

# BIOLOGICAL MATERIALS SHIPPING MANUAL

**OFFICE OF SAFETY** 

**3851 Campus Rd. Stop 9031 Grand Forks, ND 58202** 

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# **CONTENTS**

I.	INTRODUCTION	1
II.	REGULATIONS	1
III.	GLOSSARY OF TERMS	2
IV.	RESPONSIBILITIES	5
V.	TRAINING REQUIREMENTS	
VI.	SHIPPING OVERVIEW	
VII.	SHIPPING PROCEDURES	
VIII.		
1.		
2.		
3. 4.		
5.		
6.		9
IX.	PACKAGING BIOLOGICAL MATERIALS	10
1.	1	
2.		
Χ.	PACKAGING DRY ICE	
XI.	SHIPPERS DECLARATION FOR DANGEROUS GOODS	
XII.	CDC SELECT AGENTS	
XIII.		
XIV.		
1. 2.		
3.		
4.	*	
XV.	EXPORTING FROM THE UNITED STATES	15
XVI.	IMPORTING INTO THE UNITED STATES	15
XVII	I. EMERGENCY RESPONSE FOR AN INFECTIOUS SUBSTANCE IN TRANSPORT	15
APP	ENDIX A: INTENT TO SHIP BIOLOGICAL MATERIALS	16
APP	ENDIX B: CLASSIFICATION FLOWCHART	17
APP	ENDIX C: INDICATIVE EXAMPLES OF CATEGORY A INFECTIOUS SUBSTANCES UN # AND	
	PER SHIPPING NAME UN 2814	18
APP	ENDIX D: PACKAGING INSTRUCTION P620	20
APP	ENDIX E: PACKAGING INSTRUCTION P650	22
APP	ENDIX F: PACKAGING CHECKLIST	25
	ENDIX G: MANUFACTURERS OF SHIPPING CONTAINERS FOR INFECTIOUS SUBSTANCES DRY ICE	26
APP	ENDIX H: MARKING AND LABELING CHECKLIST	27
APP	ENDIX I: SHIPPERS DECLARATION CHECKLIST (FOR CATEGORY A)	28
	ENDIX J: EXAMPLE OF SHIPPERS DECLARATION FOR DANGEROUS GOODS	
	ENDIX K: EXPORT CONTROLS ON BIOLOGICAL MATERIALS BEING SENT OUT OF THE	
	NTRY	30

APPENDIX L: EXAMPLES OF SHIPMENTS	32
APPENDIX M: LIST OF DANGEROUS GOODS RELATED TO THE TRANSPORT OF INFECTIOUS SUBSTANCES	26
APPENDIX N: SPECIAL PROVISIONS (SP) APPLICABLE TO CERTAIN SUBSTANCES	
APPENDIX O: IMPORTANT CONTACT INFORMATION	

#### I. INTRODUCTION

Dangerous Goods are defined as "articles or substances which are capable of posing a significant risk to health, safety, property or the environment when transported by surface or air". The recommendations for the transport of Dangerous Goods were first initiated to facilitate transport of these goods while ensuring the safety of people, property and the environment.

Dangerous goods are those goods that meet the criteria of one or more of nine United Nations (UN) hazard classes. There are nine classes that relate to the type of hazard.

**Class 1: Explosives** 



**Class 4: Flammable Solids** 



Class 7: Radioactive Material



Class 2: Gases



Class 5: Oxidizer



Class 8: Corrosives



**Class 3: Flammable Liquids** 



**Class 6: Toxic and Infectious Substances** 



**Class 9: Miscellaneous Dangerous Goods** 



The Office of Safety at University of North Dakota (UND) has developed this manual to assist in the shipment of those Dangerous Goods that fall under Class 6 (specifically Infectious Substances, division 6.2) and Class 9 (specifically dry ice and genetically modified organisms). 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. If a package is incorrectly classified, packaged, labeled or documented, the carrier may refuse to accept it, or more likely, return it to the shipper. Furthermore, Federal Aviation Authority (FAA) inspectors may flag shipments. FAA inspectors typically inspect packages passing through FedEx hubs. Non-compliant packages are very easy to trace back to the shipper. Inspectors may use the event as a trigger to conduct *campus-wide inspection* of non-compliant institutions. Penalties for noncompliance with the rules are significant and could result in fines. If an individual or institution is found to be noncompliant with the regulatory requirements, they are subject to civil penalty, with a maximum penalty of \$75,000 for each violation. The maximum increases to \$175,000 if the violation results in death, substantial property damage, serious illness or severe injury to any person (49 CFR 107.329). In situations where a person willfully or recklessly violates the hazardous material regulations, the person may be subject to criminal investigation, with the potential up to 5 years in imprisonment. The maximum imprisonment time is 10 years when the violation causes an accident resulting in death or bodily injury to any person (49 CFR 107.333).

#### II. REGULATIONS

The shipping of biological material may involve multiple regulatory entities. There are five main entities that regulate the transportation of hazardous materials.

**1. Department of Transportation (DOT):** The DOT regulates transportation by air, road, rail or sea (except by US mail). A branch within the DOT known as the <u>Pipeline and Hazardous Materials Safety Administration (PHMSA)</u>

publishes and updates the <u>Federal Hazardous Materials Regulations (HMR) (Title 49 CFR 171-180)</u> every October 1<sup>st</sup> or whenever necessary.

- 2. United States Postal Service (USPS): The USPS has regulatory authority for hazardous materials sent by US mail. The regulations for Category B substances are published in the <u>USPS Domestic Mail Manual (DMM)</u> 601.10.7.4 and the regulations for exempt human or animal specimens are published in the <u>USPS Domestic Mail Manual (DMM)</u> 601.10.17.9. USPS does not transport Category A materials.
- **3. International Civil Aviation Organization (ICAO):** ICAO, within the United Nations, publishes and updates the <u>Technical Instructions for the Safe Transport of Dangerous Goods by Air (ICAO TI)</u> every 2 years. All international flights are subject to the ICAO Technical Instructions.
- **4. Occupational Safety & Health Administration (OSHA):** OSHA regulates the safe handling of human products known or not known to be infected with pathogens within the workplace through the <u>Bloodborne Pathogen Standard (BBP) 29 CFR 1910.1030</u>.
- 5. International Air Transport Association (IATA): IATA is an international trade organization that regulates and sets the standards for the shipping of dangerous goods through air. IATA publishes the <a href="Dangerous Goods Regulations">Dangerous Goods Regulations</a> (DGR) annually that corresponds (and exceeds requirements) to that of the DOT and ICAO regulations, which is why most entities choose to ship materials following IATA regulations to be in compliant with all regulating bodies.

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.

**NOTE:** All shipments are required to adhere to all regulations that the vehicle travels during transit (e.g. a shipment going from Mexico City, Mexico to Ontario, Canada by UPS must adhere to variations for Mexico, United States, Canada and UPS).

#### III. GLOSSARY OF TERMS

**Airway Bill:** A document that serves as a note of consignment to the carrier, and which is used to track a shipment during air transport. FedEx air waybills are sometimes referred to as "shipping labels, though the two are not always the same. An air waybill for FedEx will display the words "US Airbill" for domestic shipments, or "International Air Waybill" for airway bills that may be used for both domestic and international shipments.

**Biological Product:** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) applicable to the prevention, treatment, or cure of a disease or condition of human beings or animals.

**Carrier:** The Company that transports the material (e.g. FedEx).

**Category A:** An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals.

**Category B:** An infectious substance not in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs.

**Classification:** Classification is the process of establishing whether a material is a dangerous good, and to which Class (or Division, if further divided) of dangerous goods it should be assigned to.

**Consignee:** The recipient of the material.

**Culture:** An infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimen.

**Dangerous Goods** are defined as "articles or substances which are capable of posing a significant risk to health, safety, property, or the environment when transported by surface or air." The USDOT refers to these materials as "hazardous materials," and the two terms may be used interchangeably.

