

Title: NYU Shipping Biological Material and Dry Ice Written Program

Effective Date: March 2010

Revision Date: April 12, 2017

Issuing Authority: VP, Facilities and Construction Responsible

Officer: Director, Environmental Health and Safety

## **PURPOSE OF THE WRITTEN PROGRAM**

The purpose of this Procedure is to establish a framework to enable all University personnel who offer for transit the subset of Dangerous Goods referred to as 'Biological Materials' and dry ice, to do so in a manner that is compliant with existing regulations designed to protect humans, animals and the environment.

## **SCOPE OF THIS WRITTEN PROGRAM**

To ensure that the shipment of all Biological Materials and dry ice originating from the University is done in a manner that minimizes or eliminates the release of these materials.

## **WHO NEEDS TO KNOW THIS WRITTEN PROGRAM**

All University personnel who classify, identify, pack, mark, label or document Biological Materials or dry ice for shipping purposes.

## **PROCEDURES FOR IMPLEMENTATION**

### **Responsibilities:**

New York University strives for excellence in its Environmental Health and Safety (EHS) program. For this written document compliance is achieved through the following structure:

### **Department of Environmental Health and Safety**

1. Providing technical training, regulatory information, and quality assurance/quality control to research staff on biological material/dry ice shipments at NYU facilities.
2. Maintaining training records for a minimum of three years and working with laboratory and departmental representatives to coordinate training sessions for faculty and staff.
3. Auditing shipping manifests and airway bills for completion and adherence to regulations.

### **University Faculty and Staff**

1. Reading and understand this written program and the [NYU Biosafety Manual](#).

2. Attending the necessary Biological Materials and Dry Ice Shipment training.
3. **Those who do** not take the training are prohibited from shipping biological materials.
4. Maintaining all shipping manifests and airway bills.
5. Ensuring activities at NYU are in compliance with all applicable government, University, and department policies and regulations.

### Shipper

1. Classifying, identify, pack, mark, label and document shipments for transport by air or ground.
2. Making arrangements with the consignee and the courier.
3. Furthering, any special arrangements such as import/export permits and Material Transfer Agreements (MTA).
4. Confirming that the consignee has obtained all necessary import permits as well as checking with the consignee whether he/she received all packages.

### Consignee

1. Obtaining any import permits if necessary based on federal regulations.
2. Inspecting the package and enclosed documents and inform the shipper that the consignment has arrived.
3. Reporting any leakage to the shipper as well as contact the 24 hour emergency telephone number written on the shipment manifest (if applicable).

### Office of Industrial Liaison (OIL)

1. Assisting research by facilitating a Material Transfer Agreement.

## WRITTEN PROGRAM DEFINITIONS

**Biological Product-** Products derived from living organisms, that are manufactured and distributed in accordance with the requirements of national governmental authorities which may have special licensing requirements, and are used either for prevention, treatment or diagnosis of disease in human or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines and diagnostic products. Biological products transported for final packaging, distribution, or uses by medical professionals are not subject to shipping regulations. Biological products that do not meet these requirements must be assigned to Category A or Category B as appropriate.

**Carrier-** Person or entity engaged in the transportation of passengers or property via air, land, or water using a common, contracted, private or civil vessel.

**Consignee-** Recipient of shipped package.

**Consignment** -The "good" or package that is shipped.

**Culture-** The purposeful amplification of microorganisms (e.g., through growth on a slant or in liquid media) or the product of such an amplification process, or the product of this amplification process.

**Dangerous Goods-** Substances or materials which are capable of posing a risk to health, safety, property or the environment and as such are regulated by either US or International authorities when transported in commerce. For purposes of this Policy Dangerous Goods and Hazardous Materials have the same meaning.

**Department of Transportation (DOT)** - The United States Government entity responsible for establishing and enforcing shipping regulations within the United States.

**IATA-** International Air Transport Association, a trade group of the world's airlines. Their annual publication, *Dangerous Goods Regulations*, define the minimum requirements for shippers and carriers of Dangerous Goods.

