A.

a. Packaging

The triple packaging concept (explained in Section V) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 602. See Appendix B for a list of packaging suppliers. Make sure to specify if you are shipping a refrigerated sample (ice packs or dry ice). The maximum quantity of infectious substance that can be shipped by air in one package is 4 L or 4 kg. The maximum quantity that may be shipped via passenger aircraft is 50 mL or 50 g.

b. Labeling

The outer container of a Category A infectious substance shipment must display the following information:

- Sender and recipient's full name and address;
- Infectious substance label (Figure 1);
- "UN2814, Infectious substance, affecting humans" and net quantity Or "UN2900, Infectious substance, affecting animals" and net quantity;
- The text "Person responsible: (a 24/7 phone number)";
- Class 9 label (Figure 2), including UN1845 and net weight, if packaged with dry ice; and
- Cargo Aircraft Label, when shipping over 50 mL or 50 g

3. Category B Infectious Substances

Category B infectious substances are materials that are infectious, but do not meet the standard for inclusion in Category A. Category B infectious substances are assigned to UN3373.

a. Packaging

The basic triple packaging concept applies to Category B infectious substances. Purchase packaging that complies with IATA Packing Instruction 650. See Appendix B for a list of some packaging suppliers. Be sure to specify if the shipment is a refrigerated sample (e.g., ice packs or dry ice). For Category B infectious substances, the maximum quantity of liquid per primary receptacle is 1 liter and outer packaging must not contain more than 4 L or 4 kg.

b. Labeling

The outer container of a Category B infectious substance shipment must display the following information:

- The sender and recipient's full name and address;
- The words "Biological Substance, Category B";
- UN3373 label (Figure 4);
- The text "Person responsible: (24/7 phone number); and
- Class 9 label (Figure 2), if packaged with dry ice.

4. Patient Specimens

Patient specimens that have a minimal likelihood of containing pathogens are exempt from many shipping requirements. Professional judgment is used to determine if a specimen contains pathogens and should be based on the patient's medical history, symptoms, local conditions and individual circumstances. If there is more than a "minimal likelihood" that a patient specimen contains pathogens, it must be shipped as a Category A infectious substance (UN2814 or UN2900) or a

Category B infectious substance (UN3373). Patient specimens unlikely to contain pathogens must be prepared for shipment as follows:

a. Packaging

- Leak-proof primary container;
- Leak-proof secondary packaging;
- Fragile primary containers must be wrapped or separated to prevent breakage;
- Absorbent material must be placed between the primary and secondary containers to absorb entire contents so that no liquid release will reach the outer packaging; and
- Outer packaging must be durable enough for its intended use with at least one side 100 X 100 mm or more.

b. Labeling

The outer package must be marked with "Exempt human specimen," or "Exempt animal specimen."

5. Biological Products

Biological products are derived from living organisms and manufactured for use in the prevention, diagnosis, treatment or cure of diseases in humans or animals and are certified by the USDA, FDA or other national authority. Examples of biological products include certain viruses, therapeutic serums, toxins, antitoxins, vaccines, blood, and blood products. Biological products transported for final packaging, distribution, or use by medical professionals are not subject to biological shipping regulations. Biological products that do not meet these criteria must be assigned to UN2814, UN2900 or UN3373, as appropriate.

6. Genetically Modified Organisms or Microorganisms

Genetically modified organisms (GMO) or microorganisms (GMMO) are organisms and microorganisms in which genetic

material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs that are not infectious but that can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are assigned to UN3245. GMOs and GMMOs that are infectious must be assigned to UN2814, UN2900 or UN3373.

a. Packaging

These materials are packed for shipment in the same way as Category A infectious substances, except there are no testing requirements for the packaging; this packaging variation is IATA Packing Instruction 913. Packages designed for Packing Instruction 913 may not be available from most vendors. In this case, use packages compliant with Packing Instruction 602. The maximum allowable quantity per primary receptacle is 100 mL or 100 g. There is no maximum net quantity per package.

b. Labeling

The outer container of a GMO or GMMO assigned to UN3245 must display the following information:

- The sender and recipient's full name and address;
- Class 9 label and
- Genetically modified microorganisms, UN3245, and net quantity.

IV. Packaging Biological Materials

Potentially hazardous biological materials must be packaged to withstand leakage of contents, shocks, temperature, pressure changes and other conditions that can occur during ordinary handling in transportation. Packaging your material(s) appropriately is accomplished by purchasing certified packaging. Refer to Appendix B for vendors that can supply certified packaging for biological materials. When ordering, specify what type of material(s) you will be shipping: *Category A infectious substances, Category B infectious substances,* etc. Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

A. Triple Packaging

Biological materials must be packaged according to the triple packaging principle. The three elements of triple packaging include: *primary receptacle, leak-proof secondary container,* and *durable outer container*. Infectious substances in Category A and B, patient specimens and genetically modified microorganisms must be packaged in this way, with slight variations.

The **primary container** holds the biological material; it must be leak-proof. It must be labeled with the name of the contents. A leak-proof seal, such as a heat seal, skirted stopper or metal crimp, is required. If the container has a threaded lid, it must be secured with waterproof tape (e.g. Parafilm, etc.). Petri plates cannot be used as primary receptacles. Lyophilized substances can only be shipped in flame sealed glass ampoules or rubber stopped glass vials with metal seals. Packaging purchased for shipping infectious substances usually does not include the primary container.

The **secondary container** holds one or more primary containers, and must also be leak-proof. Secondary containers for all Category A and liquid Category B infectious substances must meet specific pressure test standards when shipping liquids. Containers purchased from commercial vendors are designed to meet the necessary standards. If you are shipping any liquid, there must be enough absorbent material in the secondary container to absorb *all* of the liquid in the primary receptacle(s). If multiple primary containers are used, they must be wrapped to prevent contact between them so they do not break during transport. The **outer container** must be rigid and have one side that is at least 100 mm X 100 mm, in order for required markings and labels to fit. The outer package must be of adequate strength for its capacity, mass, and intended use. An **itemized list** of package contents must be included between the outer and secondary container. The outer package should be marked to identify hazardous contents, including the proper shipping name, UN number and net quantity for each substance, if required.

B. Other Packaging Requirements

Overpacks. An overpack can be used to combine several triple packages into one large package. This may be done

to save on shipping charges when shipping multiple samples. Each triple package inside the overpack must be properly marked and labeled. The outside of the overpack must bear the same markings and labels as the triple packages within including hazard labels and proper shipping names. The outer container of the overpack must also be marked with the word, "Overpack."

Dry Ice. If a shipment includes dry ice the outer packaging must allow for the release of carbon dioxide gas when the solid sublimates. Dry ice must be placed outside the secondary packaging. Interior supports must be provided to secure the secondary container as the refrigerant sublimates. Dry ice is considered a miscellaneous hazard (Class 9). Packages containing dry ice must bear a Class 9 label and be marked with the proper shipping name, UN number, and net quantity, (e.g., Dry Ice, UN1845, 3 kg). Packages designed for dry ice often are pre-labeled and marked. A Shipper's Declaration for Dangerous Goods is not required for shipments in which dry ice is the only hazardous material. Dry ice is included on declarations for shipments that include other hazardous materials such as infectious substances.

Liquid Nitrogen. Biological materials can be shipped refrigerated with liquid nitrogen in dry shippers, which are insulated packages containing refrigerated liquid nitrogen fully absorbed in a porous material. Special packing regulations apply to shipments containing nitrogen. Contact EHS at 8-5640 if you need to ship materials with liquid nitrogen.

V. Shipper's Declaration for Dangerous Goods

A Shipper's Declaration for Dangerous Goods must be completed when shipping a Category A infectious substance assigned to UN2814 or UN2900or a GMO or GMMO assigned to UN3245. A declaration is not required for shipments in which dry ice is the only hazardous material. A declaration is not required for shipments of Category B infectious substances assigned to UN3373. *Improperly completed declarations are the most common cause of package refusal.*

Contact EHS at 8-5640 before completing or signing the Shipper's Declaration for Dangerous Goods.

- Declarations must be typewritten or computer-generated; handwritten declarations will not be accepted.
- Declarations must be printed in color to display the red-striped border.
- Always print at least **four** copies: provide three to the carrier And keep one for your records.
- Remember to sign and date each copy.
- Regulations require that you must retain your copy for **2 years**.

VI. CDC Select Agents

The U.S. Department of Health and Human Services has developed a list of biological agents (see Appendix G) that have the potential to pose a severe threat to public health. Special regulations apply to the use and transfer of these materials, including registration with the LSU Inter-Institutional Biological & Recombinant DNA Safety Committee (IBRDSC) and the Centers for Disease Control and Prevention. If you are planning to, or currently work with, any select agents and have not registered, contact Dr. Gregory Hayes at 8-5640. Specific shipping restrictions apply to these agents which are not discussed in this document.

VII. Shipping Company Restrictions

Some shipping companies may have requirements that are more restrictive than those discussed in this document. Consider the following information before planning a shipment.

DHL. DHL will accept shipments made according to IATA or DOT regulations. Shipments made according to instructions in this manual will be acceptable to DHL.

FedEx. FedEx Express and FedEx Ground will accept shipments prepared according to instructions in this manual. FedEx will not accept any material considered to be in Risk Group 4. A Risk

Group 4 pathogen is one that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available.

United States Postal Service (USPS). The USPS has highly restrictive regulations concerning the shipment of hazardous materials by mail. Category A materials may not be mailed with the USPS. USPS will accept shipments of UN3373 and exempt patient specimens. For more information, refer to Section XII.

UPS. UPS will not accept shipments of Category A materials. UPS will accept shipments of UN3373 and exempt patient specimens.

VIII. International Shipments

Shipping and receiving animals and animal-derived materials, infectious or biohazardous agents, biological toxins, and genetically modified organisms may require the approval of federal agencies, both domestic and foreign. Regulations that govern the transfer of biological materials help to minimize or eliminate the possible threats to public health and agriculture. Packages shipped internationally generally require increased preparation time due to the additional paperwork required for such packages. An import/export permit may be required when shipping biological materials internationally. Check the following U.S. governmental agencies for permits and additional information.

APHIS Agricultural Permits

[http://aphisweb.aphis.usda.gov/ppq/permits/**]**
Telephone: 1-877-770-5990
APHIS permits are required to import or domestically transfer a plant pest, plant biological agent, or other material listed below.

EXPORT/IMPORT

- Arthropods (insects and mites)
- Arthropods inhabiting dung or of medical/veterinary significance
- Bees and bee related articles
- Biological materials containing animal material
- Butterflies
- Cell cultures of bovine or other livestock origins

- Cut flowers
- Earthworms
- Endangered species
- Endangered species of wild fauna and flora
- Entomopathogens
- Farm animals
- Foreign cotton and covers
- Fruits and vegetables
- High consequence livestock pathogens and toxins
- Indian corn or maize, broomcorn and related plants
- Infectious agents of livestock
- Khapra beetle products
- Live arthropods for display or educational purpose
- Livestock
- Moths
- Noxious weeds
- Nursery stocks (including seeds)
- Parasitic plants
- Plant pathogens
- Predators and parasitoids of arthropods
- Prohibited material for research purposes
- Rice and rice related articles
- Seeds
- Snails and slugs
- Soil
- Sugarcane products and by-products (including parts of the sugarcane plant)
- Tissue culture materials of bovine or other livestock origins
- Weed biocontrol
- Wildlife
- Wood products

CDC Permit to Import or Transport Agents or Vectors of Human Disease

[http://www.cdc.gov/od/ohs/biosfty/imprtper.htm**]**
Telephone: 1-404-498-2260

CDC permits are required when shipping any infectious agent known or suspected to cause disease in humans, unsterilized specimens of human or animal tissues (including blood and other fluids), or biological vectors of infectious animals, bats, insects, arthropods and snails.