**Dangerous Goods Accident:** A dangerous goods accident is an occurrence involving dangerous goods during transport which may cause serious injury or fatality to a person, or cause major damage to property or the environment.

**Dangerous Goods Incident**: A dangerous goods incident occurs when, during transport, the dangerous goods cause minor property or environmental damage, which are not fatal or do not cause serious injury.

**Division 6.2 (Infectious Substance):** A material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals.

**Etiological Agents**: Etiological agents are those microorganisms which cause disease. For example, *Mycobacterium tuberculosis* is the etiological agent that causes the disease of Tuberculosis. For transportation purposes, etiological agents and infectious substances are synonymous.

**Excepted**: Excepted is a term used in the regulations to denote a substance is not subject to the regulations, or that the regulations do not apply to the substances. The exceptions are outlined in the regulations, and are conditional to the specific requirements defined therein.

**Exempt Patient Specimens**: Human or animal specimens which are not likely to contain an infectious substance. In order to classify a specimen as an Exempt patient specimen, professional judgment is required. Factors such as the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions **must** be considered.

**Exposure**: Exposure occurs when the infectious substance inside the package leaks to the outer packaging, or contaminates the outside of the package. Any leaks contained within the secondary leak-proof packaging would not be considered exposures.

**Federal Aviation Authority (FAA)** inspectors are responsible for policing dangerous good transported by air. They have the authority to conduct unannounced facility audits to confirm compliant shipping practices, and to impose fines and penalties for non-compliance.

Genetically modified microorganisms (GMMOs) and organisms (GMOs): Genetically modified microorganisms not meeting the definition of infectious substance are classified in Class 9 (Miscellaneous dangerous substances and articles, including environmentally hazardous substances). GMMOs and GMOs are not subject to dangerous goods regulations when authorized for use by the competent authorities of the countries of origin, transit and destination. Genetically modified live animals shall be transported under terms and conditions of the competent authorities of the countries of origin and destination.

Handling Labels: Handling labels outline specific handling directions pertaining to the substances inside the package.

**Hazard Labels**: Indicate the class and division of the material inside the package. They are often assigned specific color schemes, or include images for easy identification. All labels are in the form of a square set at an angle of 45<sup>0</sup> (diamond shaped).

**Hazardous Materials Employee:** A Hazardous Materials Employee is any person involved in the preparation, marking, labeling, documentation, or transportation of a shipment containing dangerous goods. Hazardous Materials Employees are required to receive training pertaining to the USDOT and IATA regulations and their responsibilities with respect to these regulations.

**Identification**: Identification of dangerous goods involves selecting the correct Proper shipping name and UN number from the List of Dangerous Goods.

**List of Dangerous Goods**: The list of Dangerous Goods is an extensive list of known dangerous goods. The List of Dangerous Goods provides valuable information necessary in the preparing shipments of dangerous goods.

**Manufacturer**: A manufacturer is any person or organization that designs, or assembles from separate components, a package intended to contain dangerous goods.

Manufacturer's Instructions for Use/Closure Instructions: The manufacturer's instructions for use outline the package design; or in other words, the components used when the package was tested. The manufacturer's instructions also indicate the size, quantity and type of primary containers permitted in the package.

**Medical or Clinical Wastes:** Medical or clinical wastes are wastes derived from the medical treatment of animals or humans or from bio-research.

**Not Regulated**: Not regulated substances are not subject to the transport regulations and therefore have on packaging, marking, labeling or documentation requirements.

**Operator**: The operator (or carrier) is the party that accepts the shipment and moves the dangerous goods from the shipper to the consignee.

**Overpacks**: An overpack is an enclosure used to consolidate two or more fully-compliant package, or used to provide refrigeration, protection or convenience for a package or packages.

**Package**: The packaging plus its contents or, in other words, the completed product prepared for transportation.

**Packaging**: Packaging includes the receptacle(s) and other components or materials necessary for the package to perform its containment function, in accordance with the regulation's minimum packing requirements.

**Packing**: Packing is the act of placing the material to be transported into appropriate packaging, in accordance with the manufacturer's instructions.

**Pathogen**: A pathogen is a microorganism (bacteria, virus, rickettsiae, parasite, fungi and prion) that can cause disease in humans or animals.

**Patient Specimens**: Patient specimens are human or animal materials, collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

**Shipment**: All of the components offered to the operator, including all packages or overpacks, and any documentation.

**Shipper:** The party whose name appears on the air waybill, shipper's declaration (if applicable), and package (if applicable), and who is responsible for compliance with the regulations.

**Shipper's Declaration:** An IATA term used to describe the approved format for legal shipping or transport documents. The Shipper's Declaration conveys all necessary information pertaining to the dangerous goods shipment.

**Small Quantities of Dangerous Goods**: The term "Small quantities of dangerous goods" refers to dangerous goods in De Minimis, Exported or Limited quantities.

**Small Quantity Exemption**: The term "Small quantity Exemption" refers to 30mL of other dangerous goods permitted to be shipped with a Category A or Category B infectious substance according to Packing Instructions 620 and 650

**Special Provisions**: Special Provisions are used to clarify specific allowances for shipments of some dangerous goods.

**Triple Packaging**: Triple packaging includes three distinct layers of protection for biological or infectious substance shipments: primary receptacles, secondary packaging and outer packaging.

**UN Numbers**: UN numbers are 4-digit numbers assigned to dangerous goods by the UN Subcommittee of Experts, and are associated with specific Proper shipping names.

#### IV. RESPONSIBILITIES

#### A. Shippers (consignor) Responsibilities

Shippers are responsible for the preparation of dangerous goods. The shipper can also be held liable and subject to fines and other penalties.

# **Shippers must:**

- Classify the dangerous goods
- Properly package, mark and label the dangerous goods
- Arrange legal requirements
- Document the shipment
- Be appropriately trained

#### **B.** Operators (courier) Responsibilities

The operator is also the courier of the shipment and deals with the acceptance, handling, loading, transport and delivery of the dangerous goods. The operator may reject any package that they feel is improperly labeled, marked or packaged. The courier can also be held liable and subject to fines and other penalties.

#### **Operators must:**

- Inspect packages for damage or leakage and detect errors
- Use acceptance checklist
- Ensure safe loading, storage and transport
- Report any issues with the proper authorities
- Be appropriately trained

#### C. Receiver (consignee) Responsibilities

The receiver or consignee is the party associated with the final destination. The receiver can also be held liable and subject to fines and other penalties.

#### **Receivers must:**

- Help obtain any permits or documents
- Inspect the packaging for damage or leakage
- Verify the itemized list of contents
- Open the package in an appropriate environment
- Report back to the shipper regardless of results
- Notify the proper authorities, operator and the shipper if incidents occur
- Be appropriately trained

#### V. TRAINING REQUIREMENTS

Federal regulations 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. Office of Safety will conduct Biological Materials Shipping Training on a bi-annual basis as per the Transport, Shipment and Receipt of

Hazardous Materials and Dangerous Goods UND policy (<a href="http://und.edu/finance-operations/files/docs/6-22-transport-hazardous-materials.pdf">http://und.edu/finance-operations/files/docs/6-22-transport-hazardous-materials.pdf</a>).

The below areas of training will be covered as per the requirements by DOT (with the exception of bullet #5, reserved for enhanced hazards).

#### 1. General Awareness/Familiarization Training

This training allows for the general knowledge to enable the employee to recognize and identify hazardous materials.

# 2. Function-Specific Training

This training addresses the Hazardous Material Regulations (HMR) requirements applicable to the function(s) performed by the hazmat employee in order to successfully conduct their duties in regards to the shipment.

### 3. Safety Training

This training addresses the hazards associated with the dangerous goods and the safe handling and emergency response procedures (OSHA Bloodborne Pathogen Standard training may fulfill the DOT's safety training (49 CFR 172.704(b)). Additionally, the training will include emergency response information, measures to protect the employee from hazards in the workplace and procedures for avoiding accidents.