**Prion-** A disease-causing agent that is not considered to be bacterial, fungal, or viral, and contains no genetic material. A prion is a protein that occurs normally in a harmless form within the brain. By folding into an aberrant shape, the normal prion becomes a transmissible infectious agent that is able to co-opt and induce abnormal folding of other normal cellular prion proteins in the brain, leading to brain damage. It is implicated in a number of diseases in a variety of mammals including [bovine spongiform encephalopathy](#) (BSE, also known as "mad cow disease") in [cattle](#) and [Creutzfeldt-Jakob disease](#) (CJD) in humans. Prion diseases are usually rapidly progressive and always fatal.

**Proper Shipping Name (PSN)**- Names assigned to Dangerous Goods that must be used, exactly as written, when shipping a package. These names can be found in the IATA List of Dangerous Goods (IATA 4.2), ICAO 3.2.1 and 49CFR 172.101. The UN Number from the list of Dangerous Goods always precedes the *PSN*. This four digit number is assigned by UNCOE to identify a substance or group of substances. The prefix UN must always be used in conjunction with the numbers.

**Research Staff**- Principal Investigators, Post-doctoral Fellows, Graduate students, research scientists, research coordinators, laboratory directors, managers, technicians, and veterinary staff.

**Regulated Medical Waste**- Regulated Medical Waste (RMW) refers to material regulated under federal, state and/or local regulations. It is waste which is generated in the diagnosis, treatment or immunization of human beings or animals, in research pertaining thereto, or in production and testing of biologicals. This includes but is not limited to, agents that are infectious to humans and associated biologicals (serums, vaccines, antigens, and antitoxins), cultures and stocks, pathological waste (tissue, organs, body fluids and anatomical parts (animal or human)), human blood and blood products (includes items that are saturated with blood), and gloves used in the handling of such waste. Shipments of RMW are assigned a *PSN* "Regulated medical waste" and UN3291.

**Shipper**- New York University faculty, staff, or administration, who have any involvement in the process of shipping Biological Material or Dry Ice.

**United Nations Committee of Experts on the Transport of Dangerous Goods (UNCOE)** - Governing body responsible for developing rules and regulations regarding the air transport of Dangerous Goods.

# UNIVERSITY WRITTEN PROGRAM

## TRAINING

NYU, in accordance with international and Federal regulations, requires that anyone in any aspect of shipping biological materials or dry ice must first be trained; refresher training is required every **two years**. Due to the severity of fines and legal action from improperly labeled shipments, there are no exceptions to this. Training is provided by EHS. Research staff that plan to ship Biological Materials and/or packages containing Dry Ice, must be trained by EHS in the following areas:

- a. General Awareness training: provides familiarity with the requirements and allows employees to classify and identify hazardous materials (dangerous goods) for shipping.
- b. Labeling and packaging shipments according to IATA and DOT regulations.
- c. Safety, which includes emergency response, proper handling procedures, and documentation procedures.
- d. Security, which describes the procedures to ensure that shipments from theft, or diversion and that only trained, qualified people come into contact with the package.
- e. Enhanced Security which is applicable to shipments that pose an elevated hazard or security threat due to accidental or intentional release. (NYU does not ship materials meeting this requirement.)

If it is critical to ship a biological material or dry ice in a condensed time frame which does not allow for standard training, Researchers must contact EHS, who will provide assistance and ensure all appropriate procedures are followed.

## SHIPPING CLASSIFICATIONS

### Infectious Substances

Infectious Substances are known or reasonably expected to contain pathogens. Pathogens are defined as micro-organisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals. There are two categories of infectious substances.

