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Shipping Biological Materials

1. Purpose / Background

The purpose of this document is to ensure that biological materials are shipped in compliance with all applicable regulations. Non-compliance with the shipping regulations may result in fines, imprisonment, and/or loss of shipping privileges.

In order to ship regulated biological materials, individuals must be trained and certified in the International Air Transport Association (IATA) and the Department of Transportation (DOT) shipping regulations. The EHS Office will train and certify individuals to ship certain regulated biological. Alternatively, EHS personnel will assist you in shipping regulated biological material by providing the appropriate packages, labels, and paperwork (EHS does not supply dry ice).

To determine if your biological shipment is regulated by IATA or DOT, refer to Section 4.1, Biological Material Classification, or contact the MIT EHS Office for guidance. If the material that you intend to ship is regulated, then you must complete the Intent to Ship Biological Materials Form in Appendix A and submit it to the MIT EHS Office.

The packaging and documentation instructions provided in this SOP is for the use of MIT personnel that have been trained and certified to ship regulated biological materials. As noted above, MIT EHS Office will train and certify individuals to ship biological materials on dry ice excluding Category A infectious substances (see 4.1.3).

2. Scope

This SOP outlines requirements for shipping biologicals that are regulated under DOT 49 CFR Part 173 and IATA Dangerous Goods Regulations, 52nd Edition, 2011. The transport of select agents has additional requirements that are not covered in this SOP (see Appendix B for a list of Select Agents). Please contact the MIT EHS Office for information on these additional requirements.

3. Prerequisites

You must be IATA and DOT trained and certified in order to ship regulated biological materials.


4. Shipping Regulations

4.1 Biological Material Classification

- Non-regulated (DOT/IATA) Biological Material
- Exempt Patient or Animal Specimens
- Category A Infectious Substance
- Category B Biological Substance
- Genetically Modified Micro-Organisms (GMMOs) and Organisms (GMOs)
- Biological Products
- Regulated Medical Waste

4.1.1 Non-regulated (DOT/IATA) Biological Material

- Substances which are unlikely to cause disease in humans or animals. Examples of biological materials that are considered non-infectious include:
 - Nucleic acids (DNA or RNA)

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- purified protein
- BL1 microorganisms e.g. *Bacillus subtilis*, *Saccharomyces cerevisiae*, murine cell lines
- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk, such as human or animal tissue fixed in 10% formalin. Please note: the fixative may be regulated as a chemical depending on the amount in the sample. Please contact the MIT EHS Office for more information.
- Environmental samples that do not pose a significant risk of infection such as food, water, soil, or dust samples.
- Dried blood spots or specimens for fecal occult blood detection/screening test placed on absorbent filter paper or other material.
- Blood or blood components collected for the purpose of transfusion and tissue or organs for use in transplantation.


Please note: for shipments containing human blood or other potentially infectious human material, the primary or secondary container must be marked with a biohazard symbol per OSHA requirements.

4.1.2 Exempt Patient Specimen

Definition of Exempt Patient Specimens: patient specimens for which there is minimal likelihood that pathogens are present. Exempt patient specimens are not subject to IATA regulations if the specimen is transported in packaging for exempt patient specimens (see section 4.3.4 below).

Definition of Patient Specimens: collected directly from humans or animals, including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluid swabs, and body parts being transported for research, diagnosis, investigational activities, or disease treatment or prevention.

- If there is any reason to suspect that the patient specimen contains a pathogen, it would be classified as an Infectious substance category A or B depending on the pathogen.
- In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt. That judgment should be based on the known medical history, symptoms, and individual circumstances of the source, whether human or animal, and endemic local conditions. **If the medical history or other patient information is unknown, then the MIT EHS Office would classify patient specimen as an Infectious substance category B.**
- Examples of exempt patient specimens: blood or urine tests to monitor cholesterol, blood glucose, hormone, or PSA levels; tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.
- Exempt patient specimens are not subject to IATA regulations if the specimen is transported in packaging for exempt patient specimens (see section 4.3.4 below).

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4.1.3 Infectious Substance Category A


Definition of Infectious substance category A: Infectious substance which is transported in a form that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

- Infectious substance category A materials are forbidden to be taken aboard aircraft in carry-on or checked baggage, or on a person. They must always be consigned via a carrier, e.g. FedEx or DHL. Please note: UPS does not accept Infectious substance category A packages and FedEx does not accept Risk Group 4 agents.
- **IATA Table 3.6.D Indicative Examples of Infectious Substances Category A** is in Appendix C of this SOP. This list is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.
- **Many of the agents listed in IATA Table 3.6D are also Select Agents. Additional requirements apply to the transport of Select Agents that are not covered in this SOP (see Appendix B for a list of Select Agents). Please contact the EHS Office (x2-3477) for more information.**
- The IATA Table 3.6.D indicates “cultures only” after infectious agents that are required to be shipped as category A if they are cultures.
- Live animals may not be used to transport infectious substances unless the infectious substance cannot be sent by any other means. Infected live animals may only be transported under terms and conditions approved by the Associate Administrator for Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA).