# 4. Security Training

This training addresses the security concerns applicable to hazardous materials.

### 5. In-depth Security Training

Required for shipments involving Select Agents & Toxins, this training concentrates more in-depth on security.

Please contact UND Office of Safety (701.777.3341) if you or your department requires training.

**NOTE:** ICAO and IATA require that recurrent training must take place within 24 months of previous training to ensure dangerous goods employee's knowledge is up-to-date with the current regulations. The DOT requires recurrent training at least once every three years, or whenever there is a significant change to the regulations (49 CFR 172.704).

#### VI. SHIPPING OVERVIEW

Follow these steps when shipping biological materials and dry ice.

- Classify your materials for shipment.
- Package, mark, and label your material(s) appropriately.
- Fill out the Shipper's Declaration for Dangerous Goods form (If Applicable). If you are shipping Select Agents, special regulations apply. Contact the Biological Safety Officer (701.777.2444) for more information.
- If you plan on importing or exporting biological materials, permits may be required.

#### VII. SHIPPING PROCEDURES

The following procedures will be implemented for all shipments of biological material at UND according to UND's policy for the Transport, Shipment and Receipt of Hazardous Materials and Dangerous Goods (<a href="http://und.edu/finance-operations/files/docs/6-22-transport-hazardous-materials.pdf">http://und.edu/finance-operations/files/docs/6-22-transport-hazardous-materials.pdf</a>). For the purpose of this section, the term "shipper" shall represent the researcher unless noted.

#### 1. Shipping Risk Assessment

The shipper will submit a completed Intent to Ship Biological Materials form (**Appendix A**) to Office of Safety. The fillable form is available on the Office of Safety website (<a href="https://und.edu/finance-operations/office-of-safety/biological-safety.cfm">https://und.edu/finance-operations/office-of-safety/biological-safety.cfm</a>).

# 2. Material Transfer Agreement (MTA)

The shipper will contact the Office of UND Intellectual Property Commercialization & Economic Development (701.777.6772) to inquire if a Material Transfer Agreement (MTA) is required (https://und.edu/research/intellectual-property/admin.cfm).

#### 3. Export Controls

The shipper will contact the Export Control Officer (701.777.2049) to inquire if there are any concerns in regards to Export Controls (<a href="https://und.edu/research/resources/export-controls.cfm">https://und.edu/research/resources/export-controls.cfm</a>).

#### 4. Classification of Dangerous Goods

The Office of Safety will *approve* the Intent to Ship Biological Materials form to verify the appropriate packaging and regulations for the shipment type.

### 5. Personnel Training

All UND individuals involved in the shipping process will be confirmed to have the appropriate training necessary. (**NOTE:** UND Office of Safety will conduct Biological Materials Shipping Training on a bi-annual basis).

#### 6. Packaging & Labeling

The shipper will properly package, label and mark the material once an approval is received (For example: An approval from Office of Safety for appropriate classification and packaging). **NOTE:** Only packaging and labels from an *approved vendor* will be utilized. Please refer to **Appendix G** for more information regarding manufacturers of shipping containers for infectious substances and dry ice.

#### 7. Package Shipped

After approvals are received for MTA (UND Intellectual Property Commercialization & Economic Development) and Export Controls (Export Controls Officer - If Applicable) the shipper will ship the packaging through an appropriate courier (Example: FedEx UPS etc.).

#### 8. Shipment Confirmation

The shipper shall confirm that the shipment has arrived at its location in a safe manner.

#### VIII. 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. Exempt Human Specimens or Exempt Animal 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 (Refer to **Section XIII**). Refer to the Classification Flowchart (**Appendix B**) to assist with classification of biological materials.

**NOTE:** All specimens or packaging containing dry ice or liquid nitrogen must be shipped properly (Refer to **Section IX-Other Packaging Requirements**). All samples preserved with flammable or corrosive materials, such as ethanol or formalin, must be shipped appropriately.

#### 1. Shipping of 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. Some examples of Unregulated Biological Materials include:

- 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.

**NOTE:** When mailing these items with the USPS, follow packaging guidelines for non-regulated items. (Refer to **Section XIII**).

#### 2. Shipping of Category A Infectious Substances

**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.

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 C**.

### a. Packaging

The triple packaging concept (explained in **Section IX**) applies to Category A infectious substances. Purchase packaging compliant with IATA Packing Instruction 620 (Refer to **Appendix D**). 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;
- "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, including UN1845 and net weight, if packaged with dry ice; and
- Cargo Aircraft Label, when shipping over 50 mL or 50 g

Please refer to **Appendix D** for more information about labeling of Category A infectious substance.

#### 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 (Refer to **Appendix E**). 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;
- The text "Person responsible: (24/7 phone number); and
- Class 9 label, if packaged with dry ice.

#### 4. Exempt Human Specimens or Exempt Animal Specimens

According to 49CFR 173.134(b)(11), include any "human or animal sample (including, but not limited to, secreta, excreta, blood and its components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of non-infectious diseases, such as cancer biopsies, and for which there is a low probability the specimen is infectious." Human and animal cell lines that are not reasonably suspected to contain pathogens can be classified as exempt specimens. 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). Exempt Human Specimens or Exempt Animal Specimens 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 959. Packages designed for Packing Instruction 959 may not be available from most vendors. In this case, use packages compliant with Packing Instruction 620 (**Appendix D**). 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.

**NOTE:** Refer to the checklist in **Appendix F** to ensure that your package has been properly prepared. Check the box as you complete each step.

#### IX. 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 G** for vendors that can supply certified packaging for biological materials. When ordering, specify what type of material(s) you will be shipping (For example: Category A infectious substances, Category B infectious substances, only Dry Ice etc.). Different categories have slightly different packaging needs, but all follow the basic triple packaging requirements described below.

#### 1. 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 <u>primary container</u> 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.

**NOTE:** 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.

#### 2. Other Packaging Requirements

**a. 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."

- **b. 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 Office of Safety at 701.777.3341 if you need to ship materials with liquid nitrogen.
- **c. Formalin and Formaldehyde:** Title 49 CFR provides two entries for formaldehyde solutions in the Hazardous Materials Table Part 172.101:
  - Formaldehyde solutions, flammable, e.g. full strength formalin 37% (UN1198)
  - Formaldehyde solutions not less than 25% Formaldehyde (UN2209)
  - Formaldehyde solutions 10-24.9% (25% formalin) (UN3334), shipped by air

Shipments of 10-24.9% formaldehyde solutions shipped by highway only do not require classification as a hazardous material. 10% Formalin solutions containing 3-4% Formaldehyde and are not regulated for transport by air or highway.

#### d. Packaging specimens with preservatives:

- The inner receptacle must not exceed 30ml and the outer package must not exceed 500 ml. Liquids must not completely fill inner packaging at a temperature of 55°C (130°F)
- Closures of inner packaging must be held securely in place with tape, wire, or other positive means
- Intermediate packaging must contain enough absorbent to absorb all of the liquid
- The intermediate packaging must be securely packed in a strong rigid outer packaging

**NOTE:** See Appendix G for a list of some packaging suppliers.

#### X. PACKAGING DRY ICE

Dry ice is classified by DOT and IATA as a "miscellaneous" hazard, class 9. Dry ice is considered hazardous for three reasons:

- 1. Explosion hazard: Dry ice releases large volumes of carbon dioxide gas as it sublimates. If packaged in a container that does not allow for release of this gas, it can explode, causing personal injury and/or property damage.
- **2. Suffocation hazard:** A large volume of carbon dioxide gas emitted in a confined space can create an oxygen deficient atmosphere.
- 3. Contact hazard: Dry ice is a cryogenic material that causes severe frostbite upon contact with skin.