- a. Category A, Infectious Substances: 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 resulting from release of the substance from its package. If the substance has the potential to cause disease in both humans and animals, it must be labeled with its Proper Shipping Name (PSN) preceded by the correct UN number assigned by UNCOE (United Nations Committee of Experts on the Transport of Dangerous Goods). The PSN for a Category A Infectious Substance affecting humans and animals is "Infectious substance, affecting humans" and the associated number is UN2814. If it only

has the potential to only cause disease in animals, it must be labeled with PSN “Infectious substance, affecting animals only” and preceded by “UN2900”. When shipping a Category A substance, a Technical Name is also required in parenthesis directly after the PSN. This Technical Name must be a recognized name used in scientific journals and books. See Appendix 1 for examples.

- b. Category B, Infectious Substances: An infectious substance not in a form generally capable of causing permanent disability or life threatening, or fatal disease in otherwise healthy humans or animals, when exposure to it occurs. They are assigned to *PSN* “Biological substance, category B” and UN3373.

### **Genetically Modified Organisms and Microorganisms (GMO, GMMO)**

Organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMO’s and GMMO’s are assigned a *PSN* “Genetically modified micro-organisms” and UN3245.

### **Dry Ice**

DOT and IATA classify Dry Ice as a “miscellaneous” hazard, class 9. Dry Ice is considered a hazardous material during transportation for three reasons:

- a. Explosion hazard: Dry Ice releases a large volume of carbon dioxide gas as it sublimates. If packaged in a container that does not allow for release of the gas, it may explode, causing personal injury or property damage.
- b. Suffocation hazard: A large volume of carbon dioxide gas emitted in a confined space may create an oxygen deficient atmosphere.
- c. Contact hazard: Dry Ice is a cryogenic material that causes severe frostbite upon contact with skin.

### **Exempt Patient Specimen**

Patient specimens are those 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. Patient specimens for whom there is minimal likelihood of pathogens present are not subject to regulation if the specimen is packed in leak-proof packaging which is marked with the words “Exempt human specimen” or “Exempt animal specimen”. Exempt Patient Specimens are not assigned a Proper shipping name or UN number, as they are not found on the List of Dangerous Goods. Consequently, they are not assigned specific packing instructions.

### **Exempt Quantities**

Excepted Quantities of dangerous goods are small amounts of certain dangerous goods that are permitted relaxed packaging and labeling requirements when used as a preservative or stabilizer. Amounts of 30 ml or less per primary receptacle of flammable liquids (Class 3), corrosives (Class 8), or miscellaneous dangerous goods (Class 9) may be classified as excepted quantities. Common

preservatives used for this purpose include ethanol, formaldehyde  $\geq 4\%$ , and acetic acid

Chemical preservatives used in excepted quantities (<30mL per primary container) to ship Category A or Category B are exempt from labeling requirements. If used as a preservative for any material that cannot be classified as Category A, Category B or GMO, these are subject to the requirements of their respective hazard class.

### **Non-regulated Biological Material**

Non-regulated materials are exempt from dangerous goods shipping regulations if not combined with any additional hazardous material that is subject to regulation such as, Category A or Category B materials, patient specimens, or genetically modified organisms or microorganisms. Biological materials that are exempted from Dangerous Goods Regulations listed are:

- a. Dried blood spots collected by applying a drop of blood to absorbent material, or fecal occult blood screening samples
- b. Environmental samples (including food and water) that do not pose a significant infection risk Substances containing microorganisms (not including GMMO) that are non-pathogenic to humans or animals (e.g. E. coli K12)
- c. Blood or blood components collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation
- d. Any tissues or organs intended for use in transplantation
- e. Substances in a preserved, neutralized, or inactivated state such that any pathogens no longer pose a risk of infection
- f. Purified nucleic acid or protein, antibodies
- g. Biological products derived from living organisms which are used for the prevention, treatment, or diagnosis of disease in humans or animals and that have received approval from the FDA (e.g., vaccines) These materials must be packaged in accordance with their approval

## **SHIPPING AND PACKAGING PROCEDURES**

Consult with EHS to determine specific requirements for your materials. Biosafety will assist in determining what permits may be required, proper hazard classification, and packaging requirements for the material. All packages and labels must adhere to applicable requirements of the Interstate Shipment of Etiologic Agents (42 CFR Part 72 and DOT/IATA requirements) and be performed by a trained shipper. Typical hazard classes associated with the shipment of biologicals materials is as followed:

1. UN 2814, Infectious Substances, Affecting Humans
2. UN 2900, Infectious Substances, Affecting Animals
3. UN 3373, Biological Substance, Category B
4. UN 1845, Carbon Dioxide, Solid
5. UN 3245, Genetically Modified Organisms or Genetically Modified Microorganisms

Biological materials must be packaged according to the triple packaging principle (see Appendix 2) with slight variations depending on the shipping classification. The three elements of triple packaging include: primary receptacle, leak-proof secondary container, and durable outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100mm x 100mm (4' x 4'). For liquids, absorbent material must be placed between the primary receptacle(s) and secondary container to contain released liquids. Multiple fragile primary receptacle(s) must be individually wrapped or separated to prevent contact. Enclose a list of contents between the secondary and outer packaging.

### **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."

### **Packaging Dry Ice**

When shipping packages containing dry ice there are five basic requirements for all shipments of dry ice:

- a. Gas venting: packages must allow for release of carbon dioxide gas. Dry ice must never be sealed in a container with an airtight seal such as a jar with a threaded lid or a plastic cooler. When transporting in a vehicle, the box should not be placed inside the passenger compartment to prevent carbon dioxide accumulation within the vehicle.
- b. Package integrity: a package containing dry ice must be of adequate strength for intended use. It must be strong enough to withstand the loading and unloading normally encountered in transport. It must also be constructed and closed in order to prevent any loss of contents that might be caused by vibration or by changes in temperature, humidity, or altitude.
- c. Package materials: do not use plastics that can be rendered brittle or permeable by the temperature of dry ice. This problem can be avoided by using commercially available packages intended to contain dry ice.
- d. Waybill: the waybill (also referred to as the airbill) must include the statement "Dry ice, 9, UN1845, [number of packages] X [net weight in kilograms]."
- e. Labeling: the outermost container must be labeled with a hazard class 9 label, UN1845 and net weight of dry ice in kilograms.

When shipping biological materials with your dry ice, you must comply with the requirements of both shipping of biological materials and dry ice. The following must be done:

- a. Dry ice must be placed outside the secondary packaging.
- b. Secure your samples in such a way that when the dry ice sublimates, they will not move freely inside the insulated box. This can be accomplished by wedging your samples in



place with cardboard or Styrofoam. Fragile containers such as glass tubes or vials should be wrapped in cushioning material.

All packaging or opening of primary containers containing potentially infectious materials will be performed in a biological safety cabinet located in a BSL-2 laboratory space depending on the material. Further information on shipping and packaging of biological materials can be found in the [NYU Biosafety Manual](#) and on the [Biosafety Shipping webpage](#). See Appendix 3, for a list of manufacturers of certified shipping containers for infectious substances, patient specimens & dry ice.

### **Marking and Labeling**

All hazard labels must be durable and either self-adhesive or directly printed onto the outer package. Self-printed labels attached with clear tape are not acceptable. The label must be at least 2" x 2" in size. Letters and numbers must be at least 6 mm tall and the diamond lines must be at least 2 mm thick. When more than one hazard diamond or UN identification number label is used on the same package (e.g. UN3373, UN1845 etc.), both labels must be on the same side of the box. Labels must not be bent around edges or corners of boxes. Markings and labeling must not touch or overlap one another. Labels displaying the hazard class or UN identification number must meet specified dimensions and remain unmarked and unobscured. These must be oriented "on point," upright and in diamond orientation.

The international biohazard symbol may be on the primary or secondary container if the shipment consists of human blood/body fluids, but hazmat package exteriors should not be labeled with the biohazard symbol. This is not a recognized hazmat shipping label and its similarity to a Category A infectious material symbol may only serve to confuse the carrier and lead to return of packages that do not meet other Category A requirements. See Appendix 4, for examples of shipping labels.