INFECTIOUS SUBSTANCES

- It is impractical to list all of the several hundred species of infectious substances. In general, an import permit is needed for any infectious substance known or suspected to cause disease in man.

BIOLOGICAL MATERIALS

- Unsterilized specimens of human and animal tissues (such as blood, body discharges, fluids, excretions or similar material) containing an infectious agent requires a permit in order to be imported.

VECTORS

- **Animals**: Any animal known or suspected of being infected with an organism capable of causing disease transmissible to man may require a CDC permit. Importation of live turtles of less than 4 inches in shell length and all nonhuman primates requires an importation permit issued by the Division of Quarantine.

- **Bats:** All live bats require an import permit from the CDC and the U.S. Department of Interior, Fish and Wildlife Services.

- **Insects or Arthropods:** All live fleas, flies, lice, mites, mosquitoes, or ticks require a CDC import permit, regardless of infection status. Permits are required for adult forms, as well as eggs, larvae, pupae, and nymph stages. Any other living insect or arthropod, known or suspected of being infected with any disease transmissible to man requires a CDC import permit.

- **Snails:** Any snail species capable of transmitting a human pathogen require a permit from the Centers for Disease Control.

Commerce Department – Bureau of Industry and Security (BIS) [http://www.bis.doc.gov/index.htm**]**
A permit may be required from the Commerce Department, when exporting infectious agents of human, plant, and animal diseases, including genetic material, and products which might be used for culture of large amounts of agents (Commerce Control List Supplement No. 1 to Part 774 Category 1, pages 54 - 59)

HUMAN PATHOGENS and TOXINS

Bacteria

- *Bacillus anthracis*
- *Brucella abortus*
- *Brucella melitensis*
- *Brucella suis*
- *Burkholderia mallei* (*Pseudomonas mallei*)
- *Burkholderia pseudomallei* (*Pseudomonas pseudomallei*)
- *Chlamydia psittaci*
- *Clostridium botulinum*
- *Clostridium perfringens,* epsilon toxin producing types
- Enterohaemorrhagic *Escherichia coli,* serotype O157 and other verotoxin producing serotypes
- *Francisella tularensis*
- *Salmonella typhi*
- *Shigella dysenteriae*
- *Vibrio cholerae*
- *Yersinia pestis*

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Japanese encephalitis virus
- Junin virus
- Kyasanur Forest virus

- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkey pox virus
- Murray Valley encephalitis virus
- Nipah Virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Powassan virus
- Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Rabies virus cultures
- Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer Encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox
- Yellow fever virus

Toxins and Rickettsia

- Abrin
- Aflatoxins
- Botulinum toxins
- Cholera toxin
- *Clostridium perfringens* toxins
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- *Staphylococcal aureus* toxins

- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum Album Lectin 1 (Viscumin)
- *Bartonella quintana* (*Rochalimea quintana*, *Rickettsia quintana*)
- *Coxiella burnetii*
- *Rickettsia prowasecki*
- *Rickettsia rickettsii*

ANIMAL PATHOGENS and TOXINS

Bacteria

- Mycoplasma mycoides

Viruses

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (certain highly pathogenic strains – see the Export Administration Regulations for more information)
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Lassa virus
- Newcastle disease virus
- Peste des petits ruminants virus
- Porcine enterovirus type 9 (swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)
- Rinderpest virus
- Sheep pox virus
- Swine fever virus (Hog cholera virus)
- Teschen disease virus
- Vesicular stomatitis virus

GENETIC ELEMENTS/GENETICALLY MODIFIED ORGANISMS

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.

- Genetic elements that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."

Technical Note: Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.

- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.

- Genetically modified organisms that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins."

PLANT PATHOGENS

Bacteria Fungi

- *Xanthomonas albilineans*
- *Xanthomonas campestris* pv. citri including strains referred to as *Xanthomonas campestris* pv. *citri* types A,B,C,D,E or otherwise classified as *Xanthomonas citri*, *Xanthomonas campestris* pv., *Aurantifolia* or *Xanthomonas campestris* pv., *Citrumelo.*
- *Colletotrichum coffeanum* var. *virulans* (*Colletotrichum kahawae*)
- *Cochliobolus miyabeanus* (*Helminthosporium oryzae*)
- *Magnaporthe grisea* (*pyricularia grisea/pyricularia oryzae*)
- *Microcyclus ulei* (*Dothidella ulei*)
- *Puccinia graminis* (*Puccinia graminis* f. sp. *tritici*)

- *Puccinia striiformis* (*Puccinia glumarum*)

FDA Import Permits
[http://www.fda.gov/ora/import/**]**
All food (except most meat and poultry), drugs, biologics, cosmetics, medical devices, and electronic products that emit radiation require a permit or registration before importation into the United States.

Fish and Wildlife Service Permit Station
[http://international.fws.gov/permits/permits.html**]**
Telephone: 1-800-770-0150
A permit may be required for transporting fish, wildlife, endangered species, or materials found in the list below.

EXPORT

- African elephant ivory
- Animals
- Artificially propagated plants
- Asian elephant ivory
- Biological samples
- Captive-born export
- Circuses/traveling animal exhibitions
- Goldenseal
- Ginseng
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Raptors
- Trophies by taxidermist
- Wildlife

IMPORT

- African elephant
- African elephant ivory
- African leopard
- Argali
- Asian elephant ivory
- Biological samples

- Birds
- Bontebok
- Circuses/traveling animal exhibitions
- Marine mammals
- Museum specimens
- Personal pet
- Plants
- Polar bears
- Scientific and zoological breeding or display
- Sport hunted trophy
- White rhinoceros
- Wildlife

IX. Exporting from the United States

Depending on the nature of the shipment, a U.S. export permit may be required when sending your package. Additionally, an import permit may be required in the country where the package is being shipped. If your shipment requires an export permit, it must be completed and approved by the appropriate government agency prior to shipment. **Note:** Packages may be opened and inspected when leaving the United States or at any time by any inspection service provided by other countries. In order to assure that your package is safely delivered to its intended destination, always consider the following:

1. If necessary, obtain an export permit from the appropriate governmental organization prior to shipment.

2. Package and label the material according to the guidelines listed in this manual.

3. Include a courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious.

X. Importing into the United States

All shipments entering the United States are processed by the U.S. Bureau of Customs and Border Protection. An import permit may be required to deliver the package even if a permit is not required by the originating country. Check with the appropriate governmental organization prior to shipment of the material. **Note:** Packages may

be opened and inspected upon entry into the United States. In order to assure that your package is safely delivered to its intended destination, always consider the following:
If necessary, obtain an import permit from the appropriate governmental organization prior to shipment.

1. Package and label the material according to the guidelines listed in this manual.

2. Consider including a courtesy letter with the shipment. The **importer** is legally responsible for assuring that foreign personnel package, label, and ship the infectious materials according to USPHS and IATA regulations. Shipping labels containing the universal biohazard symbol, the address of the importer, the permit number, and the expiration date are also issued to the **importer** with the permit. The **importer** must send the labels and one or more copies of the permit to the shipper. The permit and labels inform the U.S. Customs and Border Protection and U.S. Division of Quarantine personnel of the package contents.

XI. United States Postal Service Mailings

The United States Postal Service (USPS) does not allow Category A infectious substances to be mailed. Follow the procedures below when mailing Category B substances, exempt patient specimens and non-regulated items.

A. Mailing Category B Substances

Follow packaging and labeling requirements listed in Section IV(B)(2) and note the following variations:

- Shipments of both liquid and solid substances must be packaged in a pressure tested primary or secondary container; and

- Category B substances may be mailed as First-Class, Priority, or Express mail.

B. Mailing Exempt Human and Animal Specimens

Follow packaging and labeling requirements listed in Section IV(C) and note the following variations:

- Inner containers and the total volume per package are limited to 500 mL or 500 g;

- Outer packaging must me rigid; and

- Exempt specimens must be mailed as First-Class, Priority, Express, or Package Services mail.

C. Mailing Non-Regulated Materials

According to USPS regulations, specific packing instructions apply when mailing non-regulated materials. The following are examples of non-regulated biological materials:

- Biological products not containing Category A or Category B substances;

- Blood or blood products collected for transfusion or preparation of blood products;

- Tissues or organs intended for transplantation;

- Dried blood spots; and

- Dried specimens for fecal occult blood detection.

Quantity limits and form of substance (liquid or solid) determine the packaging requirements for non-regulated materials. Refer to the appropriate category below to determine how to package you material.

1. Non-Regulated Liquid Substance, Not Exceeding 50 ml

Primary container and total package contents may not exceed 50 ml. Primary receptacle must be leak-proof and properly sealed. Include cushioning and enough absorbent to absorb entire contents of liquid. Enclose the primary container(s) in a leak-proof secondary container (e.g. plastic bag). Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

2. Non-Regulated Liquid Substance, Exceeding 50 ml
Primary container must not exceed 50 ml; total package may not exceed 500 ml. Package in triple packaging. Include cushioning and enough absorbent to absorb entire contents of liquid. Label primary or secondary container with a biohazard symbol. No other labeling is required.

3. Non-Regulated Dry Substance
Primary container must be sift-proof and must be enclosed in a sift-proof secondary container. Label primary or secondary container with a biohazard symbol. No other labeling is required. Secondary container may serve as the outer container.

Appendix A - Indicative Examples of Category A Infectious Substances / UN # and Proper Shipping Name Microorganism / UN 2814

Infectious substance affecting humans

- *Bacillus anthracis* cultures
- *Brucella abortus* cultures
- *Brucella melitensis* cultures
- *Brucella suis* cultures
- *Burkholderia mallei - Pseudomonas mallei* - Glanders cultures
- *Burkholderia pseudomallei - Pseudomonas pseudomallei* cultures
- *Chlamydia psittaci* - avian strains cultures
- *Clostridium botulinum* cultures
- *Coccidioides immitis* cultures
- *Coxiella burnetii* cultures
- Crimean-Congo hemorrhagic fever virus
- Dengue virus cultures
- Eastern equine encephalitis virus cultures
- *Escherichia coli*, verotoxigenic cultures
- Ebola virus
- Flexal virus
- *Francisella tularensis* cultures
- Guanarito virus
- Hantaan virus
- Hantavirus causing hemorrhagic fever with renal syndrome
- Hendra virus
- Hepatitis B virus cultures
- Herpes B virus cultures
- Human immunodeficiency virus cultures
- Highly pathogenic avian influenza virus cultures
- Japanese Encephalitis virus cultures
- Junin virus
- Kyasanur Forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- *Mycobacterium tuberculosis* cultures
- Nipah virus
- Omsk hemorrhagic fever virus
- Poliovirus cultures

- Rabies virus cultures
- *Rickettsia prowazekii* cultures
- *Rickettsia rickettsia* cultures
- Rift Valley fever virus
- Russian spring-summer encephalitis virus cultures
- Sabia virus
- *Shigella dysenteriae* type 1 cultures
- Tick-borne encephalitis virus cultures
- Variola virus
- Venezuelan equine encephalitis virus
- West Nile virus cultures
- Yellow fever virus cultures
- *Yersinia pestis* cultures

UN 2900 – Infectious substance affecting animals

- African swine fever virus cultures
- Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus cultures
- Classical swine fever virus cultures
- Foot and mouth disease virus cultures
- Lumpy skin disease virus cultures
- *Mycoplasma mycoides* - Contagious bovine pleuropneumonia cultures
- Peste des petits ruminants virus cultures
- Rinderpest virus cultures
- Sheep pox virus cultures
- Goatpox virus cultures
- Swine vesicular disease virus cultures
- Vesicular stomatitis virus cultures

* This list is not exhaustive. New or emerging pathogens not on the list may meet the criteria to be included in Category A.