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. 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. Refer to the checklist in **Appendix H** to ensure that your package has been properly marked and labeled. Check the box as you complete each step. Note the only markings that is required for and Exempt specimen patient specimen package is the following: "Exempt Human Specimen" or "Exempt Animal Specimen" as appropriate.

**NOTE:** Reusing a dry ice shipping box is a good use of resources. If you choose to reuse a box, completely cover or obliterate all unnecessary marking such as hazard labels, addresses, old FedEx (or other courier) labels and/or barcodes. **Only reuse a box if you can personally verify it is not contaminated and its integrity is intact. A box should not be reused if it is torn, cut, stained, or if the insulation is cracked or broken.** 

#### XI. SHIPPERS 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 UN2900 or 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 Office of Safety at 701.777.3341 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.

Please refer to the checklist in **Appendix I** for filling a shipper's declaration (For Category A). An example of a shipper's declaration is given in **Appendix J**.

#### XII. CDC SELECT AGENTS

The U.S. Department of Health and Human Services has developed a list of biological agents (<a href="http://www.selectagents.gov/SelectAgentsandToxinsList.html">http://www.selectagents.gov/SelectAgentsandToxinsList.html</a>) 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 Institutional Biosafety Committee and the Centers for Disease Control and Prevention. Currently no work with select agents is carried out at UND. Specific shipping restrictions apply to these agents which are not discussed in this document.

#### XIII. 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 will not be mailed with the USPS. USPS will accept shipments of UN3373 and exempt patient specimens. Please check their website for more information (http://pe.usps.gov/text/dmm300/601.htm#wp1107780).

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

#### XIV. 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.

#### 1. APHIS Agricultural Permits

(https://www.aphis.usda.gov/wps/portal/aphis/resources/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

### 2. CDC Permit to Import or Transport Agents or Vectors of Human Disease

[http://www.cdc.gov/od/eaipp/importapplication/agents.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.

#### a. 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.

#### b. 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.

#### c. 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.

#### 3. FDA Import Permits

[http://www.fda.gov/ForIndustry/ImportProgram/]

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.

#### 4. U.S. Fish & Wildlife Service

http://www.fws.gov/permits/ 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

#### XV. 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:

- If necessary, obtain an export permit from the appropriate governmental organization prior to shipment.
- Package and label the material according to the guidelines listed in this manual.
- Include a courtesy letter with the shipment describing the contents in detail including information about whether the material is infectious.

**NOTE:** Please refer to **Appendix K** for more information regarding export controls on biological materials being sent out of the country

#### XVI. 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.
- Package and label the material according to the guidelines listed in this manual.
- 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.

#### XVII. EMERGENCY RESPONSE FOR AN INFECTIOUS SUBSTANCE IN TRANSPORT

The best advice to give in case of an emergency:

- 1. Stay upwind.
- 2. Keep unauthorized personnel away.
- 3. Do not allow anyone to touch or walk through spilled material.
- 4. Do not allow cleanup of the spill or disposal of the material except under the supervision of an expert.

NOTE: Please refer to Appendix L for examples of Biological Material shipments. Additionally, refer to Appendix M and N for a list of dangerous goods related to the transport of infectious substances.

#### APPENDIX A: INTENT TO SHIP BIOLOGICAL MATERIALS

After reading *Shipment of Biological Materials Manual* and *The Transport, Shipment and Receipt of hazardous Materials and Dangerous Goods Policy*, fill out this form to qualify to ship dangerous materials at UND. Office of Safety 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.

What regulated material(s) you are shipping via mail or courier that you intend to ship. Also, list the mailing service you intend to	9
What packaging will you use to ship your material(s)? Include co each material you intend to ship.	ompany name and product number for chosen packaging for
Cucil muccian y ou moona to sarp.	
Have you contacted UND Intellectual Property Commercializati	on & Economic Development for MTA related paperwork?
☐ Yes ☐ No (If not, please note this is a requirement. Contact [michael.p.sadler@research.und.edu] for more information)	UND's Legal & Marketing Assistant
Have you contacted UND Export Controls Office to satisfy export	rt control laws and regulations?
☐ Yes ☐ No ☐ N/A For International Shipping please fill the UND Export Control I	nternational Shipment Review Form
(https://und.edu/research/about/ files/docs/und export control Officer (john.miller@UND.edu)	shipment form.doc) and submit to UND's Export Control
Check those that should appear on your package:	APPROVALS
Class 6.2 label	Office of Safety
☐ Class 9 label ☐ UN3373 label	Signature:
Cargo Aircraft label	
Dry ice, UN1845, net weight_kg	UND Intellectual Property Commercialization &
Infectious substance, affecting humans, UN2814, net quantity	<b>Economic Development</b>
Infectious substance, affecting animals, UN2900, net quantity	Signature:
Name, Address and Phone Number of Shipper	
Name and Address of Consignee	<b>UND Export Controls Office</b>
Person Responsible: 24 hour telephone number  Overpack	Signature:
☐ "Exempt Human Specimen," or "Exempt Animal Specimen."	
Genetically modified microorganisms, UN3245, net quantity	
Diagnostic Specimens	
Other Dangerous Goods (List:	
	)
Fill out a Shipper's Declaration for Dangerous Goods (if your shipn	
ship must be included in the "Nature and Quantity of Dangerous Goo	
I understand the hazards associated with the materials noted above. A outlined in this manual.	Also, I understand the snipping requirements for those materials, as
Print name:En	nail·
	one #:

Please return, in campus mail or email, to Office of Safety: 3851 Campus Rd. Stop 9031 Grand Forks, ND 58202 Tel: 701.777.3341 Fax: 701.777.4132 Email: und.safety@email.und.edu

Signature: \_\_\_\_\_\_\_ Date: \_\_\_\_\_\_

### APPENDIX B: CLASSIFICATION FLOWCHART Submit for Classification Have any pathogens been neutralized / inactivated? Is it known not to contain infectious substances? Are all micro-organisms present non-pathogenic for humans/animals Yes to any Is it a dried blood spot/fecal occult blood? Is it an environmental sample, e.g. food and water that is not considered to pose a significant health risk? Is it for transplant / transfusion? No to All Does it meet the Yes definition of a Category A substance? No Is it a patient specimen for which there is only Yes a minimal likelihood that pathogens are present? UN 2814 Not subject to the infectious Subject to provisions of the substance, UN 3373 "Exempt Human **Dangerous Goods** affecting humans; **Biological** (or Animal) Regulations or UN 2900 substance Specimen" unless meeting the Infectious Category B provisions criteria of another substances, class or division affecting animals (as appropriate)

# APPENDIX C: INDICATIVE EXAMPLES OF CATEGORY A INFECTIOUS SUBSTANCES UN # AND PROPER SHIPPING NAME UN 2814

This table 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. In addition, if there is doubt as to whether or not a substance meets the criteria if must be included in Category A.