### **FEDERAL PERMITS FOR TRANSFER AND USE**

Many biological materials require federal permits for the transport and use of those agents. These permits are required for a wide range of activities, which state many of the stipulations required to maintain approval. Faculty who conduct research with biological materials that require federal permits must notify and send a copy of the permit(s) to Biosafety. More information on federal agencies issuing permits can be found in the [NYU Biosafety Manual](#) and on [the Biosafety Shipping website](#).

### **SHIPPERS DECLARATION OF 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.

Additionally all shippers must complete a [Hazardous Materials Declaration](#), found on the Mail Services website. When shipments require a Declaration, EHS must be contacted to ensure that training requirements have been fulfilled and that all other aspects of the shipping process are compliant.

## **COMMERCIAL VENDORS FOR SHIPPING DANGEROUS GOODS**

The courier NYU uses for shipping biological materials and dry ice is UPS. UPS will not accept shipments in Category A. UPS will accept shipments of UN3373 and exempt patient specimens. Those that would like to transport Category A materials will have to make other arrangements with a different carrier service.

## **RECORDKEEPING**

Shippers are required to retain all documentation related to shipping of dangerous goods (e.g. commercial invoices, UPS waybills, applicable import/export permits) for a minimum of two years. Training certificates must be maintained for a minimum of three years. Improperly shipped packages can elicit an FAA inspection of the shipper's university. As such, all shipping records may be reviewed during laboratory assessments.

## **RELEVANT RESOURCES**

Shipping of regulated biological materials and dry ice must comply with the U.S. Department of Transportation (DOT), [CFR 49 Part 171-180](#), and the International Air Transport Associations (IATA) [Dangerous Goods Regulations](#). Individual who fail to comply with the regulations may have their shipments refused by airlines or other carriers. They are also at risk for the fines and/or jail terms described below.

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

## **APPENDICES**

1. Examples of Category A Infectious Substances
2. Triple Packaging
3. Manufacturers of Certified Shipping Containers for Infectious Substances, Patient Specimens & Dry Ice
4. Examples of Shipping Labels

## APPENDIX 1

### Examples of Category A Infectious Substances

Examples given are not all-inclusive, and are merely indicative of the criteria used to classify a material. Any infectious substances that meet these criteria including new or emerging pathogens, must be included in Category A for the purposes of transportation.