4.1.4 Biological Substance, Category B

Definition of Biological substance category B: An infectious substance that does not meet the category A definition, but which is known or reasonably expected to contain pathogens. Pathogens are microorganisms (bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. Please note: the proper shipping name for Infectious substance category B is Biological Substance, Category B.

- Biological Substance, Category B materials are forbidden to be taken aboard aircraft in carry-on or checked baggage, or on a person.
- Examples of biological materials that the MIT EHS Office classifies as Biological substance category B:
 - Cultures of pathogens that do not meet the definition of Infectious substance category A, e.g. *Salmonella typhimurium*, *Staphylococcus aureus*, *Streptococcal spp.*
 - Adenoviral or lentiviral vectors that are replication incompetent
 - Established human cell lines, primary human cells, human body fluids (unless known to be pathogen-free)
 - Non-human primate cells, tissues and body fluid
 - Patient or animal specimens that contain or are suspected of containing pathogens that do not meet the definition of category A or a pathogen that is listed in Table 3.6.D as “culture only”, e.g. a blood sample from a patient with hepatitis B virus infection.

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- Patient or animal specimens that cannot be classified as pathogen-free because the medical history, symptoms, local endemic conditions or other patient information is unknown.
- **DOT exclusive motor vehicle exception:** Biological products or patient samples that do not contain category A infectious substances are not subject to DOT shipping requirements for infectious materials when these materials are transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials. HMR. 49 CFR173.134(b)(10)

Please note: cultures of category B infectious substances are not included in this exception. Cultures of category B substances must meet all of the DOT packaging and labeling requirements even when transported in a private motor vehicle.

4.1.5 Genetically Modified Micro-Organisms (GMMOs) and Organisms (GMOs)

Definition of GMOs: organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.


- **DOT/IATA Regulated GMOs:**
 - GMMOs/GMOs which meet the definition of an infectious substance must be shipped as an Infectious substance category A or B.
 - GMMOs/GMOs which do not meet the definition of infectious substance, but have been purposely altered through genetic engineering in a way that does not occur naturally.
 - GMMOs/GMOs which are known or suspected to be dangerous to humans, animals or the environment.
 - Animals which contain, or are contaminated with, genetically modified organisms that meet the definition of an infectious substance. Please note: these animals are forbidden for air transport.
- **DOT/IATA Non-regulated GMMOs/GMOs**
 - GMMOs/GMOs that are authorized for use by the appropriate national authority for the country that the material is being shipped to/within. For example, GMMOs/GMOs plant material that has been approved for environmental release by the US APHIS is exempt. Each country has specific GMMOs/GMOs regulations. Do not attempt to ship a GMMOs/GMOs internationally without knowing the receiving country's regulations.

4.1.6 Biological Products

Definition of Group 1 Biological Products: manufactured or packaged in accordance with the requirements of appropriate national authorities, e.g. FDA or USDA, and transported for the purposes of final packaging or distribution, and used for health care by medical professionals or individuals.

Group 1 biological products are not regulated by IATA or DOT. Examples include licensed diagnostic kits and investigational new drugs that are regulated by the FDA or USDA.

Definition of Group 2 Biological Products: biological products that do not meet the group 1 definition and are known or reasonably believed to contain infectious substances.

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Group 2 biological products must be shipped as Infectious substance category A or Biological substance category B.

4.1.7 Regulated Medical or Clinical Waste

Definition: wastes derived from the medical treatment of animals or humans or from bio-research

- Decontaminated medical or clinical waste which previously contained infectious waste is not regulated unless they meet the criteria for inclusion in another hazard class.
- Regulated medical waste that does not contain category A infectious substances is assigned to UN 3291.
- Regulated medical waste containing category A infectious substances is assigned to UN 2814 or UN 2900 and must be shipped as an infectious substance category A.