UN Number and Proper Shipping Name	Microorganism	
	Bacillus anthracis (cultures only)	
UN 2814	Brucella abortus (cultures only)	
Infectious substance	Brucellamelitensis (cultures only)	
affecting humans	Brucella suis (cultures only)	
arreeting numans	Burkholderia mallei-Psuedomonas mallei-Glanders (cultures only)	
	Burkholderia pseudomallei-Psuedomonas pseudomallei (cultures only)	
	Chlamydia psittaci-avian strains (cultures only)	
	Clostridiumbotulinum(culturesonly)	
	Coccidioides immitis (cultures only)	
	Coxiella burnetti (cultures only)	
	Crimean-Congo hemorrhagic fever virus	
	Dengue virus (cultures only)	
	Eastern equine encephalitis virus (cultures only)	
	Esherichia coli, verotoxigenic (cultures only)	
	Ebola virus	
	Flexal virus	
	Francisellatularensis(culturesonly)	
	Guanarito virus	
	Hantaan virus	
	Hantaviruses causing hemorrhagic fever with renal syndrome	
	Hendra virus	
	Hepatitis B virus (cultures only)	
	Herpes B virus ( cultures only)	
	Human immunodeficiency virus (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)	
	Rickettsiarickettsii(culturesonly)	
	Rift valley fever virus (cultures only)	
	Russian spring-summer encephalitis virus (cultures only)	
	Sabia virus	
	Shigella dysenteriae type 1 (cultures only)	
	Tick-borneencephalitisvirus(culturesonly)	
	Variola virus	
	Venezuelan equine encephalitis virus (cultures only)	
	West Nile virus (culture only)	
	Yellow fever virus (cultures only)	
	Yersinia pestis (cultures only)	
	1613mm/csms/cmmicsomy)	

UN Number and Proper	Microorganism						
Shipping Name							
	African swine fever virus (cultures only)						
UN 2900 Infectious substances	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (culturesonly)						
affecting animals	Classical swine fever virus (cultures only)						
	Foot and mouth disease virus (cultures only)						
	Lumpy skin disease virus (cultures only)						
	Mycoplasmamycoides-ContagiousContagious bovine pleuropneumonia (cultures only)						
	Peste 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)						

**Category B**: An infectious substance which does not meet the criteria for inclusion in Category A must be assigned to UN 3373.

# APPENDIX D: PACKAGING INSTRUCTION P620 (Guidance on regulations for the Transport of Infectious Substances 2015-2016)

Infectious substances in Category A and designated as UN 2814 or UN 2900 may only be transported in packaging that meets the United Nations class 6.2 specifications and complies with Packing Instruction P620, which is reproduced below. The various provisions mentioned are set out in the United Nations Model Regulations.

NOTE: Variations applying to air transport are highlighted in grey.

P620 PACKING INSTRUCTION P620

This instruction applies to UN 2814 and UN 2900.

The following packaging's are authorized provided the special packing provisions described below are met: Packaging's meeting the requirements of Chapter 6.3 and approved accordingly consisting of:

- (a) Inner packaging's comprising:
  - (i) leakproof primary receptacle(s);
  - (ii) a leakproof secondary packaging;
  - (iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;
- (b) A rigid outer packaging.

Drums (1A1, 1A2, 1B1, 1B2, 1N1, 1N2, 1H1, 1H2, 1D, 1G); Boxes (4A, 4B, 4N, 4C1, 4C2, 4D, 4F, 4G, 4H1, 4H2); Jerricans (3A1, 3A2, 3B1, 3B2, 3H1, 3H2).

The smallest external dimension shall be not less than 100 mm (4 in).

#### Additional requirements:

- 1. Inner packaging's containing infectious substances shall not be consolidated with inner packaging's containing unrelated types of goods. Complete packages may be overpacked in accordance with the provisions of 1.2.1 and 5.1.2; such an overpack may contain dry ice.
- 2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:
  - (a) Substances consigned at ambient temperatures or at a higher temperature. Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leakproof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;
  - (b) Substances consigned refrigerated or frozen. Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with 6.3.3. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or overpack shall be leakproof. If dry ice is used, the outer packaging or overpack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;
  - (c) Substances consigned in liquid nitrogen. Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;
  - (d) Lyophilized substances may also be transported in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

Continued on next page

- 3. Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C (-40 °F to +130 °F).
- 4. Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosive substances) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) may be packed in each primary receptacle containing infectious substances. These small quantities of dangerous goods of Classes 3, 8 or 9 are not subject to any additional requirements of these Regulations when packed in accordance with this packing instruction.
- 5. Alternative packaging's for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.

#### Special packing provisions

- 1. Shippers of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport.
- 2. An itemized list of contents shall be enclosed between the secondary packaging and the outer packaging, When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A, the words "suspected category A infectious substance" shall be shown, in parenthesis, following the proper shipping name on the document inside the outer packaging.
- Before an empty packaging is returned to the shipper, or sent elsewhere, it must be disinfected or sterilized to nullify any hazard and any label or marking indicating that it had contained an infectious substance must be removed or obliterated.

# APPENDIX E: PACKAGING INSTRUCTION P650 (Guidance on regulations for the Transport of Infectious Substances 2015-2016)

The text of United Nations Packing Instruction P650, in use for the transport of infectious substances in category B assigned to UN 3373 by all surface modes of transport is reproduced below. The shaded text on the right hand side indicates the ICAO variations to these instructions that apply to the transport by air. The various provisions mentioned are set out in the United Nations Model Regulations.

NOTE: Variations applying to air transport are displayed on a grey background.

P650 PACKING IN	ISTRUCTION P650
This packing instruction applies to UN 3373	on passenger and cargo aircraft, and cargo aircraft only (CAO).

- (1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between cargo transport units and between transport units and warehouses as well as any removal from a pallet or overpack for subsequent manual or mechanical handling. Packaging's shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.
- (2) The packaging shall consist of at least three components:
  - (a) a primary receptacle,
  - (b) a secondary packaging, and
  - (c) an outer packaging of which either the secondary or the outer packaging shall be rigid

The outer packaging must be rigid.

- (3) Primary receptacles shall be packed in secondary packaging's in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packaging's with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.
- (4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with each side having a length of at least 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high. The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.



- (5) At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.
- (6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in 6.3.5.2 of these Regulations at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

Continued on next page

#### (7) For liquid substances

(a) The primary receptacle(s) shall be leakproof;

and must not contain more than 1 litre;

- (b) The secondary packaging shall be leakproof;
- (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;
- (d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;
- (e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar).

in the range of -40  $^{\circ}$ C to +55  $^{\circ}$ C (-40  $^{\circ}$ F to +130  $^{\circ}$ F).

(f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

#### (8) For solid substances

(a) The primary receptacle(s) shall be siftproof;

and must not exceed the outer packaging mass limit;

- (b) The secondary packaging shall be siftproof;
- (c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.
  - (d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;
- (e) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during transport then a packaging suitable for liquids, including absorbent materials, shall be used.
- (9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen
  - (a) When dry ice or liquid nitrogen is used as a coolant, the requirements of 5.5.3 shall apply. When used, ice shall be placed outside the secondary packaging's or in the outer packaging or an overpack. Interior supports shall be provided to secure the secondary packaging's in the original position. If ice is used, the outside packaging or overpack shall be leakproof.
  - (b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost
- (10) When packages are placed in an overpack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the overpack.
- (11) Infectious substances assigned to UN 3373 which are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Regulations.

Infectious substances assigned to UN 3373 that are packed and marked in accordance with this packing instruction are not subject to any other requirement in these Instructions except for the following:

(a) the name and address of the shipper and the receiver (consignee) must be provided on each package;

Continued on nextpage

- (b) the name and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package;
- (c) classification must be in accordance with provision 2;6.3.2 of the ICAO Technical Instructions:
- (d) the incident reporting requirements in provision 7;4.4 of the ICAO Technical Instructions must be met (these refer to operators);
- (e) the inspection for damage or leakage requirements in provisions 7;3.1.3 and 7;3.1.4 of the ICAO Technical Instructions (these refer to operators);
- (f) passengers and crew members are prohibited from transporting infectious substances either as, or in, carry-on baggage or checked baggage or on their person.
- (12) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for transport.
- (13) Other dangerous goods shall not be packed in the same packaging as Division 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3 (flammable liquids), 8 (corrosives) or 9 (miscellaneous dangerous substances and articles, including environmentally hazardous substances) may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements in these Instructions need be met.

#### **Additional requirement:**

Alternative packaging's for the transport of animal material may be authorized by the competent authority in accordance with the provisions of 4.1.3.7.

APPENDIX F: PACKAGING CHECKLIST

Use this checklist to ensure that your package has been properly prepared. Check the box as you complete each step.