#### **Infectious Substances, Affecting Humans, UN2814**

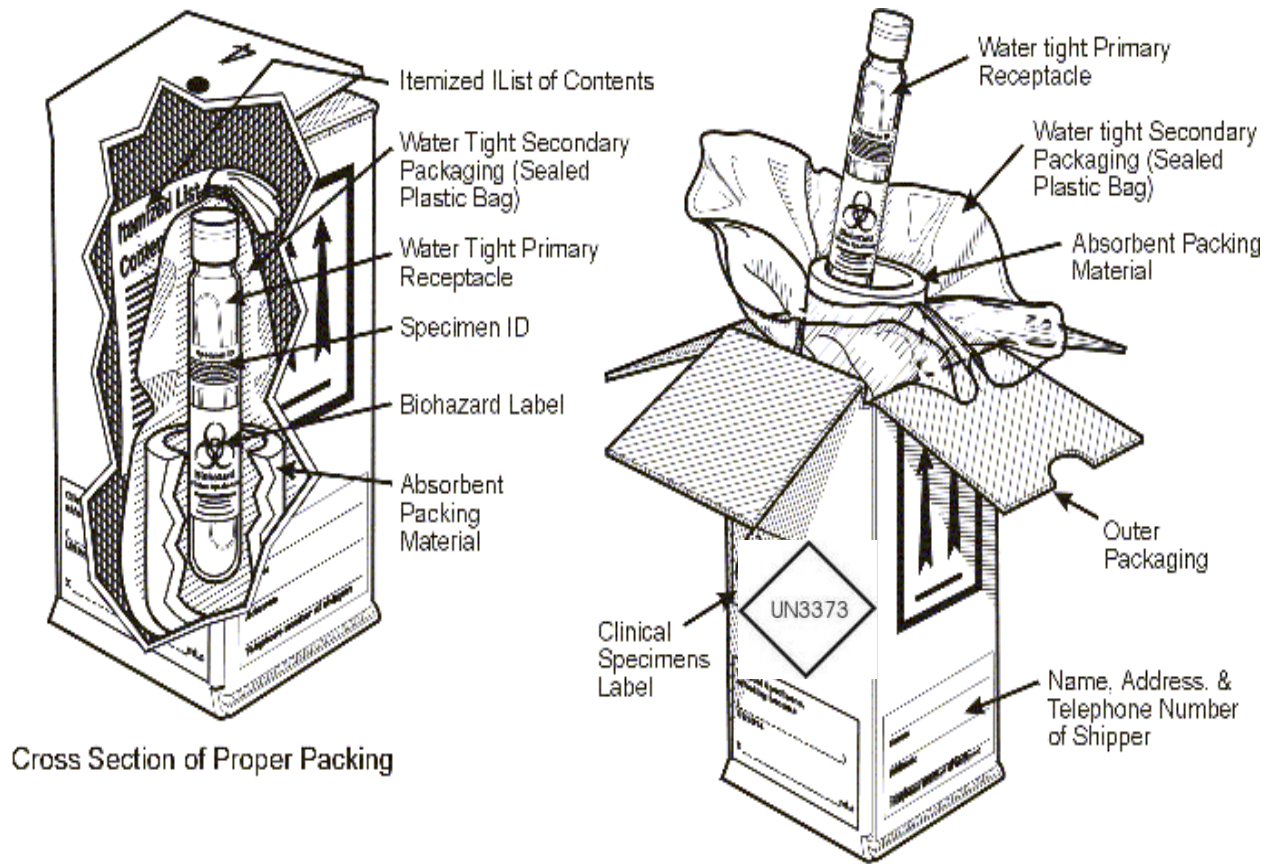
Bacillus anthracis (cultures only)  
Brucella abortus (cultures only)  
Brucella melitensis (cultures only)  
Burkholderia mallei – Pseudomonas mallei – Glanders (cultures only)  
Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)  
Chlamydia psittaci – avian strains (cultures only)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

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

#### **Infectious Substances, Affecting Animals, UN2900**

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

**APPENDIX 2**  
**Triple Packaging**



### APPENDIX 3

#### Manufacturers of Certified Shipping Containers for Infectious Substances, Patient Specimens & Dry Ice

Air Sea Atlanta  
1234 Logan Circle  
Atlanta, GA 30318  
Phone: 404-351-8600  
[www.airseatlanta.com](http://www.airseatlanta.com)

Berlin Packaging  
1195 Washington Pike  
Bridgeville, PA 15017  
Phone: 800-2-BERLIN  
[www.berlinpackaging.com/](http://www.berlinpackaging.com/)

CARGOpak Corporation  
PO Box 98686  
Raleigh, NC 27615  
Phone: 800-266-0652  
[www.cargopak.com](http://www.cargopak.com)

Inmark, Inc.  
675 Hartman Road, Suite 100  
Austell, GA 30168  
Phone: 800-646-6275  
[www.inmarkinc.com](http://www.inmarkinc.com)

ThermoSafe  
3930 N. Ventura Drive  
Arlington Heights, IL 60004  
Phone: 800-323-7442  
[www.thermosafe.com](http://www.thermosafe.com)

SAF-T-PAK, Inc.  
899 Airport Park Rd Ste A  
Glen Burnie, MD  
21061-2557  
Phone: 800-814-7484  
[www.saftpak.com](http://www.saftpak.com).

Therapak Corporation  
4305 Hamilton Mill Road  
Suite 200  
Buford, Georgia 30518

**APPENDIX 4**  
**Examples of Shipping Labels**



**Biological substance, Category B**