Appendix B – Manufacturers of Shipping Containers for Infectious Substances and Dry Ice

Air Sea Atlanta
1234 Logan Circle
Atlanta GA 30318
Phone: 404-351-8600
http://www.airseaatlanta.com

All-Pak, Inc.
Corporate One West
1195 Washington Pike
Bridgeville, PA 15017
Phone: 800-245-2283
http://www.all-pak.com

CARGOpak Corporation
3215-A Wellington Court
Raleigh, NC 27615
Phone: 800-266-0652
http://www.cargopak.com

DG Supplies, Inc.
5 Boxal Drive
Cranbury, NJ 08512
Phone: 800-347-7879
http://www.dgsupplies.com

EXAKT Technologies, Inc.
7416 N Broadway Ext., Suite E
Oklahoma City, OK 73116
Phone: 800-923-9123
http://www.exaktpak.com

HAZMATPAC, Inc.
5301 Polk St., Bldg. 18
Houston, TX 77023
Phone: 800-347-7879
http://www.hazmatpac.com

Inmark, Inc.
220 Fisk Drive S.W.
Atlanta, GA 30336-0309
Phone: 800-646-6275

http://www.inmarkinc.com

JIT Certified, Inc.
1740 Fenpark Drive
Fenton, MO 63026
Phone: 800-962-8636
http://www.jitcertifed.com

Polyfoam Packers Corporation
2320 S. Foster Avenue
Wheeling, IL 60090
Phone: 888-765-9362
http://www.polyfoam.com

SAF-T-PAK, Inc.
10807 - 182 Street Edmonton,
Alberta, Canada, T5S 1J5
Phone: 800-814-7484
http://www.saftpak.com
Source Packaging of New
England, Inc.
405 Kilvert St.
Warwick, RI 02886
Phone: 800-200-0366
http://www.sourcepak.com

Therapak Corporation
1440 Arrow Highway, Unit A
Irwindale, California 91706
Phone: 888-505-7377
http://www.therapak.com

Appendix C – Intent to Ship Hazardous Materials

After reading *Shipment of Biological Materials Manual*, fill out this form to qualify to ship dangerous materials at LSU. EHS will review this completed form and upon successful completion and demonstration of knowledge of applicable regulations you will be certified to ship those materials designated on this form.

1. What regulated material(s) might you ship via mail or courier service? List all hazardous materials that you intend to ship. Also, list the mailing service you intend to use.

2. What packaging will you use to ship your material(s)? Include company name and product number for chosen packaging for each material you intend to ship.

3. Check those that should appear on your package:

- ☐ Class 6.2 label
- ☐ Class 9 label
- ☐ UN3373 label
- ☐ Cargo Aircraft label
- ☐ Dry ice, UN1845, net weight _____ kg
- ☐ Infectious substance, affecting humans, UN2814, net quantity
- ☐ Infectious substance, affecting animals, UN2900, net quantity
- ☐ Name, Address and Phone Number of Shipper
- ☐ Name and Address of Consignee
- ☐ Person Responsible: 24 hour telephone number
- ☐ Overpack
- ☐ "Exempt Human Specimen," or "Exempt Animal Specimen."
- ☐ Genetically modified microorganisms, UN3245, net quantity
- ☐ Diagnostic Specimens

4. Fill out a Shipper's Declaration for Dangerous Goods (if your shipments require one). An example of each material you intend to ship must be included in the "Nature and Quantity of Dangerous Goods" section.

I understand the hazards associated with the materials noted above. Also, I understand the shipping requirements for those materials, as outlined in this manual.

Print name:
Signature:
Date:
Please return, in campus mail, to EHS –.

Appendix D – APHIS Plant Pathogens, HHS Select Infectious Agents & USDA High Consequence Livestock Pathogens/Toxins

[1] **APHIS Plant Pathogen**
[2] **HHS Select Infectious Agent**
[3] **USDA High Consequence Livestock Pathogen or Toxin**
[4] **USDA-HHS Overlap Agent**

Viruses

1. African horse sickness virus [3]
2. African swine fever virus [3]
3. Akabane virus [3]
4. Avian influenza virus (highly pathogenic) [3]
5. Bluetongue virus (exotic) [3]
6. Camel pox virus [3]
7. Cercopithecine herpes virus (Herpes B virus) [2]
8. Classical swine fever virus [3]
9. Crimean-Congo haemorrhagic fever virus [2]
10. Eastern equine encephalitis virus [4]
11. Ebola viruses [2]
12. Foot and mouth disease virus [3]
13. Goat pox virus [3]
14. Hendra virus
15. Japanese encephalitis virus [3]
16. Lassa fever virus [2]
17. Lumpy skin disease virus [3]
18. Malignant catarrhal fever virus (Alcelaphine herpesvirus type 1) [3]
19. Marburg virus [2]
20. Menangle virus [3]
21. Monkeypox virus [2]
22. Newcastle disease virus (velogenic) [3]
23. Nipah virus [4]
24. Peste des petits ruminants virus [3]
25. Rift Valley fever virus [4]
26. Rinderpest virus [3]
27. Sheep pox virus [3]
28. South American haemorrhagic fever viruses [(Junin, Machupo, Sabia, Flexal, Guanarito)] [2]
29. Swine vesicular disease virus [3]
30. Tick-borne encephalitis complex (flavi) viruses [Central European Tick-borne encephalitis, Far Eastern Tick-borne encephalitis (Russian Spring and Summer

encephalitis, Kyasanur Forest disease, Omsk Hemorrhagic Fever)] [2]

31. Variola major virus (Smallpox virus) and Variola minor Alastrim) [2]
32. Venezuelan equine encephalitis virus [4]
33. Vesicular stomatitis virus (exotic) [3]

Prion

1. Bovine spongiform encephalopathy agent [3]

Toxins

1. Abrin [2]
2. Botulinum neurotoxins [4]
3. Clostridium perfringens epsilon toxin [4]
4. Conotoxins [2]
5. Diacetoxyscirpenol [2]
6. Ricin [2]
7. Saxitoxin [2]
8. Shigatoxin and Shiga-like ribosome inactivating proteins [4]
9. Staphylococcal enterotoxins [4]
10. Tetrodotoxin [2]
11. T-2 toxin [4]

Bacteria

1. *Bacillus anthracis* [4]
2. Botulinum neurotoxin producing strains of *Clostridium* 4
3. *Brucella abortus* [4]
4. *Brucella melitensis* [4]
5. *Brucella suis* [4]
6. *Burkholderia mallei* [4]
7. *Burkholderia pseudomallei* [4]
8. *Candidatus* Liberobacter africanus[1]
9. *Candidatus* Liberobacter asiaticus[1]
10. *Coxiella burnetii* [4]
11. *Cowdria Ruminantium* (Heartwater) [3]
12. *Francisella tularensis* [4]
13. *Liberobacter africanus, Liberobacter asiaticus* [1]
14. *Mycoplasma capricolu/M.* F38/*M. mycoides capri* (contagious caprine pleuropneumonia) [3]
15. *Mycoplasma mycoides mycoides* (contagious bovine

pleuropneumonia) [3]
16. *Ralstonia solanacearum* race 3 biovar 2 [1]
17. *Rickettsia prowazekii* [2]
18. *Rickettsia rickettsii* [2]
19. *Xanthomonas oryzae* pv. oryzicola [1]
20. *Xylella fastidiosa* (citrus variegated chlorosis strain) [1]
21. *Yersinia pestis* [2]

Fungi

1. *Coccidioides immitis* [4]
2. *Coccidioides posadasii* [2]
3. *Peronosclerospora philippinensis* [1]
4. *Sclerophthora rayssiae var zeae* [1]
5. *Synchytrium endobioticum* [1]

Exemptions

Exemptions to these rules can be found on the following websites:

- http://www.cdc.gov/od/sap/sap/exclusion.htm
- http://www.aphis.usda.gov/programs/ag_selectagent/

In addition, the following select agents or toxins are exempt:

1. Any select agent or toxin that is in its naturally-occurring environment provided it has not been intentionally introduced, cultivated, collected or otherwise extracted from its natural source.

2. Non-viable select agent organisms or nonfunctional toxins.

3. Toxins under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor, if the aggregate amount does not, at any time, exceed the following amounts:

- 100 mg of abrin
- 0.5 mg of botulinum neurotoxins
- 100 mg of *Clostridium perfringens* epsilon toxin

- 100 mg of conotoxins
- 1,000 mg of diacetoxyscirpenol
- 100 mg of ricin
- 100 mg of saxitoxin
- 100 mg of shigatoxin
- 5 mg of staphylococcal enterotoxins
- 100 mg of shiga-like ribosome inactivating proteins
- 100 mg of tetrodotoxin
- 1,000 mg of T–2 toxin

Genetic Elements, Recombinant Nucleic Acids, and Recombinant Organisms

1. Nucleic acids that can produce infectious forms of any of the select agent viruses.

2. Recombinant nucleic acids that encode for the functional form(s) of any of the select agent toxins if the nucleic acids:

a) can be expressed *in vivo* or *in vitro*; or
b) are in a vector or recombinant host genome and can be expressed *in vivo* or *in vitro*.

3. Select agents that have been genetically modified.

Restricted Experiments

1. Experiments utilizing recombinant DNA that involve the deliberate transfer of a drug resistance trait to select agents that are not known to acquire the trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine or agriculture.

2. Experiments involving the deliberate formation of recombinant DNA containing genes for the biosynthesis of select toxins lethal for vertebrates at an LD50 < 100 ng/kg body weight.

APPENDIX XI

IBRDSC Policy - Transgenic Animals

Adopted May 29, 2012

Transgenic Animals *NOTE: the purchase or transfer of commercial whole transgenic rodents is exempt from IBRDSC review under the NIH Guidelines [Section III-D-4-c (2) and Appendix C-VI].*

Transgenic animals are any whole vertebrate animal in which the animal's genome has been altered by stable introduction of recombinant DNA into the germ-line of the animal.

All activities that are conducted with the goal of producing transgenic animals by use of recombinant DNA technologies described in the NIH guidelines, must be reviewed and approved by the IBRDSC and IACUC. Methods for producing transgenic animals: DNA microinjection, retrovirus-mediated gene transfer and embryonic stem cell mediated gene transfer.

Physical and Biological Containment Levels: The containment levels required for research involving rDNA associated with or in animals, is based on the experiments in **Section III of the NIH Guidelines**. For physical containment of smaller animals there are 4 containment levels established in **Appendix G** of the NIH Guidelines (BL1, BL2, BL3 and BL4). For larger animals such as cattle, swine, sheep, goats, horses and poultry there are also 4 containment levels outlined in **Appendix Q** (BL1–Animals (N), BL2-N, BL3-N and BL4-N).

Experiments Involving Transgenic Rodents and Animals:
The physical and biological containment levels for experiments involving Whole Transgenic Vertebrate Animals must conform to NIH Guidelines.

Section III-E-3: Experiments Involving Transgenic Rodents (BL1)

"This section covers experiments involving the generation of rodents in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived therefrom, into the germ-line (transgenic rodents). Only experiments that require BL1 containment are covered under this section; experiments that require BL2, BL3, or

BL4 containment are covered under Section III-D-4, Experiments Involving Whole Animals."