	Category A	Category B	Exempt Human/Animal Specimen
Good Quality Packaging			
Outer Packaging displays the UN Specification Mark 4G/Class 6.2/YYYY CCC/MFG		N/A	N/A
Manufacturer's Instructions read and followed			N/A
Primary receptacles sealed and watertight			
Multiple fragile primaries wrapped individually			
Sufficient absorbent inside each secondary			
Secondary packaging properly sealed and watertight			
Primary/secondary 95kPA pressure tested			N/A
Itemized list enclosed inside the package but outside the secondary			N/A
Rigid outer packaging			N/A
Check minimum dimensions	All dimensions at least 100 mm	Two sides at least 100 mm x 100 mm	

# APPENDIX G: 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

# APPENDIX H: MARKING AND LABELING CHECKLIST

Use this checklist to ensure that your package has been properly marked and labeled. Check the box as you complete each step. Note the only markings that is required for and Exempt specimen patient specimen package is the following: "Exempt Human Specimen" or "Exempt Animal Specimen" as appropriate.

	Category A	Category B	Dry Ice			
Hazard Label Affixed						
	AFECTOR INTERIOR	UN 3373	4			
Proper Shipping Name	Infectious substance,	Biological substance,	Dry Ice or Carbon			
	affecting humans or	category B	dioxide, solid			
	infectious substance,					
	affecting animals					
Technical Name		N/A	N/A			
	Note: Optional on the					
	package					
UN Identification Number	UN 2814 □	N/A (already in label)	UN 1845 🗌			
Weight/Quantity of		N/A				
Dangerous Good	(Optional in most cases)					
Name and phone number			N/A			
of a person responsible		Note: Optional if on air waybill				
Address of Shipper		Ď				
Address of consignee						

# APPENDIX I: SHIPPERS DECLARATION CHECKLIST (FOR CATEGORY A)

suc	At least three originals (shipper keeps a copy and at least two to the carrier who will deliver a copy to the consignee)		]
General Considerations	Any mistakes or changes: single line cross-out and full signature of certifier (individual signing the declaration)		]
Cons	Form matches IATA specifications (Size A4, red hatchings, information content, etc.)		
tion	Address of the consignor (must match information on the package) including names and telephone numbers.		
forma	Air waybill number (if known)	(option	 nal)
Transportation Information	Airport / city of departure ( if known )	(option	 nal)
sportati	Airport / city of destination (if Known)	(option	nal)
ran	Strike-out the non-applicable shipment type (radioactive)		
L	Strike-out the non-applicable aircraft limitation box		
Jo	UN number (include "UN")		
ity o	Proper shipping name ( no abbreviations, must appear exactly as from the list of dangerous goods )		
iture and Quantity Dangerous Goods	Technical name in parentheses after the PSN for Category A		
Qu us (	Class and Division (6.2 for infectious, 9 for dry ice)		
nd erou	Number and type of outer packaging ( 1 fiberboard box )		
re a mgo	Quantity (volume or weight, must match the information on package)		
atu De	Packing instruction (620, or 954 as applicable)		
Z	Authorization (special provisions, import permit numbers, exemptions, etc.)		
	Include the name and number of the person responsible for the shipment		
nal ng ion	(include the country and area code)	<del></del>	1
tion dlin nat	24-hour emergency response telephone number( if required, include the country and area code )		<u> </u>
Additional Nature and Quantity of Handling Dangerous Goods	Name and title of the certified individual signing the declaration		<u> </u>
A F	Place and date of signature		<u> </u>
	Signature ( may be electronic, printed or stamped )		

# APPENDIX J: EXAMPLE OF SHIPPERS DECLARATION FOR DANGEROUS GOODS

# (Sections marked in $\underline{red}$ need to be filled)

SHIPPER'S	DECLARATION FOR DANGEROUS GOODS						
3 P	Or. Emily Williams University of Pennsylvania 160 Chestnut St. hiladelphia, Pa. 19104 15-746-0987				Air Waybill No.  Page 1 of P Shipper's Reference Nu (optional)	Pages imber	
Consignee	Dr. Eli Watts University of California 3456 Heaven Street San Francisco, Calif. 30987						
	onsible for Shipment: Dr. Eli Watts 435-098-4657			+			
Pour cor	npleted and signed copies of this Declaration m	iust be nanded to tr	ie operator.	_	WARNING		
This ship (delete non	present DETAILS  ment is within the limitations prescribed for:  -applicable)  NGER CARGO CARGO ONLY  ONLY  C	Airport of Depar Philadelphia	ture		Failure to comply in al applicable Dangerous may be in breach of the ject to legal penalties.	Goods R	egulations
Airport o	of Destination Disco		d		Shipment Type (delete non-app NON-RADIOACTIVE	telicable)	X
NATURE	AND QUANTITY OF DANGEROUS GOODS						
	Dangerous Goods Identifica	tion					
UN or ID No.	Proper Shipping Name		Class or Division (Subsidiary Risk)		Quantity and Type of Packing	Packing Instruc- tions	Authorizatio
UN2814 <b>e</b>	Infectious substance, affecting humans (Mycobacterium tuberculosis)		6.2		30 ml	620	
E	f		g	h	1	j	k
UN1845	Dry Ice		9	ш	5 kg (all packed in one fibreboard box)	954	
Additiona	l Handling Information	L		l	<u> </u>		
	I Chan Tark 1 200 A	24.0200					
I hereby d described marked ar transport	y Telephone Number Chem Trek 1-800-4 eclare that the contents of this consignment are above by the proper shipping name, and are of d labelled/placarded, and are in all respects in according to the applicable international and na s. I declare that all of the applicable air transpor	fully and accurately classified, packaged proper condition fo tional governmenta	Place ar	nd Date	ignatory Dr. Emily Willia University of Pennsylvar		<b>m</b> 1, 2011

# APPENDIX K: EXPORT CONTROLS ON BIOLOGICAL MATERIALS BEING SENT OUT OF THE COUNTRY

#### **International Shipping**

UND's international shipping must comply with export and import control laws and regulations. The laws and regulations may require UND to obtain an export license for shipments of items, software and technology outside of the U.S. The Office of Research Development & Compliance is charged with determining whether an export license is required for the shipment of items, software, technology, and information outside of the United States. All UND personnel who engage in international shipping are responsible for ensuring compliance with U.S. export control laws and regulations. Shipping without obtaining the appropriate license or other government approval, or failing to file accurate export or shipping documentation, may result in the confiscation of the shipped items, fines and/or jail time.

The Export Control Officer will assist you in evaluating if the export is in compliance with export control laws and regulations, and if the export and shipping documentation has been correctly prepared and filed. For items not export controlled, review and clearance to ship may take only a few minutes. For an export controlled item needing a license, it may take 30-90 days to obtain approval from the government. Federal regulations require UND to keep records of shipments for five years after the date of the shipment.

Personnel involved with shipping also need to recognize that the destination country for the shipment may have restrictions on what can be imported.

#### **Biological Materials**

Risk management protocols, (e.g., Institutional Biosafety Manual) also require that the transfer of biological materials by UND to another person strictly adhere to UND's protocols. In certain cases, such materials may also be export controlled under the EAR and in rare cases under the ITAR. As such, individuals planning to export biological materials shall work directly with the ECO to determine whether export control requirements are being met, and what if any special arrangements (including export licensing, destination control statements, end user agreements, and authorization from other government agencies regulating biological materials) shall be affected pursuant to such transfers.

#### **Exports**

Shipping anything to a destination outside the U.S. is an export regardless of whether the item is sold, used for research, loaned, donated or only outside of the U.S. temporarily. Most items, including certain software and information, are subject to some facet of export controls.

UND is the shipper of record regardless of who prepares the forms (FedEx, UPS, DHL or the customs broker). The freight forwarder cannot be relied on for UND's export control compliance. The freight forwarder relies on the information provided to them by UND.

#### **Export Checklist**

All items to be exported must be reviewed prior to shipment to determine the need for a license or other government approval. The review includes determining:

- The item(s) export control classification or category;
- If the shipment is to an embargoed or sanctioned country;
- If the shipment to the destination country requires a license:
- The end-user; and
- If the end-use is prohibited.