See Appendix G for the Biological Material Classification Table

4.2 DOT Incident Reporting (171.15, 171.16)

Telephone Report to CDC:

As soon as practical but no later than 12 hours after the occurrence, the operator or carrier must report a release (fire, breakage, spillage, or suspected contamination) of an infectious substance category A or B in any mode of transportation (including loading, unloading, and temporary storage) by calling Director, Centers for Disease Control and Prevention, U.S. Public Health Service, Atlanta, Ga., 800-232-0124. The following information must be included in the telephone report:

- Name of reporter
- Name and address of person represented by reporter
- Phone number where reporter can be contacted
- Date, time, and location of incident
- The extent of injury, if any
- Class or division (Class 6.2), proper shipping name, and quantity of hazardous materials involved, if such information is available, and
- Type of incident and nature of hazardous material involvement and whether a continuing danger to life exists at the scene.

Written Report to DOT:

In addition to the telephone report, the operator or carrier must submit a written Hazardous Materials Incident Report on DOT Form F 5800.1 (01-2004) within 30 days of discovery of the incident.

For more information on reporting requirements for incidents please review 49 CFR 171.15 and 49 CFR 171.16 or visit the following Pipeline and Hazardous Materials Safety Administration (PHMSA) website: <http://www.phmsa.dot.gov/hazmat/incident-report>


4.3 Packaging, Labeling, and Shipper's Declaration

4.3.1 General Packaging Information

- Triple layer, leak-proof packaging is mandatory for shipping all regulated biological material including exempt patient specimens. Triple layer, leak-proof packaging is described below.

An official hardcopy of this document exists in the EHS Office or on the EHS website.

See Legal Disclaimer at: <http://ehs.mit.edu/site/content/legal-disclaimer>

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- **Primary leak-proof container:** the tube or jar that contains the biological substance. Please note: multiple fragile primary containers must be individually wrapped or separated to prevent contact between them
 - **Secondary leak-proof container with absorbent material:** The primary container is placed in the secondary container, e.g. a sealable plastic bag, with adequate absorbent material surrounding the primary container. There must be enough absorbent material to absorb all of the liquid in the primary containers.
 - **Rigid outer container.** The secondary container is placed in a rigid outer container. Additional padding/absorbent material may be necessary to prevent the contents from rattling or moving around during transport.
- Packages must be able to withstand all of the normal bumps, vibrations, and drops that may occur during transport. For air transport, pressure and temperature changes to which packages are likely to be exposed must be considered.
 - For liquid substances, primary closures must be held securely, tightly and effectively in place by secondary means (e.g. tape, parafilm, locking rings, heat seals). When secondary means of closure cannot be applied, the primary container must be securely closed and placed in an additional leak-proof liner.
 - Specially manufactured and tested packaging materials are necessary for Infectious substances category A and B as specified below. The manufacturer's directions must be followed exactly as given.

4.3.2 Infectious substance category A

- **Packaging:**
 - **Follow IATA Dangerous Goods Regulations Packing Instruction 620**
 - Use vendor purchased and UN tested packaging
 - Use triple layer, leak-proof packaging as described in 4.3.1
 - Maximum amount per package is 50 mL or 50 grams if shipped via passenger aircraft.
 - Maximum amount per package is 4 L or 4 kg if shipped via cargo only aircraft.
 - A list of contents must be included inside the package.
 - Infectious lyophilized (freeze-dried) substances must be in primary receptacles that are flame-sealed glass ampules or rubber-stopped glass vials fitted with metal seals.
 - If screw caps are used for liquid infectious substances shipped at ambient temperatures or higher, then an adhesive tape, paraffin sealing tape, or a manufactured locking closure must be used to secure the cap.
- **Labels & Markings:**
 - Full name and address of sender (shipper) and recipient (consignee).
 - Full name and phone number of a person responsible for the shipment.
 - Infectious substance label.
 - Proper shipping name and UN number:
 - UN 2814, Infectious substance, affecting humans or
 - UN 2900, Infectious substance, affecting animals
 - Net quantity of the infectious substance in mL or L for liquids; in mg or kg if solid.
 - If shipping over 50 mL or 50 g per package: "cargo aircraft only" label.

An official hardcopy of this document exists in the EHS Office or on the EHS website.

See Legal Disclaimer at: <http://ehs.mit.edu/site/content/legal-disclaimer>

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- If packaged with dry ice: Class 9 label, UN 1845, net weight of dry ice.
 - See Appendix E for an illustrated example.
- An itemized list of contents must be enclosed between the secondary packaging and outer packaging.
- **Shipper's declaration:**

A shipper's declaration is required for Infectious substances category A. FedEx mandates using an approved software program to complete the shipper's declaration. Provide at least three original copies to the carrier and retain one original copy for your records. The shipper's declaration must be printed in color to display the red border. A completed sample shipper's declaration is in Appendix D.