Section III-D-4: Experiments Involving Whole Transgenic Animals

"This section covers experiments involving whole animals in which the animal's genome has been altered by stable introduction of recombinant DNA, or DNA derived into the germ-line (transgenic animals) and experiments involving viable recombinant DNA-modified microorganisms tested on whole animals.

- III-D-4-a: Whole Animal Experiments that do not use Risk Group 2-3 organisms. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BL1 or BL1-N and appropriate to the organism under study.

- III-D-4-b: Whole Animal Experiments that do use Risk Group 2-3 organisms. For experiments involving recombinant DNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-D-1, Experiments Using Human or Animal Pathogens (Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems the appropriate containment shall be determined by the Institutional Biosafety Committee.

Please note: *Designations such as "whole transgenic animals" and "whole animals" include transgenic rodents for this section unless covered in Section III-E-3 "Experiments Involving Transgenic Rodents (BL1) as shown above. "Caution – Special care should be used in the evaluation of containment conditions for some experiments with transgenic animals. For example, such experiments might lead to the creation of novel mechanisms or increased transmission of a recombinant pathogen or production of undesirable traits in the host animal. In such cases, serious consideration should be given to increasing the containment conditions."*

Instructions for Compliance

Before initiating any research project that is expected to generate whole transgenic vertebrate animals the Principal Investigator must conduct the following steps:

1. The PI must complete an Institutional Animal Care and Use Committee (IACUC) application form which will allow the IACUC

to review the animal usage. They must also register the project with the IBRDSC.

2. In accordance with IBRDSC Policy, the IBRDSC registration form must include the following information:

    - the purpose of the project
    - animal species
    - transgene name
    - transgene function
    - transgene source
    - vector(s) used
    - method of animal transformation
    - physical location of the laboratories and research animals at LSU
    - indication if the gene encodes a toxin or other hazardous agent
    - method of disposal

3. Based on the information on the registration form, the IBRDSC will determine the extent of institutional review. In some instances, the project may need to be referred to the NIH Office of Biotechnology Activities (OBA) for review.

4. Before transgenic animals or their tissues can be shipped to or from the University or scientists at other institutions, the IBRDSC registration form must clearly describe the animals and/or animal tissues, and include but not be limited to, gene constructs, plasmids and genetic changes in the animals. International shipments may require special review due to export requirements.

5. When any transgenic animal is euthanized or dies, the carcass must be disposed of by incineration (recommended) or digestion. This disposal requirement applies to transgenic animals, potentially transgenic animals, "no-takes" in the production of transgenic animals, and progeny of transgenic animals. There are no exceptions to this policy without review and written approval from the IBRDSC.

6. The PI is responsible for reporting the inadvertent release of transgenic animals, improper disposal of transgenic animals or other incidents in the laboratory or vivarium to the Biosafety

Professional, who shall report them to the IBRDSC, attending Veterinarian and to the NIH, if necessary.

7. The PI is responsible for training graduate students, teaching assistants and staff about the policies and procedures for transgenic animal handling and appropriate carcass disposal.

8. Any breeding of transgenic, non-rodent vertebrate animal species (including but not limited to sheep, cows, pigs and other large vertebrate animals) requires registration and approval by the IBRDSC and IACUC. The IBRDSC shall refer to Appendix G and Q of the NIH Guidelines to determine appropriate containment.

9. Any breeding of two different transgenic vertebrate animal models requires registration and approval of the IBRDSC and IACUC. The IBRDSC may refer to Appendix G and Q of the NIH Guidelines as necessary to determine appropriate containment.

10. For BL3-N research records regarding experimental animal use and disposal must be maintained in a permanent record book.

APPENDIX XII

LSU Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC)

Policy: Transgenic Plants

Adopted 4/26/2012

Transgenic plants are plants possessing a single or multiple genes, transferred from a different species and created in the laboratory using recombinant DNA technology. Plants with a "non-regulated" status (commercially available) from USDA Animal and Plant Health Inspection Service (APHIS) are not a part of this policy.

All research involving transgenic plants/seeds at LSU A&M and the LSU AgCenter and all of their associated research farms/stations must be approved by the IBRDSC prior to the start of any work. Even if some projects may qualify as exempt under the NIH Guidelines they still must register with the IBRDSC and be assessed.

Containment: The NIH guidelines outline methods for preventing the dissemination of plants (Appendix P-III-A-1). Appropriate containment and laboratory procedures must be clearly indicated in the IBRDSC registration form.

Disposal: Transgenic plants, including seeds and soil must be inactivated before disposal. Inactivation should be done by autoclaving and this should be clearly indicated on the IBRDSC registration form. There are no exceptions to this policy.

Environmental Release of Transgenic Plants and Seeds/ USDA APHIS Field Test Permits: The IBRDSC approves projects using transgenic plants grown in labs, growth chambers or greenhouses. Projects conducted outside of these locations constitute an environmental release and therefore must have an approval from the USDA APHIS Office. The IBRDSC requires an IBRDSC approval, a copy of the APHIS permit and plot information before the experiment starts.

Interstate Transfer: Receiving: Complete an IBRDSC registration if you are planning to receive transgenic plants and/or seeds.

Shipping: For shipping transgenic plants and/or seeds, refer to USDA-APHIS permitting and DOT requirements.

Research Incidents: NIH and LSU policies require that research related incidents be reported immediately to the IBRDSC through the Biological Safety Manager. Incidents include illnesses, inadvertent releases, improper disposal of biohazardous or recombinant DNA materials, failures in following the NIH Guidelines, etc.

APPENDIX XIII

IBRDSC Policy - Biological Waste Management

Approved: May 29, 2012

PURPOSE:
The purpose of this document is to provide information, requirements, guidelines, and procedures for the handling and disposal of potentially infectious biological waste for all departments and units of the Louisiana State University. Potentially infectious biological waste includes waste potentially infectious to humans, animals, plants, or the environment. It includes, but is not limited, to the following:

- Materials generated by research involving live or attenuated plant or animal pathogenic organisms.
- Materials generated from work involving recombinant DNA.
- Materials from and including toxins of biological origin and infectious agents.
- Materials from and including pathological wastes including tissue, organs, body parts and fluids.
- Materials from humans and primates including blood, blood products, blood collection bags, tubes and vials.
- Sharps (needles, scalpels, razor blades, pipettes) used or unused, generated in health care or laboratory settings.
- Animal carcasses or animal wastes (i.e., feces, bedding).
- Any material which has been mingled with potentially infectious biological waste. Potentially infectious biological waste may be called biohazardous waste, medical waste, biomedical waste, red bag waste, infectious waste, or pathological waste. For simplicity, this document will refer to all such material as "Potentially infectious biological waste".

Attachment A: A listing of Definitions

Attachment B: Biological Waste Procedures for Louisiana State University, School of Veterinary Medicine and Louisiana AgCenter

Attachment C: Stericycle® Packaging Guidelines

The following instructions apply to generators of potentially infectious biological waste.

Training - At LSU, waste generators may be engaged in health care, veterinary work, athletics or research. The waste generator is the Principal Investigator, faculty member, or other person with operational responsibility. Waste generators must assure that all personnel are trained in proper disposal procedures of potentially infectious biological waste. In addition, LSU employees who are reasonably anticipated to come into contact with human or primate blood, tissues, or blood products must adhere to the University Bloodborne Pathogen program. Please contact Pat West with EHS at 225/578-0534 for information on the Bloodborne Pathogen program.

IBRDSC Registration - Laboratories that work with recombinant DNA; pathogens of humans, livestock animals, or plants; or biological toxins must complete a Registration Document for Biohazards or Recombinant DNA Research. This form is available from EHS and must be submitted for review and approval to the Inter-Institutional Biological and Recombinant DNA Safety Committee (IBRDSC). https://sites01.lsu.edu/wp/ehs/biological-safety-registration-of-biohazard-recombinant-dna-research/

Responsibility - The Principal Investigator, faculty member, or other person with operational responsibility shall assure compliance with these requirements within his or her laboratory or area of responsibility.

Segregation - Potentially infectious biological waste must be segregated in the laboratory. Any wastes that could produce laceration or puncture injuries must be appropriately segregated and disposed of as "SHARPS".

- Keep potentially infectious biological waste separate from radioactive waste. Potentially infectious biological waste that contains radioactive material must be disposed of according to procedures of Radiation Safety. Radiation Safety can be contacted at 225-578-2008 or http://www.radsafety.lsu.edu/.

- Keep potentially infectious biological waste separate from hazardous chemical waste. Potentially infectious biological waste which also contains hazardous chemicals must be treated to eliminate the biohazard, and then managed as hazardous chemical waste through Lisa Pepitone with the EHS Department at 225-252-2169 or https://sites01.lsu.edu/wp/ehs/. Hazardous chemicals must never be sent to the landfill or discharged into the sewer.

Containers and Packaging– Containers must be appropriate for the contents. Containers must not leak. Containers must maintain their integrity if chemical or thermal treatment is used. Containers of potentially infectious biological waste must be closed at all times and prior to and after autoclaving.

- Autoclaved material – There is a separate procedure for containers and packaging for autoclaved material. "Procedures for Decontamination by Autoclaving" is available as a separate policy.

- Sharps (unautoclaved) – Sharps should be placed in rigid, puncture resistant containers. Never bend, recap, or remove needles. Broken or unbroken glass, needles, pipettes, scalpels, razor blades, slides and any sharp objects capable of laceration or puncture injuries are to be placed in Sharps containers. Sharps containers must not be overfilled. Sharps containers are not supplied by LSU or the waste vendor. Sharps containers are to be sealed and placed in red bags containing the biohazardous symbol. Red bags are placed in the boxes containing the biohazardous symbol. Red bags and boxes are provided by the waste vendor.

- Solid Potentially infectious biological waste (unautoclaved)- Should be placed in the red bags containing the biohazardous symbol. Do not overfill red bags. Red bags are placed in cardboard boxes with the biohazardous symbol and sealed. Do not exceed 35 pounds or weight limit as posted on the box. Red bags are closed according to directions printed on the box. Any

leaking bags/boxes will be repackaged by the generator. Red bags and boxes are provided by the waste vendor.

- Liquid Potentially infectious biological waste (unautoclaved) - Liquids must not be placed in red bag/boxes. Liquids must be solidified in containers for placement in red bags/vendor boxes. Only <15 ml leak proof containers and vacutainer tubes are eligible for disposal in red bags/vendor boxes. They must be packaged in rigid containers, taped securely, and placed in doubled red bag.

- Attachment C is the Stericycle Packaging Guidelines. Stericycle is the current waste disposal vendor.

Labeling and Marking Requirements – Containers holding potentially infectious biological waste must be clearly labeled, including the biohazard symbol. Generators must provide the following information, on the outside of any box of potentially infectious biological waste – Principal Investigators name, building and room number where the waste was generated. Only indelible or waterproof ink or marker fluid may be used to write this information on the box.

Treatment - Potentially infectious biological waste must be rendered harmless by appropriate treatment. Potentially infectious biological waste at LSU is treated by thermal or chemical disinfection or by incineration. In some circumstances composting, disposal by landfill or digestion can be used. In Louisiana, disposal of potentially infectious biological waste is regulated by the Department of Health and Hospitals, specifically Title 51, Part XXVII of the Louisiana Public Health Sanitary Code. General guidelines are provided in this document. Waste treatment of potentially infectious biological waste should only be performed by trained personnel. Contact Dr. Gregory Hayes at 225/578-4658 or Dr. Quinesha Morgan at 225/578-4235 for additional information.

- Dry heat treatment – 160 C for 2 hours minimum. Time of exposure begins after attaining the specific temperature and does not include lag time.

- Autoclaving – 121 C at 15 PSI for 30 minutes minimum. Longer times may be required depending on the amount of the waste, the presence of water and the type of container used. A Procedure for Decontamination by Autoclaving is available.