This review must occur whether the item to be shipped is processed through Campus Postal Services or is done individually by the College, School, Division or Department. To assist with evaluating the export control concerns, please prepare the <a href="UND Export Control International Shipment Review Form">UND Export Control International Shipment Review Form</a> and send to the Export Control Officer for review prior to shipping any item.

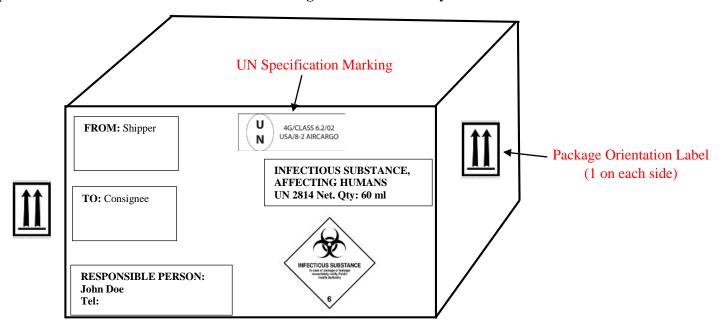
For information on export control matters, as well as contacts for additional information/guidance, please review the website of the Office of Research Services at <a href="https://und.edu/research/resources/export-controls.cfm">https://und.edu/research/resources/export-controls.cfm</a> or contact

John Jay Miller Export Control Officer University of North Dakota Twamley Hall Room 105 264 Centennial Drive Stop 7134 Grand Forks, ND 58202-7134

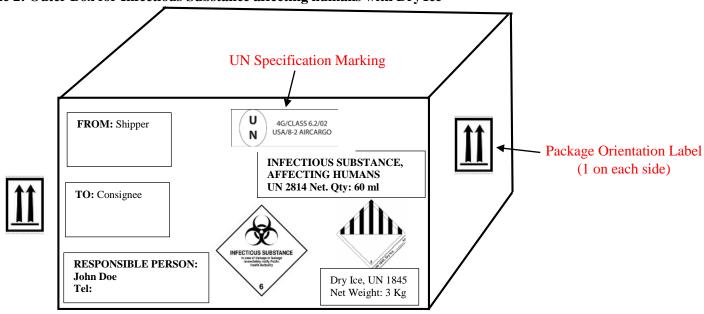
Tel: 701.777.2049 Fax: 701.777.6708 john.miller@UND.

#### APPENDIX L: EXAMPLES OF SHIPMENTS

Example 1: Outer Box for Infectious Substance affecting humans without Dry Ice

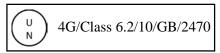


**Example 2: Outer Box for Infectious Substance affecting humans with Dry Ice** 



**NOTE:** According to Section 7.2.4.4 of the IATA Dangerous Goods Regulations (DGR), orientation labels or packages with pre-printed orientation labels are required on combination packages and overpacks containing liquid dangerous goods. The labels must be visible on at least two opposite sides to show the proper package orientation so that the closures will be in an upright position. The orientation arrows are not required on single packages or on packages or overpacks containing solid dangerous goods. The orientation label is not necessary for flammable liquids in inner packaging's of 120 milliliters or less, infectious substances in primary receptacles of 50 milliliters or less, or radioactive materials.

#### **UN Specification Marking**

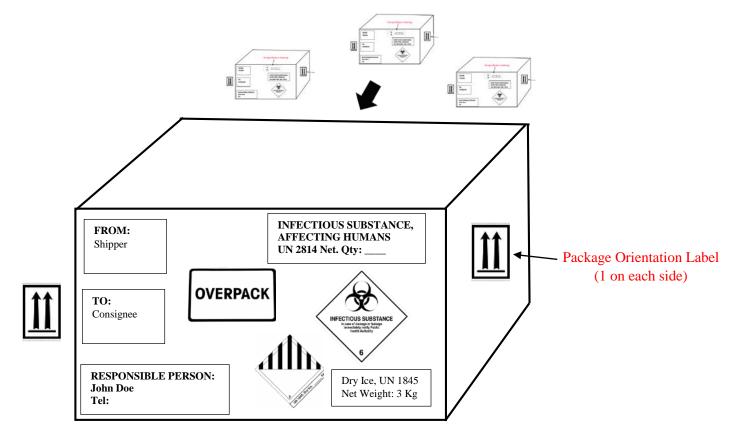


#### This marking comprises:

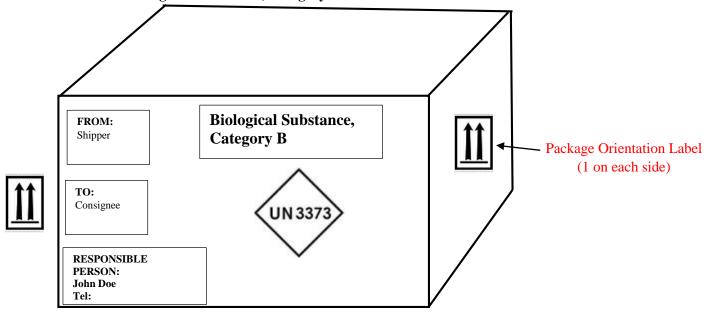
- The United Nations packaging symbol
- An indication of the type of packaging (in this example a fiberboard box (4G))
- An indication that the packaging has been specially tested to ensure that it meets the requirements for Category A infectious substances (Class 6.2)
- The last two digits of the year of manufacture (in this example 2010)
- The competent state authority that has authorized the allocation of the mark (in this example GB, signifying Great Britain)
- The manufacturer's code specified by the competent authority (in this example 2470)

#### **Example 3: OVERPACK SHIPMENT**

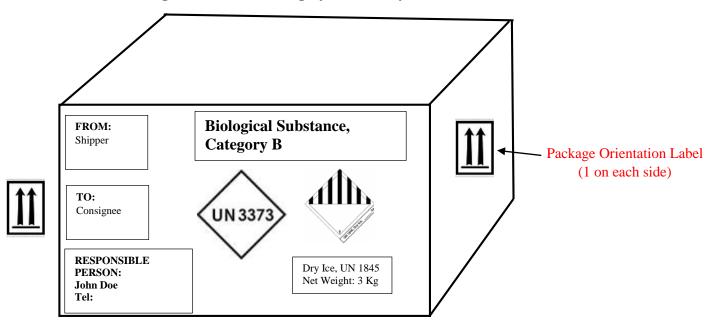
- Large boxes that contain several correct package specification inner boxes
- Allows you to send several vials of 50 ml or 50 mg



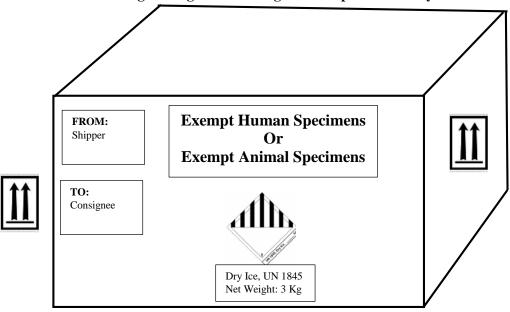
Example 4: Outer Box for "Biological Substances, Category B"



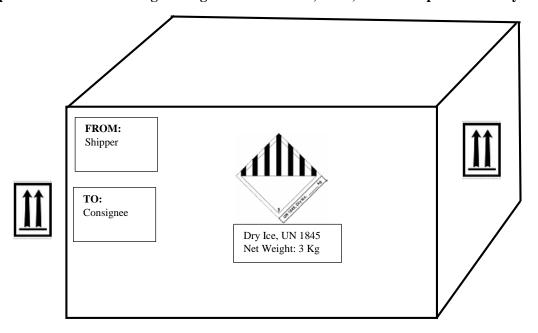
Example 5: Outer Box for "Biological substances, Category B" with Dry Ice