 - **Shipper and Consignee:** enter full name and address of shipper and receiver (consignee); in the consignee box include the name and phone number of the person responsible for the shipment.
 - **Transport details:** if shipping more than 50 mL or 50 g, indicate "cargo aircraft only" restriction by crossing out the passenger aircraft box. If shipping less than 50 ml, then cross out the "cargo aircraft only" box. Airport of departure and destination will be completed by the carrier, leave blank.
 - **Shipment type:** Cross out "radioactive" to indicate you are shipping a non-radioactive substance.
 - **UN Number:** enter UN 2814 if infectious to humans or enter 2900 if infectious to animals. If infectious to both humans and animals, use UN 2814.
 - **Proper shipping name:** enter Infectious substance, affecting humans or Infectious substance, affecting animals. Enter the technical name of the agent in parenthesis, e.g. Infectious substance, affecting humans (Ebola Virus).
 - **Class or division:** enter 6.2 for infectious substance, enter 9 for dry ice.
 - **Packing group:** leave blank for infectious substance, enter III for dry ice.
 - **Quantity and type of packaging:** enter the net quantity for each material (infectious substance and dry ice) in metric units. For example: 2 tubes x 1 mL. At the bottom of this column, enter "All packed in one fiberboard box".
 - **Packing instruction:** enter 620 for infectious substance, enter 954 for dry ice.
 - **Authorization:** leave blank or SP A140 if Technical Name is omitted from packaging.
 - **Additional handling instructions:** enter 1-800-424-9300 next to the Emergency Telephone Number. This is Chemtrec's 24-hour phone number. You must notify Chemtrec before every shipment.
 - Enter your name, title, location, and date. Each copy of the declaration must have an original signature.

4.3.3 Biological Substance Category B packaging

- **Packaging:**
 - **Follow IATA Dangerous Goods Regulations Packing Instruction 650**
 - Use triple layer, leak-proof packaging as described in 4.3.1
 - The completed package must be capable of passing a 1.2 meter drop test as described in IATA DGR 6.5.1.1
 - Maximum amount for each primary container is 1 L.
 - Maximum amount per package is 4 L.
 - Infectious lyophilized (freeze-dried) substances must be in primary receptacles that are flame-sealed glass ampoules or rubber-stopped glass vials fitted with metal seals.

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- For solid substances, the primary container must be sift proof and not exceed 4kg per primary container and per total package.
- If screw caps are used for liquid infectious substances shipped at ambient temperatures or higher, then an adhesive tape, paraffin sealing tape, or a manufactured locking closure must be used to secure the cap.

- **Labels & Markings:**

- Full name and address of sender (consignor) and recipient (consignee).
- Full name and phone number of a person knowledgeable and responsible for the shipment (this is permitted to be on the airway bill instead of on the outer packaging).
- UN 3373 label.
- Proper shipping name: Biological substance category B.
- If packaged with dry ice: Class 9 label, UN 1845, net weight of dry ice.
- See Appendix F for an illustrated example.

- An itemized list of contents must be enclosed between the secondary packaging and outer packaging.
- If an airway bill is used, the “nature and quantity of goods” box must show “UN 3373”, the text “biological substance, category B” and the number of packages
- **Shipper’s declaration:** Not required

4.3.4 Exempt Patient Specimen Packaging

- **Packaging and labeling on outer container:**
 - Use triple layer, leak-proof packaging as described in 4.3.1
 - The outer container must have at least one surface with minimum dimensions of 10 cm x 10 cm.
 - Mark the outer package “Exempt human specimen” or “Exempt animal specimen”.
 - If packaged with dry ice: Class 9 label, UN 1845, net weight of dry ice.
- **Shipper’s declaration:** Not required.

4.3.5 Genetically modified micro-organism (GMMOs) and Organism (GMOs) packaging


- **Packaging:**
 - If a GMMOs/GMOs meets the definition of a category A or B infectious substance, then follow the instructions given above for category A or B packaging.
 - Follow IATA Dangerous Goods Regulations Packing Instruction 959
 - Use triple layer, leak-proof packaging as described in 4.3.1
- **Labels & Markings:**
 - Full name and address of sender (consignor) and recipient (consignee).
 - UN 3245 label.
- **Shipper’s declaration:** Not required for Class 9 GMMOs/GMOs or , but is required for GMMOs/GMOs classified as Infectious substance category A
- GMMOs/GMOs are prohibited from carry-on or checked baggage.

4.3.6 Dry Ice

- **Packaging:**

An official hardcopy of this document exists in the EHS Office or on the EHS website.