- Chemical Disinfection – For chemical disinfection the appropriate concentration of sodium hypochlorite is a 10% solution. An appropriate contact time is 30 minutes or overnight before disposal into the sewer. Undiluted household bleach has a general shelf life of six months to one year. A 10% bleach solution could degrade within 24 hours. Other EPA approved chemical disinfectants or sterilants may be used according to manufacturer's direction.

- Digestion – A managed anaerobic digestion process in which microorganisms break down biodegradable material in the absence of oxygen.

- Composting – An aerobic digestion process in which microorganisms break down biodegradable material in the presence of oxygen. The "microbial pesticides" in compost may include thermophiles and mesophiles, also detritivores which reduce many pathogens. Thermophilic (high-temperature) composting is well known to destroy many seeds and nearly all types of pathogens (exceptions may include prions).

- Landfill - A landfill site is a site for the disposal of waste materials by burial and is the oldest form of waste treatment. Historically, landfills have been the most common methods of organized waste disposal and remain so in many places around the world.

Disposal methods

- Autoclave - There is a separate procedure for disposal by autoclaving. "Procedures for Decontamination by Autoclaving".

- Solid Animal Waste (BSL1 and BSL-2) – Animal waste, including bedding, that is infectious or potentially infectious can be composted unless it contains infectious rDNA. Infectious rDNA bedding must be incinerated, disinfected by thermal treatment, i.e., autoclaved or tissue digestion. Autoclaved material may then be placed in black trash bags, sealed tightly, and placed in the regular trash.

  Special handling of animal waste is only required for animals utilized for research. The biosafety levels of concern would be BSL 2 and 3 or animals involved in research utilizing select agents, or research involving radioactive materials and

persistent chemicals (over and above routine therapeutic pharmaceuticals). The method of handling feces and other waste (bedding) on research animals is directly related to the type of research being done.

- Medical Waste or waste known to contain infectious diseases organisms must be disposed of in compliance with applicable regulations.

  Following is a summary of the regulations of the Louisiana Department of Health and Hospitals: This agency has regulations governing the packaging, labeling, storage, transportation, and treatment of medical waste, contained in the Louisiana Sanitary Code, Chapter XXVII.

  Definitions and Exclusions - The regulations define several categories - medical waste, infectious biomedical waste, and potentially infectious biomedical waste. The latter is used most extensively throughout the regulations, and is defined, in pertinent part, as follows: "...waste considered likely to be infectious by virtue of what it is or how it may have been generated in the context of health care or health care like activities."

  "Potentially Infectious Biomedical Waste" includes, but is not limited to the following:

  1) Cultures and stocks of infectious agents and associated biologicals, I including cultures from medical and pathological laboratories, from research and industrial laboratories.

  2) Human pathological wastes including tissue, organs, body parts and fluids that are removed during surgery or autopsy.

  3) Human blood, human blood products, blood collection bags, tubes and vials.

  4) Sharps used or generated in health care or laboratory settings.

  5) Bandages, diapers, "blue pads," and other disposable materials if they have covered

infected wounds or have been contaminated by patients isolated to protect others from the spread of infectious diseases.

6) Any other refuse which has been mingled with potentially infectious biomedical waste.

Eating utensils, animal carcasses and bedding, and "very small quantities" (less than 250 grams or 1/2 pound) of human or animal tissue, clean dressings, and clean surgical wastes from persons or animals not known to be infected, are excluded from the definition of potentially infectious biomedical waste. The last two categories of material must be disposed in tightly closed plastic bags or other impervious containers.

Animal carcasses and tissues and wastes from large animals must be disposed either as potentially infectious biomedical waste, or according to regulations of the Livestock Sanitary Board. Carcasses, tissue, and wastes of pets may be buried, rendered [cooked at a minimum temperature of 250 degrees Fahrenheit for at least thirty (30) minutes], incinerated, or disposed either in accordance with these regulations or on the order of a licensed veterinarian.

Packaging and Labeling - Potentially infectious biomedical waste (i.e., medical waste) must be packaged in a manner that prevents exposure to the material. Liquids must be in a sturdy, leak-resistant container. Sharps must be in a closed, rigid, break-resistant, puncture-resistant container. Plastic bags and other containers must be clearly labeled, impervious to moisture, strong enough to prevent tearing or bursting under normal conditions, and closed prior to transport. A second level of containment is necessary if the material is to be stored prior to transport.

All containers of potentially infectious biomedical waste must be labeled "Potentially Infectious Biomedical Waste," "Medical Waste," or "Infectious Waste." Untreated waste must bear the name and address of the generator or transporter when it leaves the generator's premises. Treated waste that is still recognizable must carry a supplemental label to specify the treatment method used,

the date of treatment, and the name or initials of the person responsible for treatment. All labels must be clearly visible and legible, and must be water resistant. Note: There are no requirements in the DHH Regulations that state that the bags, boxes, containers, etc., be a certain color.

Storage and Transport - Potentially infectious medical wastes must be stored in a secure manner. Compactors shall not be used for storage, except for small quantities (defined as a single package containing less than 11 pounds of waste other than sharps or less than 2.2 pounds of sharps), wastes can be transported off the site where they were generated only by transporters permitted by the State Health Officer.

Small quantity generators, including doctors', dentists', and veterinarians' offices and private households, may transport small quantities of properly packaged and labeled wastes to approved large quantity generators, permitted storage facilities, or permitted treatment facilities without meeting the requirements for transport and treatment that large quantity generators must meet.

Transportation of potentially infectious waste (except by small quantity generators, as described above) is governed by Section 27:023 of the regulations. This section contains provisions for transporter permits; written contracts between generators and transporters; vehicles used in transportation; transporter operation plans (including worker safety and decontamination provisions), and delivery of potentially infectious biomedical waste only to properly permitted facilities.

Treatment and Disposal - Acceptable treatment methods for potentially infectious biomedical waste are set forth in Section 27:025 of the regulations. These include incineration; steam sterilization [generally, autoclaving at least 248 degrees Fahrenheit (120 degrees C.) and a minimum pressure of 15 psi for a minimum of 30 minutes, or longer if necessary]; disposal of liquids into a sanitary sewer system that meets the requirements of Chapter XIII of the Sanitary Code; thermal inactivation [dry heat of at

least 320 degrees F. (160 C.) at atmospheric pressure for at least 2 hours, excluding lag time]; chemical disinfection (use of chemical agents that have been approved by the State Health Officer); and irradiation (only with the written approval of the State Health Officer). Sharps must be incinerated, encased in plaster or other approved substances in a tightly closed container, or treated in some other manner that renders them unrecognizable as medical sharps and practically precludes the release of recognizable needles and syringes if compacted. Once treated, potentially infectious biomedical waste may be disposed in a permitted sanitary landfill in accordance with the Solid Waste Regulations of the Department of Environmental Quality. As noted above, treated and still recognizable medical waste must carry a supplemental label specifying the treatment method and date, and the name or initials of the person responsible for treatment.

On-site Storage and Treatment - Generators may store and treat their own potentially infectious biomedical wastes, if they obtain a proper permit and comply with substantive provisions of the regulations as to packaging, labeling, storage, transportation, and treatment.

Enforcement - These regulations are enforced by the Office of Public Health.

- Solid Waste (BSL1 & BSL-2) – All nonsharp potentially infectious biological waste should be disinfected by thermal treatment - autoclave. Autoclaved material should then be placed in black trash bags, sealed tightly, and placed in the regular trash. Large animal bedding except that involving transgenic animals or animals injected with rDNA can be disposed of in a sanitary landfill.

- Liquid Waste (BSL1 and BSL2) – Including bulk blood and blood products, cultures and stocks of etiologic agents and viruses, and cell culture material. Liquid waste may be autoclaved then discharged into the Sewer System. Liquid waste may be disinfected by chemical treatment with 10% bleach then discharged into the Sewer System. Only ≤15 ml leak proof containers and ≤15 ml vacutainer tubes are eligible for disposal

in red bags/vendor boxes. They must be packaged in rigid containers, taped securely, and placed in doubled red bag. Liquid waste may be solidified, taped securely, and placed in doubled red bag. A procedure for decontamination by autoclaving is available as a separate LSU policy.

Hypochlorite (Bleach): Contact time: At least 10 minutes. A 10:1 bleach solution/sodium hypochlorite (also called 10% bleach solution) is made by adding nine parts water to one part bleach (sodium hypochlorite). Do not autoclave bleach solutions. A laboratory stock bleach solution is usually 12.5% Sodium Hypochlorite, so a 10:1 solution will result in a final concentration of 1.25%. The diluted solution should be labeled and dated, with an expiration date of 30 days. Note that household bleach is 5.25% Sodium Hypochlorite and can be used in a 10:1 solution, but has an expiration date of one day. To be an effective disinfectant the solution should be at least 0.5% but less than 2%. Remember that even bleach stored in the unopened original container degrades by 20 percent per year, according to the Scripps Research Institute "News & Views."

- Sharps (BSL1) - All potentially infectious biomedical sharps waste will be placed in puncture proof sharps containers, which are placed in red bags and vendor boxes for incineration through the waste vendor.

- Sharps (BSL2) - All potentially infectious biomedical sharps waste should be disinfected by thermal treatment - autoclave. Autoclaved material should then be placed in red bags and vendor boxes for incineration through the waste vendor.

- Radioactive Material - Potentially infectious biological waste that contains radioactive material must be disposed of according to procedures of Radiation Safety.

- Hazardous Chemicals - Potentially infectious biological waste which also contains hazardous chemicals must be treated to eliminate the biohazard, and then managed as hazardous chemical waste through the EHS Department. Specimens in a formalin solution or other chemical solution are treated as hazardous chemical waste. Ethidium bromide and acrylamide items are treated as hazardous chemical waste.

- Animal Carcasses - Incineration through the School of Veterinary Medicine is only for use by SVM necropsy department. Prior approval must be obtained by other departments by contacting the SVM necropsy department. Small animals may be placed in doubled red bags and into vendor boxes for incineration through the waste vendor.

- Biological Toxins – Treat as hazardous waste. Must be packaged in puncture resistant containers, sealed, labeled with hazardous waste label and without biohazard labels.

- Pathological Waste - Is returned to Department of Cell Biology and Anatomy at the LA State University Health Science Center in New Orleans. There is a separate policy for the acquisition and disposal of human body parts

  Bureau of Anatomical Services
  Department of Cell Biology and Anatomy
  Louisiana State University School of Medicine
  1901 Perdido Street
  New Orleans, LA 70112-1393
  Phone: (504) 568-4032

  Problems with disposition of body parts have been the cause of large legal settlements and therefore you must be careful where you obtain human cadaveric specimens and how they are disposed of.

- Genetically engineered organism, plant, or seed - Should be deactivated by thermal treatment - autoclave. Autoclaved material should then be placed in black trash bags, sealed tightly, and placed in the regular trash.

- Prions - Disposal procedures for Prions are specific for the work involved. Please contact Dr. Gregory Hayes at 225/578-4658 or Dr. Quinesha Morgan at 225/578-4235.

- Select Agents – Disposal procedures for Select Agents are specific for the work involved. Please contact Dr. Gregory Hayes at 225/578-4658 or Dr. Quinesha Morgan at 225/578-4235.

- BSL3 Laboratory Waste – Disposal procedures for BSL3 laboratories are specific for the work involved. Please contact

Dr. Gregory Hayes at 225/578-4658 or Dr. Quinesha Morgan at 225/578-4235.

- Biological Waste Procedures for Louisiana State University and the School of Veterinary Medicine are included in Attachment B.