Example 6: Label and Marking Packages for non-regulated shipments on Dry Ice



Example 7: Label and Marking Packages for Antibodies, RNA, Protein shipments on Dry Ice



# APPENDIX M: LIST OF DANGEROUS GOODS RELATED TO THE TRANSPORT OF INFECTIOUS SUBSTANCES

								1	Passenger and c	argo airo	raft	Cargo	aircraft only
								Limite	d quantity				
Proper Shipping Name	UN No.	Class or Div	Sub Risk	Hazard Labels	State Var	SP	UN Pkg Grp	Pkg Inst	Max net Qty/ Pkg	Pkg Inst	Max net Qty/ Pkg	Pkg Inst	Max net Qty/ Pkg
1	2	3	4	5	6	7	8	9	10	11	12	13	14
Aviation regulated liquid, n.o.s.	3334	9		Misc.		A27		Y964	30 kg G	964	450 L	964	450 L
Biological substance, Category B	3373	6.2		None	GB 5					5	see 650	5	see 650
(Bio) medical waste	3291	6.2		Inf.		A117	II			622	No limit	622	No limit
Carbon dioxide, solid Dry ice	1845	9		Misc.		A48 A151				954	200 kg	954	200 kg
Clinical waste, unspecified, n.o.s.	3291	6.2		Inf.		A117	II			622	No limit	622	No limit
Ethanol Ethanol solution	1170	2		Flamm		A3 A58	II	Y341	1 litre	353	5 litres	364	60 litres
Ethyl alcohol Ethyl alcohol solution	1170	3		Liq		A180	III	Y344	10 litres	355	60 litres	366	220 litres
Formaldehyde solution, with not less than 25% formaldehyde	2209	8		Corrsv	US 4		III	Y841	1 litre	852	5 litres	856	60 litres
Formaldehyde solution, flammable	1198	3	8	Flam m Liq &		A180	III	Y342	1 litre	354	5 litres	365	60 litres
Genetically modified micro- organisms Genetically modified organisms	3245	9		Misc.		A47				959	No limit	959	No limit
Infectious substance, affecting animals only	2900	6.2		Inf.	AU 3; CA 8; VU 2	A81 A140				620	50 ml or 50 g	620	4 litres ro 4 kg
Infectious substance, affecting humans	2814	6.2		Inf.	AU 3; CA 8; VU 2	A81 A140				620	50 ml or 50 g	620	4 litres or 4 kg
Medical waste, n.o.s.	3291	6.2		Inf.		A117	II			622	No limit	622	No limit
Methanol	1230	3	6.1	Flamm liquid		A104 A113	II	Y341	1 litre	352	1 litre	364	60 litres
Nitrogen, refrigerated liquid	1977	2.2		Non- flamm gas		A152				202	50 kg	202	500 kg
Regulated medical waste, n.o.s.	3291	6.2		Inf.		A117	II			622	No limit	622	No limit

#### APPENDIX N: SPECIAL PROVISIONS (SP) APPLICABLE TO CERTAIN SUBSTANCES

The following Special Provisions are listed according to ICAO (UN):

- A3 (223) If the chemical or physical properties of a substance covered by this description are such that, when tested, it does not meet the established defining criteria for the class or division listed in column 3, or any other class or division, it is not subject to Dangerous Goods Regulations.
- A27 (276) This includes any substance which is not covered by any of the other classes but which has narcotic, noxious or other properties such that, in the event of spillage or leakage on an aircraft, extreme annoyance or discomfort could be caused to crew members so as to prevent the correct performance of assigned duties.
- A47 (219) Genetically modified micro-organisms (GMMOs) and genetically modified organisms (GMOs) packed and marked in accordance with Packing Instruction 959 are not subject to any other requirements in the Dangerous Goods Regulations.

If GMMOs and GMOs meet the definition in 2.6 of a toxic substance or an infections substance and meet the criteria for inclusion in Division 6.1 or 6.2, the requirements in the Dangerous Goods Regulations for transporting toxic substances or infectious substances apply.

- A48 Packaging tests are not considered necessary.
- A58 (144) An aqueous solution containing not more than 24% alcohol by volume is not subject to Dangerous Goods Regulations.
- A81 The quantity limits shown in columns 12 and 14 do not apply to body parts, organs or whole bodies.
- A104 A toxic subsidiary risk label, although not required by Dangerous Goods Regulations, may be applied.
- A113 (279) The substance is assigned to this classification or packing group based on human experience rather than the strict application of classification criteria set out in the Dangerous Goods Regulations.
- A117: Wastes transported under UN 3291 are wastes derived from the medical treatment of humans or animals or from bio-research, where there is a relatively low probability that infectious substances are present. Waste infectious substances which can be specified must be assigned to UN 2814 or UN 2900. Decontaminated wastes which previously contained infectious substances may be considered as not subject to Dangerous Goods Regulations unless the criteria of another class or division are met.
- A140 (318) For the purposes of documentation, the proper shipping name must be supplemented with the technical name. Technical names need not be shown on the package. When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in category A and assignment to UN 2814 or UN 2900, the words "suspected category A infectious substance" must be shown, in parenthesis, following the proper shipping name on the transport document, but not on the outer packagings.
- When dry ice is used as a refrigerant for other than dangerous goods loaded in a unit load device or other type of pallet, the quantity limits per package shown in columns 12 and 14 of the table in Annex 5 for dry ice do not apply. In such case, the unit load device or other type of pallet must be identified to the operator and must allow the venting of the carbon dioxide gas to prevent a dangerous build-up of pressure.
- A152 Insulated packagings conforming to the requirements of Packing Instruction 202 containing refrigerated liquid nitrogen fully absorbed in a porous material are not subject to Dangerous Goods Regulations provided the design of the insulated packaging would not allow the build-up of pressure within the container and would not permit the release of any refrigerated liquid nitrogen irrespective of the orientation of the insulated packaging and any outer packaging or overpack used is closed in a way that will not allow the build-up of pressure within that packaging or overpack. When used to contain substances not subject to Dangerous Goods Regulations, the words "Not Restricted" and the special provision number A152 must be provided on the air waybill when an air waybill is issued.
- A180 Non-infectious specimens, such as specimens of mammals, birds, amphibians, reptiles, fish, insects and

other invertebrates containing small quantities of UN 1170 (Ethanol), UN 1198 (Formaldehyde solution, flammable), UN 1987 (Alcohols, n.o.s.) or UN 1219 (Isopropanol) are not subject to Dangerous Goods Regulations provided the following packing and marking requirements are met:

- a) specimens are:
  - 1. wrapped in paper towel and/or cheesecloth moistened with alcohol or an alcohol solution and then placed in a plastic bag that is heat-sealed. Any free liquid in the bag must not exceed 30 ml; or
  - 2. placed in vials or other rigid containers with no more than 30 ml of alcohol or an alcohol solution;
- b) the prepared specimens are then placed in a plastic bag that is then heat-sealed;
- c) the bagged specimens are then placed inside another plastic bag with absorbent material then heatsealed;
- d) the finished bag is then placed in a strong outer packaging with suitable cushioning material;
- e) the total quantity of flammable liquid per outer packaging must not exceed 1 litre; and
- f) the completed package is marked "scientific research specimens, not restricted. Special Provision A180 applies".

The words "not restricted" and the special provision number A180 must be provided on the air waybill when an air waybill is issued.

### APPENDIX O: IMPORTANT CONTACT INFORMATION

# FOR BIOLOGICAL MATERIAL SHIPPING

Office of Safety 701.777.3341 Biological Safety Officer 701.777.2444

# **FOR EXPORT CONTROLS**

Export Control Officer 701.777.2049

# FOR MATERIAL TRANSFER AGREEMENT

Legal and Marketing Assistant 701.777.6772

(Intellectual property Commercialization & Economic Development)