See Legal Disclaimer at: <http://ehs.mit.edu/site/content/legal-disclaimer>

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- Follow IATA Dangerous Goods Regulations Packing Instruction 954
- Dry Ice must be allowed to vent
- A rigid fiberboard outer container is required

- **Labels & Markings on outer container**

- UN 1845
- Class 9 hazard marking
- Proper shipping name (Dry Ice or Carbon Dioxide, solid)
- Net weight of dry ice

- **Shipper's Declaration not required.**

4.4 Import & Export of Biological Materials:

Please see EHS Guidelines for Import and Export of Biological Materials.

<https://ehs.mit.edu/site/content/import-and-export-biological-materials-guidelines>

4.5 Security Plan

The MIT EHS Office has a Hazardous Materials Security Plan as required by IATA and DOT for shippers of Infectious substances category A.

Never leave infectious packages unattended in public areas. If an infectious substance package is lost or stolen, immediately report the incident to the MIT EHS Office 617-452-3477 (x2-3477). After business hours, report the incident to the Campus Police at 617-253-1212 (x100).

5. Roles & Responsibilities

5.1 The EHS Office is responsible for:

- Assisting DLCs in shipping regulated biological material by providing the appropriate packages, labels, and paperwork (the DLC must supply the dry ice, if necessary).
- Training and certifying individuals to ship regulated biologicals.
- Maintaining up to date guidance pertaining to shipping biological materials.
- Addressing questions or concerns pertaining to shipping biological materials.

5.2 Supervisors are responsible for:


- Ensuring that those individuals that they supervise who ship regulated biologicals consult with the EHS Office or ensuring that they have been trained and certified to ship regulated biologicals by the EHS Office.

5.3 The DLC EHS Coordinator is responsible for:

- Addressing questions or concerns regarding shipping biological materials and consulting with the EHS Office as necessary.

5.4 Individuals that ship regulated biologicals are responsible for:

- Knowing and following the regulations that pertain to them that are outlined in this SOP.
- Submitting the Intent to Ship Biological Material Form to the EHS Office if they need assistance with a shipment.

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- Completing all of the required training if they intend to ship regulated biologicals on their own.
- Reporting any incidents, problems or concerns with shipping biological materials to their supervisor and the EHS Office.

6. Training

Personnel that ship DOT or IATA regulated material must receive training in the requirements commensurate with their responsibilities every two years (IATA) or every three years (DOT). IATA regulations require the administration of a test to verify understanding of the regulations. A certificate must be issued confirming successful completion of the test.

Training must include the following:

- General awareness/familiarization with the regulations.
- Function specific training that provides detailed training in the requirements applicable to the function for which the person is responsible.
- Safety training that covers hazards presented by dangerous goods, safe handling and emergency response procedures.
- Security awareness training that addresses the nature of security risks, recognition of security risks, methods to address and reduce such risks and actions to be taken in the event of a security breach.

All MIT personnel that intend to ship regulated biologicals on their own without going through the MIT EHS Office, must complete the following courses:

- Course 250 Shipping Regulated Biological Materials Certification Class
- Course 256 Shipping Dry Ice/Non-Regulated Materials
- Course 260 General Biosafety
- Course 200 Bloodborne Pathogen Training, if shipping human materials.

8. Record Management

Records must be maintained according to the MIT Records Retention SOP.

Summary of DOT record retention requirements:

- Hazardous materials shipping papers: 2 years for shippers; 1 year for carriers.
- Training records: 3 years and 90 days after a trained employee leaves your service or no longer performs a shipping function. Training records must include name; date; instructor; description, copy or location of training materials used; and certification that the employee was trained and tested as required.
- Hazardous materials incident reports: 2 years.

9. References

The following references are available through the EHS Office:


9.1. Standards

DOT 49 CFR Part 173 - Transportation of Etiologic Agents

IATA Dangerous Goods Regulations, 54th Edition, 2013

USPHS 42 CFR Part 71 Foreign Quarantine; Part 71.54 Etiologic agents, hosts, and vectors

USPHS 42 CFR Part 72 - Interstate Shipment of Etiologic Agents

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42 CFR Part 73 Possession, Use, and Transfer of Select Agents and Toxins