Storage – Potentially infectious biological waste should be treated and disposed of promptly and not allowed to accumulate. Outer containers must be stored in a secure area protected from the elements, vandalism, insects and rodents. Unauthorized personnel must be denied access to this designated storage area. When storing containers, be sure that their labels face outward so that they can be easily seen. Containers must be sealed securely to prevent spillage or the leaking of vapors.

Inspection – Periodically, the Louisiana Department of Health and Hospitals inspects compliance at LSU facilities. The health inspector may visit health centers, laboratories, or athletic training areas. It is important to follow all rules and regulations. The biological waste management program at Louisiana State University is administered by the Office of Environmental, Health, and Safety. It is the responsibility of the researcher or person with operational authority to properly dispose of any potentially infectious biological waste that is generated as a result of research or departmental operations. These guidelines have been developed as a tool to assist in that responsibility. They address the most common general categories of biological wastes and are not intended to be all inclusive or to supersede any alternate waste management procedures specified in research protocols as approved by the IBRDSC. If you have any questions, please contact Dr. Gregory Hayes at 225/578-4658 or Dr. Quinesha Morgan at 225/578-4235 or Lisa Pepitone 225/252-2169.

Attachment A

Definitions

ATTENUATION - The act of weakening. Also the change in the virulence of a pathogenic microorganism induced by genetic modification passage through another host species, decreasing its virulence for the native host. This is the basis for the development of live vaccines.

AUTOCLAVE - A self-locking apparatus for the sterilization of materials by steam under pressure. The autoclave allows steam to flow around each article placed in the chamber. The vapor penetrates cloth or paper used to package the articles being sterilized. Autoclaving is one of the most effective methods for destruction of all types of microorganisms, including spores. The amount of time and degree of temperature necessary for sterilization depend on the articles to be sterilized and whether they are wrapped or left directly exposed to the steam.

Check IBRDSC Autoclave Validation Policy. Many industries have strict rules about monthly biological indicators on high organic loads and are required to profile generic waste loads such as sharps containers full of pipettes, etc., since many types of materials, such as plastics, do not conduct heat well. Each decon autoclave has a specific cycle time for a certain type of load. Most universities go by state law, or just specify a "safe" time, with overkill built in. Some Universities are required to test decon autoclaves weekly. The Louisiana Sanitary Code, Title 51, Part XXVII. Management of Refuse, Infectious Waste, Medical Waste, and Potentially Infectious Biomedical Waste, Chapter 11, Treatment; states "autoclaving at a temperature of at least 120°C., (248°F.), and a pressure of at least 15 pounds per square inch for at least 30 minutes".

BIOLOGICALS -Means preparations made from living organisms and their products; includes vaccines and cultures intended to be used for diagnosing, immunizing, or treating humans or animals or in research pertaining thereto.

BIOTOXIN - A poisonous substance that is a specific product of the metabolic activities of a living organism.

BULK BLOOD AND BLOOD PRODUCTS - Discarded bulk (>100 ml.) blood and blood products higher primate or human) in a free draining, liquid state; body fluids contaminated with visible blood; and materials saturated or dripping with blood.

CHEMICAL DISINFECTION - Means the use of a chemical agent such as 10% hypochlorite or EPA approved chemical disinfectant/sterilant (used according to manufacturer's direction) to significantly reduce biological activity of biohazardous material.

DISCHARGE INTO THE SEWER SYSTEM - Means the discharge or flushing of treated biological waste into Sanitary Sewer System followed by copious quantities of water.

GENERATOR - Means any person, by site, whose act or process produces regulated medical waste, or whose act first causes a regulated medical waste to become subject to regulation.

INTER-INSTITUTIONAL BIOLOGICAL AND RECOMBINANT DNA SAFETY COMMITTEE (IBRDSC) - All biological research at LSU/LSU AgCenter is to be conducted using accepted biological safety practices and in full compliance with university policies and all applicable federal rules and regulations relating to such activities. Accordingly, all projects involving recombinant DNA, pathogens of humans, livestock animals, plants, and biological toxins must be registered and reviewed by the IBRDSC.

PATHOLOGICAL WASTE- Pertains to materials from human and higher primates and includes, but is not limited to:

- Human materials removed during surgery, labor, delivery, spontaneous abortion, autopsy or biopsy including: body parts; tissues and fetuses; organs; bulk blood and body fluids.
- Laboratory specimens of blood, tissue or body fluids after completion of laboratory examination.

- Anatomical remains.

PRION: A small proteinaceous infectious disease-causing agent that is believed to be the smallest infectious particle. A prion is neither bacterial nor fungal nor viral and contains no genetic material. Prions have been held responsible for a number of degenerative brain diseases, including mad cow disease, Creutzfeldt-Jakob disease, fatal familial insomnia, kuru, and an unusual form of hereditary dementia known as Gertsmann-Straeussler-Scheinker disease.

RECOMBINANT DNA - Defined as the joining of natural or synthetic DNA segments to DNA molecules that can replicate in a living cell. Recombinant DNA research is the use of recombinant DNA for any purpose.

TRANSGENIC PLANTS AND ANIMALS – Defined as a genetically modified organism (GMO) or genetically engineered organism (GEO). This is a plant or animal whose genetic material has been altered using genetic engineering techniques. These techniques, generally known as recombinant DNA technology, use DNA molecules from different sources, which are combined into one molecule to create a new set of genes. This DNA is then transferred into a plant or animal giving it modified or novel genes. Transgenic organisms, a subset of GMOs, are organisms that have inserted DNA from a different species.

SELECT AGENT OR TOXIN - A microorganism (virus, bacterium, fungus, rickettsia) or toxin listed by HHS that could pose a severe threat to public health and safety. This term also includes:

- Genetically modified microorganisms or genetic elements from organisms listed as select agents, shown to produce or encode for a factor associated with a disease.
- Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins listed as a select agent, or their toxic submits.

The Centers for Disease Control and Prevention, Division of Select Agents and Toxins oversees the possession, use and transfer of these organisms/toxins based on the Federal Select Agent Regulation 42 CFR 73, available at http://www.cdc.gov/od/sap/docs/salist.pdf.

SHARPS WASTE - Any device having acute rigid corners or edges, or projections capable of cutting or piercing, including:

- Hypodermic needles, syringes, and blades.
- Glass pipets, microscope slides, and broken glass items.

THERMAL TREATMENT - (1) autoclaving at a temperature of not less than 121ºC., and a minimum pressure of 15 psi for at least 30 minutes (longer times may be required depending on the amount of waste, water content and the type of container used) or (2) subjecting biological material to dry heat of not less than 160ºC., under atmospheric pressure for at least two hours. (Exposure begins after the material reaches the specific temperature and does not include lag time).

The basic principle of steam sterilization, as accomplished in an autoclave, is to expose each item to direct steam contact at the required temperature and pressure for the specified time. Thus, there are four parameters of steam sterilization: steam, pressure, temperature, and time. The ideal steam for sterilization is dry saturated steam and entrained water (dryness fraction ≥97%). Pressure serves as a means to obtain the high temperatures necessary to quickly kill microorganisms. Specific temperatures must be obtained to ensure the microbicidal activity. The two common steam-sterilizing temperatures are 121oC (250oF) and 132oC (270oF). These temperatures (and other high temperatures) must be maintained for a minimal time to kill microorganisms. Recognized minimum exposure periods for sterilization of wrapped healthcare supplies are 30 minutes at 121oC (250oF) in a gravity displacement sterilizer or 4 minutes at 132oC (270oC) in a prevacuum sterilizer (Table7). At constant temperatures, sterilization times vary depending on the type of item (e.g., metal versus rubber, plastic, items with lumens), whether the item is wrapped or unwrapped, and the sterilizer type.

Minimum cycle times for steam sterilization cycles

Type of sterilizer	Item	Exposure time at 250oF (121oC)	Exposure time at 270oF (132oC)	Drying time
Gravity displacement	Wrapped instruments	30 min	15 min	15-30 min
	Textile packs	30 min	25 min	15 min
	Wrapped utensils	30 min	15 min	15-30 min
Dynamic-air-removal (e.g., prevacuum)	Wrapped instruments		4 min	20-30 min
	Textile packs		4 min	5-20 min
	Wrapped utensils		4 min	20 min

Modified from Association for the Advancement of Medical Instrumentation.

TREATMENT - Refers to chemical, thermal or mechanical processes that significantly reduces or eliminates the hazardous characteristics, or that reduce the amount of a waste.

Attachment B

Disposal Tables

BIOLOGICAL WASTE PROCEDURES FOR LOUISIANA STATE UNIVERSITY

Type of Waste	Safety Level	Proper Collection and Labeling in the Lab	Decontamination Method	Disposal After Decontamination
Liquid	BSL1 + BSL2	* Use plastic leak proof labware which can be sealed. * All liquid collection containers must be labeled with the biohazardous symbol. * Glassware may be used if absolutely necessary.	Autoclave following Autoclave Procedure or inactivate with an appropriate amount of disinfectant. Be certain to disinfect the outside of the container.	This may go down the drain.
Liquid (Where autoclaves or deactivation are not available)	BSL1 + BSL2	Solidify or encapsulate liquid.		Place in Vendor Box lined with a red vendor bag.

Solids	BSL1	* Use orange autoclave bags, contained within collection receptacles with lids; lids remain closed	Autoclave following Autoclave Procedure	Place in black trash bags in regular trash.
Solids (Where autoclaves are not available)	BSL1 + BSL2	* Use red bags contained within collection receptacles with lids; lids remain closed. * Both bags and collection receptacles must be labeled with the biohazardous symbol.		Place in Vendor Box lined with a red Vendor bag.
Solids	BSL2	* Use orange autoclave bags contained within collection receptacles with lids; lids remain closed. * Both bags and collection receptacles must be labeled with the biohazardous symbol.	Autoclave following Autoclave Procedure	Place in black trash bags in regular trash.
Sharps	BSL1 + BSL2	Use red, hard plastic Sharps containers with spill proof lids and biohazard label.	Autoclave following Autoclave Procedure	Place in Vendor Box lined with a red Vendor bag.

Sharps (Where autoclaves are not available)	BSL1 + BSL2	Use red, hard plastic Sharps containers with spill proof lids and biohazard label.		Place in Vendor Box lined with a red Vendor bag.