9.2. Other SOP/SOGs

Record Retention SOP

Guidelines for Import and Export of Biological Materials

10. Definitions

- 10.1. Biological Product Group 1:** manufactured or packaged in accordance with the requirements of appropriate national authorities, e.g. FDA or USDA, and transported for the purposes of final packaging or distribution, and used for health care by medical professionals or individuals.
- 10.2. Biological Product Group 2:** biological products that do not meet the group 1 definition and are known or reasonably believed to contain infectious substances.
- 10.3. Biological substance, category B:** the proper shipping name for a biological material that is classified as an infectious substance, category B.
- 10.4. Exempt Patient Specimens:** patient specimens for whom there is minimal likelihood that pathogens are present.
- 10.5. Genetically modified organisms:** organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.
- 10.6. Infectious substance, affecting animals:** The proper shipping name for a biological material that is classified as an infectious substance category A that affects animals.
- 10.7. Infectious substance, affecting humans:** The proper shipping name for a biological material that is classified as an infectious substance category A that affects humans or affects humans and animals.
- 10.8. Infectious substance category A:** Infectious substance which is transported in a form that is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.
- 10.9. Infectious substance category B:** An infectious substance that does not meet the category A definition, but which is known or reasonably expected to contain pathogens.
- 10.10. Pathogens** are microorganisms (bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.
- 10.11. Patient Specimens:** specimens collected directly from humans or animals, including, but not limited to, excreta, secretions, blood and its components, tissue and tissue fluid swabs, and body parts being transported for research, diagnosis, investigational activities, or disease treatment or prevention.
- 10.12. Regulated Medical Waste:** 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.

Appendix A

Intent to Ship Biological Materials Form

Please submit this form to EHS if you plan to ship anything that may be a regulated biological material. EHS will determine if the material is regulated and will assist you in properly preparing your material for shipment. For students or post docs that are moving and plan to ship themselves materials from the laboratory, please cc your PI when you email this form to EHS.

1. Biological material description (please specify the strain):
2. Source of biological material, such as ATCC or patient specimen:
3. Is the material suspected to be infectious? Is the material used at BL1 or BL2?
4. Is this material a genetically modified organism? If yes, please describe.
5. Is the material a liquid or solid?
6. Number of vials and amount (mL or mg) of material per vial:
Net quantity of shipment (mL or mg):
7. Special shipping requirements (e.g. cold packs, dry ice, etc.):
8. Is there a chemical (e.g. formalin, ethanol) in addition to a biological sample?
Chemical name and amount (ml, mg) of chemical per vial:
Manufacturer and product number:
9. Shipper's full address; include name and phone number of person responsible for shipment:
10. Shipping destination full address; include name and phone number of person responsible for shipment:
11. Shipping carrier (DHL, FedEx, UPS, etc.):
12. Do you plan to transport this material personally?
13. Do you need a shipping box from EHS Biosafety Program?
14. If yes, what box (see next page):
15. Account to charge box to:_____

BSP Staff Only:

16. BSP created paperwork, provided box, and packaged shipment: Yes/No
17. Did BSP only provide box, instruction, labels? Yes/No

BSP Person:_____ Time Involved:_____

Appendix B

Select Agent List

HHS AND USDA SELECT AGENTS AND TOXINS 7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus¹
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus¹
Reconstructed replication competent forms of the 1918
pandemic influenza virus containing any portion of the
coding regions of all eight gene segments (Reconstructed
1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins A,B,C,D,E
subtypes

OVERLAP SELECT AGENTS AND TOXINS

Bacillus anthracis *
Bacillus anthracis Pasteur strain
Brucella abortus
Brucella melitensis
Brucella suis
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus¹

USDA SELECT AGENTS AND TOXINS

African horse sickness virus
African swine fever virus
Avian influenza virus¹
Classical swine fever virus
Foot-and-mouth disease virus*
Goat pox virus
Lumpy skin disease virus
*Mycoplasma capricolum*¹
*Mycoplasma mycoides*¹
Newcastle disease virus^{1,2}
Peste des petits ruminants virus
Rinderpest virus*
Sheep pox virus
Swine vesicular disease virus

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

Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae

T-2 toxin

Tetrodotoxin

Tick-borne encephalitis complex (flavi)
viruses:

Far Eastern subtype

Siberian subtype

Kyasanur Forest disease virus

Omsk hemorrhagic fever virus

Variola major virus (Smallpox virus)*

Variola minor virus (Alastrim)*

*Yersinia pestis**

Synchytrium endobioticum

Xanthomonas oryzae

Appendix C

Please note: Many of the agents listed in IATA Table 3.6D are also Select Agents. Additional requirements apply to the transport of Select Agents that are not covered in this SOP (see Appendix B for a list of Select Agents). Please contact the MIT EHS Office (x2-3477) for information on additional requirements for transporting Select Agents.

2013 IATA DGR TABLE 3.6.D Indicative Examples of Infectious Substances Included in Category A In Any Form Unless Otherwise Indicated (This list is not exhaustive)

Infectious substances affecting humans UN2814:

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

Omsk hemorrhagic fever virus
Poliovirus (cultures only)
Rabies virus (cultures only)
Rickettsia prowazekii (cultures only)
Rickettsia rickettsii (cultures only)
Rift Valley fever virus (cultures only)
Russian spring-summer encephalitis virus (cultures only)
Sabia virus
Shigella dysenteriae type 1 (cultures only)
Tick-borne encephalitis virus (cultures only)
Variola virus
Venezuelan equine encephalitis virus (cultures only)
West Nile virus (cultures only)
Yellow fever virus (cultures only)
Yersinia pestis (cultures only)

Infectious substances affecting animals UN 2900:

African swine fever virus (cultures only)
Avian paramyxovirus type 1 - Velogenic Newcastle disease virus (cultures only)
Classical swine fever virus (cultures only)
Foot and mouth disease virus (cultures only)
Lumpy skin disease virus (cultures only)
Mycoplasmamy mycoides - Contagious bovine pleuropneumonia (cultures only)
Pestes des petits ruminants virus (cultures only)
Rinderpest virus (cultures only)
Sheep-pox virus (cultures only)
Goatpox virus (cultures only)
Swine vesicular disease virus (cultures only)
Vesicular stomatitis virus (cultures only)

Appendix D

Sample Shipper's Declaration

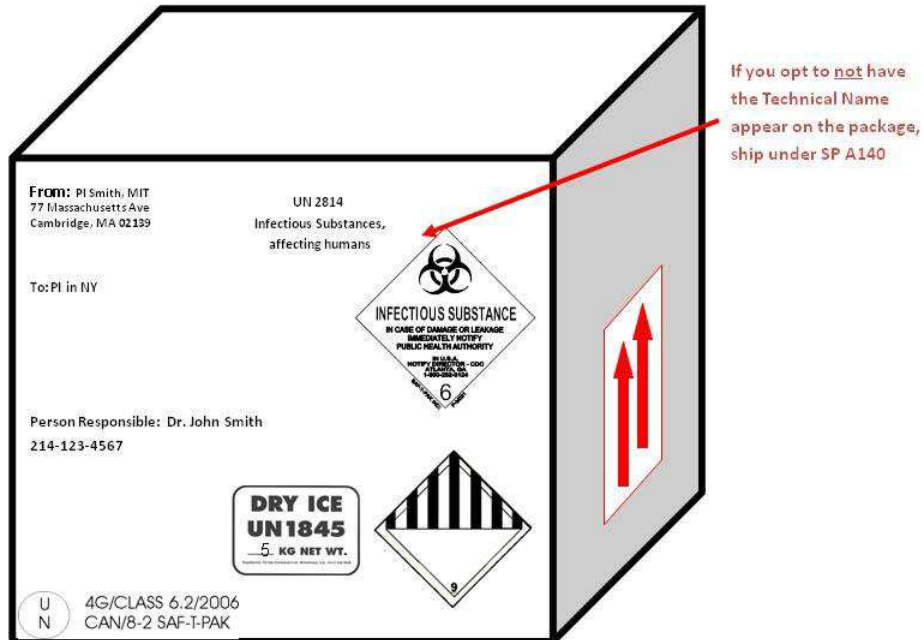
SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper Jane Miller MIT 265 Massachusetts Avenue Cambridge, MA 01239				Air Waybill No. Page 1 of 1 Pages Shipper's Reference Number (optional)			
Consignee John Smith Ohio State University 2222 University Avenue Ohio, IL 00000							
Person Responsible for Shipment name and number: John Smith 734-222-2222							
Two completed and signed copies of this Declaration must be handed to the operator.				WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.			
TRANSPORT DETAILS							
This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i>		Airport of Departure					
<div style="border: 1px solid black; padding: 2px; display: inline-block;"> PASSENGER AND CARGO AIRCRAFT </div>		<div style="border: 1px solid black; padding: 2px; display: inline-block;"> CARGO AIRCRAFT ONLY </div>					
Airport of Destination				Shipment Type <i>(delete non-applicable)</i> <div style="border: 1px solid black; padding: 2px; display: inline-block;"> NON-RADIOACTIVE </div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 10px;"> XXXXXX </div>			
NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization	
UN2814	Infectious substance, affecting humans (human immunodeficiency virus)	6.2		2 tubes x 2 ml	602		
UN1845	Dry ice	9	III	5 kg All packed in one fibreboard box	904		
Additional Handling Information							
Emergency Telephone Number 1-800-424-9300							
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory Jane Miller, Asst. Officer Place and Date Cambridge, MA 1/1/07 Signature <i>(see warning above)</i>			