BIOLOGICAL WASTE PROCEDURES FOR LOUISIANA STATE UNIVERSITY SCHOOL OF VETERINARY MEDICINE

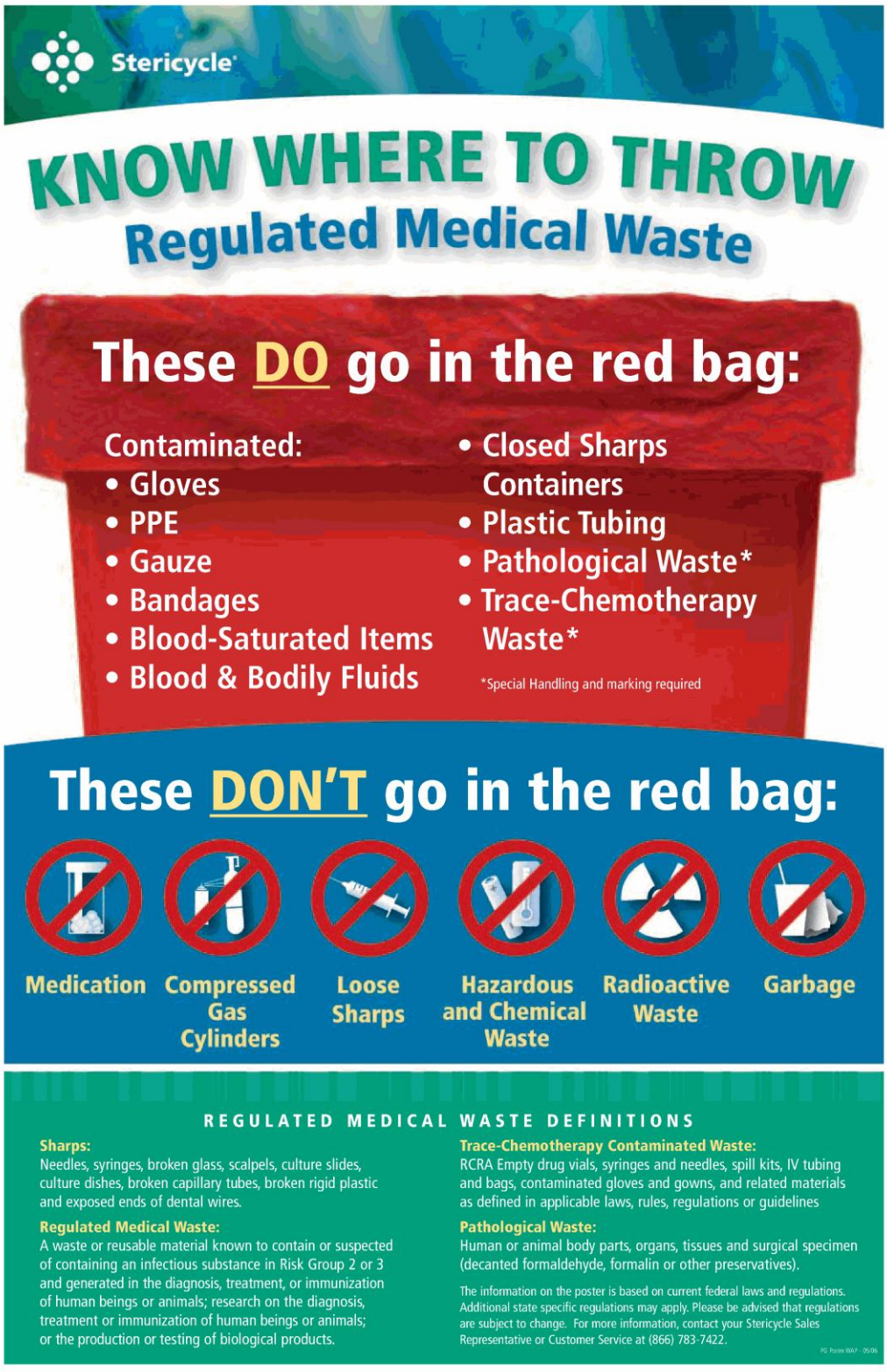
Type of Waste	Safety Level	Proper Collection and Labeling in the Lab	Decontamination Method	Disposal After Decontamination
Liquid	BSL1 + BSL2	* Use plastic leak proof labware which can be sealed. * All liquid collection containers must be labeled with the biohazardous symbol. * Glassware may be used if absolutely necessary.	Autoclave following Autoclave Procedure or inactivate with an appropriate amount of disinfectant. Disinfect outside of container.	This may go down the drain
***Solids**	BSL1 + BSL2	* Use orange/red autoclave bags contained within collection receptacles with lids; lids remain closed. * Both bags and collection receptacles	Autoclave following Autoclave Procedure	Place in Vendor Box lined with a red Vendor bag

		must be labeled with the biohazardous symbol.		
Sharps	BSL1 + BSL2	Use red, hard plastic Sharps containers with spill proof lids and biohazard label.	Autoclave following Autoclave Procedure	Place in Vendor Box lined with a red Vendor bag.

* Large animal waste (i.e., bedding of horses, cows, etc.) can be collected and disposed of in a sanitary landfill.

Attachment C

Stericycle Packaging Guidelines



Stericycle

PACKAGING PROCEDURES FOR MEDICAL WASTE DISPOSAL

Using Stericycle Corrugated Containers

STEP 1

SET UP BOX

- Turn over and seal bottom flaps with tape
- Auto-locking boxes, engage bottom flaps

STEP 2

LINE BOX WITH RED BAG

STEP 3

TIE BAG WHEN BOX IS FULL

STEP 4

SEAL TOP OF BOX

- Seal with tape
- Auto-locking boxes, engage top flaps

STEP 5

CHECK MARKINGS

- Federal markings (see picture above)
- Additional state regulations may apply, see Stericycle representative
- Apply bar code label where available

UNACCEPTABLE

Stericycle

REGULATORY REQUIREMENTS

GENERAL

- Generators are responsible for packaging their wastes.
- Each bag must be hand tied by gathering and twisting the neck of the bag and using a tie or hand knot to secure the bag, and each container must be securely closed.
- Closed bags must not be visible once secondary container is closed.
- Improperly packaged containers or damaged containers will be denied pick-up or returned to the generator.
- Only Regulated Medical Waste can be placed in Stericycle containers.

The information on the poster is based on current federal laws and regulations. Additional state specific regulations may apply. Please be advised that regulations are subject to change.

SHARPS

- Sharp materials ("sharps") must be placed in a puncture-resistant container designed for "sharps" waste. "Sharps" include needles, syringes, broken glass, scalpels, culture slides, culture dishes, broken capillary tubes, broken rigid plastic and exposed ends of dental wires.
- All sharps containers should be properly closed before being placed into secondary containers.
- No loose sharps are permitted outside of sharps containers

For information, contact your Stericycle Sales Representative or Customer Service at (866) 783-7422.

PG Poster CB - 12/06

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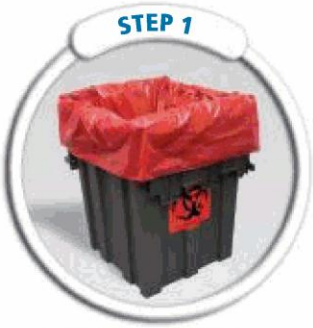
PACKAGING PROCEDURES FOR MEDICAL WASTE DISPOSAL

Using Stericycle Reusable Containers*

EXAMPLES

STEP 1



LINE CONTAINER WITH RED BAG**

STEP 2

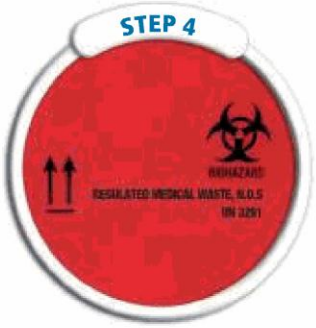
TIE BAG WHEN CONTAINER IS FULL

STEP 3

SECURE LID ON CONTAINER

- Ensure all closure and/or locking mechanisms are engaged

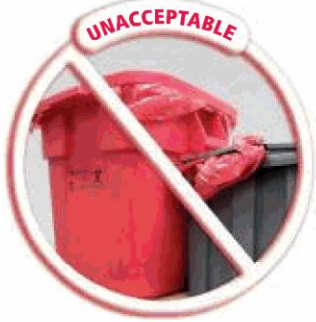
STEP 4



CHECK MARKINGS

- Federal markings (see picture above)
- Additional state regulations may apply, see Stericycle representative
- Apply bar code label where available

UNACCEPTABLE



* *Not applicable for reusable sharps containers.*
** *For large or bulk reusable containers (greater than 119 gallons), bag must meet and be marked per current ASTM requirements, limited to a maximum 46 gallons and 22 lbs.*

REGULATORY REQUIREMENTS

GENERAL

- Generators are responsible for packaging their wastes.
- Each bag must be hand tied by gathering and twisting the neck of the bag and using a tie or hand knot to secure the bag, and each container must be securely closed.
- Closed bags must not be visible once secondary container is closed.
- Improperly packaged containers or damaged containers will be denied pick-up or returned to the generator.
- Only Regulated Medical Waste can be placed in Stericycle containers.

The information on the poster is based on current federal laws and regulations. Additional state specific regulations may apply. Please be advised that regulations are subject to change.

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SHARPS

- Sharp materials ("sharps") must be placed in a puncture-resistant container designed for "sharps" waste. "Sharps" include needles, syringes, broken glass, scalpels, culture slides, culture dishes, broken capillary tubes, broken rigid plastic and exposed ends of dental wires.
- All sharps containers should be properly closed before being placed into secondary containers.
- No loose sharps are permitted outside of sharps containers

For information, contact your Stericycle Sales Representative or Customer Service at (866) 783-7422.

PG Poster CB - 6/07

PROPER DISPOSAL OF MEDICAL WASTE

Tips for Waste Segregation

ACCEPTABLE PHARMACEUTICAL WASTE

Only non-controlled, non-hazardous waste should be included in the Stericycle Rx Waste Box

95% of medical office pharmaceutical waste

- ✓ **Unused Pills**
- ✓ **Topical Ointments** (in original packaging or zip lock bags)
- ✓ **Partial Vials**

Examples:

- Aspirin, ibuprofen, naproxen
- Multivitamins
- Allergy tablets

ACCEPTABLE REGULATED MEDICAL WASTE

- ✓ **Closed Sharps Disposable Containers**
- ✓ **Visibly Bloody Gloves**
- ✓ **Visibly Bloody Plastic Tubing**
- ✓ **Visibly Contaminated PPE**
- ✓ **Saturated Gauze and Bandages**
- ✓ **Blood Saturated Items**
- ✓ **Blood and Body Fluid**

WASTE FOR SEPARATE DISPOSAL

Hazardous Waste

- ✓ **Any product that is considered by the EPA as ignitable, corrosive, reactive, or toxic**

Examples:

- Live vaccines
- Aerosols and inhalers
- Chemotherapy drugs
- Nitroglycerin products
- Epinephrine, Coumadin, Warfarin
- Nicotine
- Physostigmine
- Phentermine

Not sure if a product is hazardous? Email the complete product name and NDC number to xxxx@stericycle.com

Controlled Substance

- ✓ **Products listed on Schedule II – V of Title 21 United States Code (USC) Controlled Substances Act.**

Examples:

- Opiates (Morphine & Codeine)
- Muscle relaxants
- Depressants
- Stimulants (Amphetamines)

For a complete list, refer to section 1308 of the most recent issue of Title 21 Code of Federal Regulations (CFR) Part 1300 to end (21 CFR § 1308).

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Steri-Safe™ OSHA COMPLIANCE program

RESOURCE GUIDE

Controlled and Hazardous Pharmaceuticals Require Separate Disposal

Actual container and copy will vary by state

DO NOT TOSS

CONTROLLED

or HAZARDOUS

PHARMACEUTICALS

in your Steri•Safe™ Drug Disposal or Regulated Medical Waste Containers

List of Common CONTROLLED SUBSTANCES

Actiq®
Adderall®
Alfenta®
Alfentanil
Alprazolam
Alzapam®
Ambien®
Anexsia®
Anodynos-DHC®
Astramorph®
Ativan®
Attenta®
Azdone®
Benzedrine
Beta-phenyl-isopropylamine
Buprenex®
Buprenorphine
Butorphanol
Carisoprodol
Chlorazepate
Chlordiazepoxide
Choral Hydrate
Clonazepam
Cocaine
Cocaine® Topical Solution
Codeine
Codoxy®
Co-Gesic®
Concerta®
Dalmane®
Damason-P®
Darvocet-N®
Darvon®
Darvon-N®
Daytrana®
Demerol®
Desoxyephedrine
Dexedrine®
Dextroamphetamine
Dextrostat®
Diazepam
Diazepam®
Dilaudid®
Dilaudid-HP®
Dolacet®
Dolophine®
Dover's Powder®
Duadyne DHC®
Duocet®
Duragesic®
Duramorph
E-Lor®
Empirin® with Codeine
Endocet®
Epimorph®
Equasym®
Estazolam
Fentanyl
Fentanyl®
Ferndex®
Fiorinal® with Codeine
Flunitrazepam
Flurazepam
Focalin®
Genagesic®
Halcion®
Hydrocet®
Hydrocodone
Hydromorphone
Hydrostat IR®
Hy-Phen®
Infumorph®
Klonopin®
Levo-Dromoran®
Levorphanol
Librium®
Lorax®
Lorazepam
Lorcet®
Lortab®
Lunesta®
Mepergan®
Meperidine
Metadate®
Methadone
Methamphetamine
Methylin®
Methylphenidate
Morphine
Morphine Sulfate®
MS Contin®
MSIR®
Noctec®
Norcet®
Norco®
Novosecobarb®
Opium
Opium Tincture®
Oralet®
Oramorph SR®
Oxazepam
Oxycet®
Oxycodone
OxyContin®
OxyFAST®
OxyIR®
Percocet®
Percodan-Demi®
Propacet®
Propoxyphene
ProSom®
Resoxyn®
Restoril®
Ritalin®
Ritalina®
Ritaline®
RMS®
Rohypnol®
Roxanol®
Roxanol-SR®
Roxicet®
Roxicodone®
Roxilox®
Roxiprin®
Rubifen®
Secobarbital
Seconal®
Serax®
Soma®
Stadol®
Statex®
Sublimaze®
Temazepam
Tranxene®
Triazolam
Tylenol® with Codeine
Tylox®
Uniserts®
Valium®
Valrelease®
Vicodin®
Vicoprofen®
Wygesic®
Xanax®
Zetran®
Zydone®

List of Common HAZARDOUS SUBSTANCES

Material	Typical Use
2-Chloroethyl Vinyl Ether	anesthetics and sedatives manufacture
3-benzyl Chloride	pharmaceutical manufacturing
3-Methylchloranthrene	cancer research
Acetone	solvent in pharmaceutical formulations
Acetyl Chloride	cholesterol testing
Acrylonitrile	pharmaceutical manufacturing
Aniline	pharmaceutical manufacturing
Arsenic	veterinary medicine, severe parasitic diseases
Arsenic Trioxide	chemotherapy
Azaserine	antifungal, antineoplastic
Benzidine dichloride	pathology laboratory
Bromoform	sedative, hypnotic, antitussive
Cacodylic Acid	dermatologic
Carbon Tetrachloride	anthelmintic, pharmaceutical formulations
Chloral Hydrate	cough syrups, sleeping pills
Chlorambucil	chemotherapy
Chlornaphazin	antineoplastic
Chloroform	anesthetic
Chloropropionitrile	pharmaceutical synthesis
Creosote	antiseptic, expectorant
Cresols	antiseptics, disinfectants
Cyanide Salts	laboratory
Cyclophosphamide	chemotherapy
Daunomycin	chemotherapy
Diethylstilbestrol	anticancer agent, contraceptive
Epinephrine	emergency allergy kits, certain types of glaucoma, eye surgery, cardiac arrest
Ethyl Acetate	drug flavoring agent, topical anesthetic
Ethyl Carbamate	antineoplastic
Ethyl Ether	disinfectant, anesthetic
Ethylene Oxide	high level sterilant for surgical instruments
Formaldehyde	antiseptic, disinfectant, preservative
Formic Acid	diuretic, heart and muscle treatment
Hexachloroethane	anthelmintic (anti-worm treatment)
Hexachlorophene	skin treatment
Hexachloropropene	dialysis, pesticide
Lindane	scabicide
Maleic Anyhydride	pharmaceutical manufacture
m-Dichlorobenzene	germicides, pharmaceutical manufacturing
Melphalan	chemotherapy
Mercury	preservatives (thimerosal), antiseptics (mercurochrome), devices (thermometers, sphygmomanometers, others)
Methanol	solvent in pharmaceutical manufacture
Methylpyrilene	antihistamine
Methylthiouracil	thyroid inhibitor
Mitomycin	chemotherapy
Naphthalene	antiseptic, anthelmintic
N-butyl alcohol	bactericide, pharmaceutical manufacture, pain control, anti-hemorrhagic
Nicotine	smoking cessation, nicotine patches, etc.
Nitroglycerin	coronary vasodilator in angina treatment
o-Dichlorobenzene	germicides, pharmaceutical manufacturing
Paraldehyde	sedative, hypnotic
P-Chloro-m-Cresol	antiseptic
p-Dichlorobenzene	germicides, pharmaceutical manufacturing
Phenacetin	analgesic, antipyretic
Phenol	antiseptic, anesthetic, antipruritic (relieves itching)
Phentermine	appetite suppressant
Phenylmercuric acetate	bactericide, pharmaceutic aid in contact lens solutions and nasal sprays
Physotigmine	acholinergenics (liberates/acts like acetylcholine)
Physotigmine Salicylate	acholinergenics (liberates/acts like acetylcholine)†
Potassium Silver Cyanide	bactericide
Reserpine	hypertension, insanity, snakebite, cholera, horse tranquilizer
Resorcinol	acne, dandruff treatment, intermediate in pharmaceutical synthesis
Saccharin	sugar substitute, food preparation
Selenium sulfide	shampoos
Sodium Azide	chemical preservative in hospitals, laboratories
Streptozotocin	chemotherapy
Strychnine	veterinary tonic and stimulant
Tetrachloroethylene	anthelmintic
Thiram	antiseptic
Trichloroethylene	inhalation anesthetic, pharmaceutical manufacture
Uracil mustard	chemotherapy
Warfarin < 0.3%	anticoagulant

Affix this Resource Guide on or nearby your Steri•Safe™ Drug Disposal Container

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REGULATED MEDICAL WASTE ACCEPTANCE POLICY

Stericycle policy requires compliance with all applicable regulations regarding the collection, transportation and treatment of regulated medical waste. Federal Department of Transportation (DOT) Regulations require the generator of regulated medical waste to certify that the packaging and documentation of transported regulated medical waste complies with DOT regulations regarding waste classification, packaging, labeling and shipping documentation. To ensure that neither Stericycle nor the generator of regulated medical waste violates applicable regulations, it is imperative that all parties understand the rules regarding proper identification, classification, segregation and packaging of regulated medical waste. The purpose of this policy is to summarize the minimum requirements for preparing your medical waste for collection, transportation and treatment. Additional facility or state-specific waste acceptance policies may apply based on permit specifications. Please contact your local representative for further information. You may also call (866) 783-7422.

REGULATED MEDICAL WASTE

Stericycle accepts medical waste generated in a broad range of medical, diagnostic, therapeutic and research activities. The term "medical waste" includes biohazardous, biomedical, infectious or regulated medical waste as defined under federal, state or local laws, rules, regulations and guidelines. Except as defined by specific state regulations, this **excludes** RCRA hazardous waste pharmaceuticals, all DEA scheduled drugs including *controlled substances, bulk chemotherapy, waste containing mercury or other heavy metals, batteries of any type, cauterizers, non-infectious dental waste, chemicals such as solvents, reagents, corrosives or ignitable materials classified as hazardous waste under Federal and State EPA Regulations. In addition, Stericycle **cannot accept** bulk liquids, radioactive materials, or complete human remains (including heads, full torsos and fetuses). Stericycle **cannot accept** these excluded materials packaged as regulated medical waste. All lab wastes or materials which contain or have the potential to contain infectious substances arising from those agents listed under 42 CFR 72.3 are strictly prohibited from medical waste by federal law and must be pretreated prior to disposal. Separate protocol and packaging requirements apply for the disposal of non-hazardous pharmaceuticals. Hazardous waste transportation services may be offered in certain geographical locations, under separate contract. Please contact your local representative for details and packaging specifications.

*Un-dispensed from DEA Registrant

WASTE SEGREGATION AND PACKAGING

The generator is solely responsible for properly segregating, packaging and labeling of regulated medical waste. Proper segregation and packaging reduces the potential for accidental release of the contents and exposure to employees and the general public. DOT regulations require (49 CFR 173.197) that all packages of regulated medical waste be prepared for transport in containers meeting the following requirements: 1) rigid; 2) leak resistant; 3) impervious to moisture; 4) of sufficient strength to prevent tearing or bursting under normal conditions of use and handling; 5) sealed to prevent leakage during transport; and 6) puncture resistant for sharps. All regulated medical waste must be accompanied by a properly completed shipping document (See 49 CFR 172.202).

MANAGEMENT OF NON-CONFORMING WASTE

As required by regulation and company policy, Stericycle employees may refuse containers that are non-conforming because of their contents or are improperly packaged, leaking, damaged or likely to create a risk of exposure to employees or the general public. Any non-conforming waste identified in route to or at a Stericycle location may be returned to the generator for proper packaging or disposal. Proper segregation and packaging is essential to ensure compliant and safe handling, collection, transportation and treatment of regulated medical waste.

STERICYCLE REGULATED MEDICAL WASTE ACCEPTANCE POLICY CHECKLIST

ACCEPTED REGULATED MEDICAL WASTE

- Sharps - Means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. Sharps includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.
- Regulated Medical Waste or Clinical Waste or (Bio) Medical Waste - Means a waste or reusable material derived from the medical treatment of an animal or human, which includes diagnosis and immunization, or from biomedical research, which includes the production and testing of biological products.

ACCEPTED REGULATED MEDICAL WASTE WHICH MUST BE IDENTIFIED AND SEGREGATED FOR INCINERATION

- Trace Chemotherapy Contaminated Waste - RCRA Empty drug vials, syringes and needles, spill kits, IV tubing and bags, contaminated gloves and gowns, and related materials as defined in applicable laws, rules, regulations or guidelines
- Pathological Waste - Human or animal body parts, organs, tissues and surgical specimen (decanted of formaldehyde, formalin or other preservatives as required per hazardous waste rules).
- Non-RCRA Pharmaceuticals - Must be characterized and certified as non-RCRA hazardous material by the generator. **Excludes** all DEA scheduled drugs, including controlled substances*
- **California Only** - Solidified Suction Canisters - Suction canisters that have been injected with solidifier materials to control liquids or suction canisters made of high heat resistant plastics such as polysulfone

REGULATED MEDICAL WASTE **NOT** ACCEPTED BY STERICYCLE

- Untreated Category A Infectious Substances
- RCRA Hazardous Pharmaceutical Waste and all DEA controlled drugs, including controlled substances*
- Chemicals - Formaldehyde, formalin, acids, alcohol, waste oil, solvents, reagents, fixer developer
- Hazardous Waste - Drums or other containers with a hazard warning symbol, batteries and other heavy metals
- Radioactive Waste - Any container with a radioactivity level that exceeds regulatory or permitted limits; lead-containing materials
- Complete Human Remains (including heads, full torsos, and fetuses)
- Bulk Chemotherapy Waste
- Compressed Gas Cylinders, Canisters, Inhalers and Aerosol Cans
- Any Mercury Containing Material or Devices - Any mercury thermometers, Sphygmomanometers, lab or medical devices
- Mercury-Containing Dental Waste - Non-contact and contact amalgam and products, chairside traps, amalgam sludge or vacuum pump filters, extracted teeth with mercury fillings and empty amalgam capsules

Consult Stericycle Representative for specific requirements

Additional waste acceptance policies may apply based on state or permit specific requirements. Hazardous waste transportation services may be offered in certain geographical locations, under separate contract. Please refer to your local Stericycle Representative for additional information and options for possible hazardous waste handling. For additional information on container and labeling requirements contact our Stericycle Customer Service Department at (866) 783-7422.