Created by Andy Glode at the University of New Hampshire Office of Environmental Health and Safety

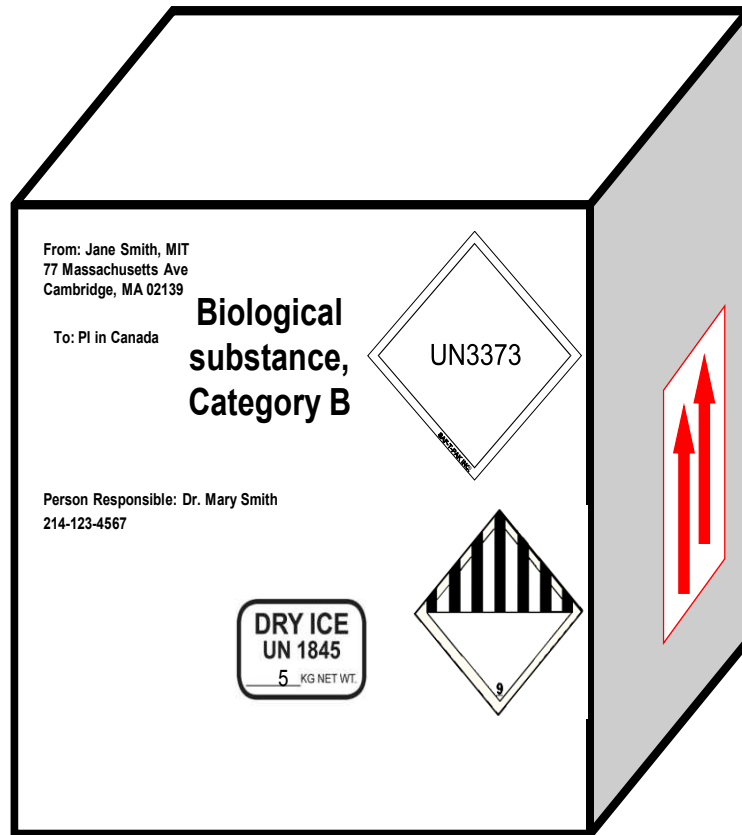
Appendix E

Packaging for Category A



Appendix F

Packaging for Category B



Appendix G

Biological Material Classification Table

Biological Material Classification Table				
Material	Known or expected	IATA	USA	Import Permits
Bacterial/viral culture	Non-pathogenic, non-recombinant	Not regulated (NR)	NR	Not likely
Bacterial/viral culture	Non-pathogenic, recombinant	Possible GMMO/GMO (Class 9)	NR	Possibly
Bacterial/viral culture	Pathogen, Risk Group (RG) 2 not listed on IATA 3.6D	Biological Substance, Category B	Biological Substance, Category B	Yes (CDC for human pathogen; USDA for animal)
Bacterial/viral culture	RG3/RG4 or not listed on IATA 3.6D	Infectious Substance, Category A	Infectious Substance, Category A	Yes
Animal cell line	(pathogen free) minimal likelihood	NR	NR	Possible USDA
Purified Protein		NR (may be toxic, Class 6.1)	NR (may be toxic, Class 6.1)	Not likely
Purified DNA/RNA	Not including whole genome viral DNA/RNA	NR	NR	Not likely
Cell culture media	Cell free	NR	NR	Possible USDA for animal components
Human/animal blood, body fluids, tissue, parts, etc.	Suspected to contain viruses or bacteria on IATA 3.6D	Infectious Substance, Category A	Infectious Substance, Category A	Yes
Human/animal	Suspected to	Biological	Biological	Not likely for

blood, body fluids, tissue, parts, etc.	contain viruses or bacteria not listed on IATA 3.6D	Substance, Category B	Substance, Category B	human; yes for animal (USDA)
Human/ animal blood, body fluids, tissue, parts, etc.	Minimal likelihood of pathogen, known patient history	Exempt if triple packaged and marked "exempt human or animal specimen"	Exempt	Not likely for human; yes for animal (USDA)
Human/ animal blood, body fluids, tissue, parts, etc.	Treated to render non-infectious	NR (formalin, alcohol, etc. may be regulated)	NR (formalin, alcohol, etc. may be regulated)	Not likely for human; yes for animal (USDA)

Note: This is a representative list of possible shipping items, but proper classification must include full review of materials, hazardous components, endemic conditions of samples, as well as additional restrictions applicable to states/countries.