Biological Materials and Dry Ice Shipments Manual

(EHS Program Manual 6.2)



1.0 Introduction

This Biological Material and Dry Ice Shipments Manual has been developed as part of the Weill Cornell Medicine (WCM) Environmental Health and Safety (EHS) Programs.

Certain biological materials, as well as dry ice and preservatives, are categorized as dangerous goods when shipped. The handling and shipping of dangerous goods are regulated by federal and international agencies, including:

- International Air Transport Association (IATA)
- U.S. Department of Transportation (USDOT)
- Federal Aviation Administration (FAA)
- United States Postal Service (USPS)
- Centers for Disease Control and Prevention (CDC)
- Occupational Health and Safety Administration (OSHA)
- U.S. Department of Health and Human Services (USDHHS)
- U.S. Department of Agriculture (USDA)
- U.S. Department of Commerce (USDOC)
- U.S. Department of Fish and Wildlife (USFWS)

Compliance with this Manual is essential to ensuring that biological materials and dry ice shipments are shipped in accordance with the stringent regulations established by these agencies. Penalties for non-compliance with these regulations are significant and could result in the following fines:

- Up to \$250,000 and up to five years imprisonment for the individual shipper.
- Up to \$500,000 per incident for the organization.
- Up to 10 years imprisonment for a willful violation resulting in the release of a hazardous material (dangerous good) that results in death or bodily injury.

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3.0 Objective

The purpose of this Manual is to provide WCM employees guidance in the proper shipping of biological materials and dry ice shipments by air as mandated by federal and international regulations as well as WCM procedures.

The shipment process includes:

- Obtaining approval from the Office of Sponsored Research Administration (OSRA) by using their Material Transfer Agreement form.
- Obtaining import, export, and/or interstate permits, if applicable.
- Training all persons shipping dangerous goods. Initial and recurrent training is required.
- Classifying the biological material.
- Determining the appropriate packing instructions and guidelines.
- Selecting the appropriate packing materials.
- Packing, marking, and labeling the package(s) properly.
- Completing, signing, and retaining all shipping documentation.
- Securing the packages prior to shipment.

3.1 SHIPPING ASSESSMENT FORM

An example of the <u>Shipping Assessment Form</u> is available for shippers who require assistance with their shipments. If assistance is required, submit a Shipping Assessment Form to <u>shipping@med.cornell.edu</u>.

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4.0 Applicability

4.1 WHOM DOES THIS MANUAL APPLY TO?

4.1.1 Shippers

The requirements of this Manual apply to all WCM faculty, staff, employees, or students who perform any of the activities in steps 4 through 9 of the shipment process identified in <u>Section 3.0 – Objective</u>. People performing any of these activities will hereby be identified as "shippers."

4.1.2 Carry-on and Checked Baggage Restrictions

IATA regulations govern the transport of dangerous goods on passenger and cargo aircraft. The IATA regulations state that no person shall carry dangerous goods or cause dangerous goods to be carried aboard an aircraft in either checked or carry-on baggage or on their person unless specifically permitted by IATA (<u>Appendix A</u>) and the airline.

4.2 WHAT DOES THIS MANUAL APPLY TO?

This Manual focuses on the IATA Air Transportation Requirements for biological materials and preservatives as identified herein. The IATA Air Transport Regulations are more restrictive for these substances, and compliance with IATA's packing instructions will ensure compliance with the ground transportation requirements established by the USDOT. If the shipper intends to ship any other biological, chemical, or radiological substance not specifically identified in this procedure, then the shipper <u>must</u> contact EHS for further instructions and training.

4.3 HOW LONG DO THE REQUIREMENTS OF THIS MANUAL APPLY?

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The shipping guidelines and requirements of this procedure are primarily derived from the 2024 IATA Dangerous Goods Regulations (65th Edition). These regulations are revised on an annual basis; therefore, this document will be revised by EHS annually.

Shippers must ensure that they possess and are compliant with the most current version of this procedure prior to conducting any shipments.

5.0 Significant Changes for 2024

IATA modifies and updates its regulations on an annual basis. This document reflects the most current regulatory shipping requirements. *There are no significant changes between 2023 and 2024.*

6.0 Import, Export, and Interstate Transport Permits

Importing (IM), exporting (EX), and interstate (IS) shipments of biological materials may require additional documentation and/or permitting for agencies such as:

- US Department of Commerce Bureau of Industry and Security (EX)
- CDC Etiological Agent Import and Transport Permits (IM and IS)
- USDA APHIS Plant Protection Quarantine (IM)
- USDA APHIS CITES Permits (IM and EX)
- USDA APHIS Veterinary Services Permits (IM, EX, and IS)
- U.S. Fish and Wildlife Permits (IM and EX)
- U.S. Food and Drug Administration (FDA) (IM and EX)

These permits and documents **must be obtained prior to shipping or receiving** the biological materials. These permits and documents may take several weeks to obtain. Contact EHS to determine if your shipment requires any permits. Failure to acquire necessary permits can result in significant fines to the institution and, in some cases fines or jail time for the shipper directly.

6.1 FOREIGN NATIONALS

Shipments to or from foreign nationals within the United States are still regulated as importing and exporting.

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7.0 Biological Material Classifications

This section focuses on the classification of biological materials. Shippers must also determine if other dangerous goods (e.g., regulated preservatives and/or dry ice) are included in the shipment. The Shipper's knowledge of the biological material and its intended use will help determine if the material is classified as one of the following:

- Non-Regulated Biological Materials
- Select Agents and Toxins
- Infectious Substance, Category A
- Biological Substance, Category B
- Patient Specimens
- Genetically Modified Micro-Organisms and Organisms
- Biological Products
- DNA Sequencing Samples to Cornell-Ithaca
- Campus-to-Campus (C2C) Bus Service

Shippers must review the following descriptions of biological materials to determine which description most accurately applies. A flowchart (<u>Appendix B</u>) is available to facilitate this process.

7.1 NON-REGULATED BIOLOGICAL MATERIALS

The following are biological materials that are exempt from the dangerous goods shipping requirements <u>unless</u> mixed, preserved, and/or otherwise shipped with a material which is still classified as a dangerous good.

- Substances that do not contain infectious substances or substances that are unlikely to cause disease in humans or animals.
- Substances containing micro-organisms (not including genetically modified micro-organisms), which are non-pathogenic to humans or animals.
- Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk.
- Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection.
- Dried blood spots, collected by applying a drop of blood onto absorbent material, or fecal occult blood screening tests.
- Blood or blood components that have been collected for transfusion or for the preparation of blood products to be used for transfusion or transplantation.
- Any tissues or organs intended for use in transplantation.

If this classification most accurately describes the biological material, refer to <u>Section 9.0 – General Biological Material Packaging</u> Requirements.

7.2 SELECT AGENTS AND TOXINS

Select agents are biological agents and toxins that have been determined to pose a serious threat to public health and safety, to animal and plant health, or to animal or plant products and are regulated by the Federal Select Agent Program. Only the WCM Responsible Official is authorized to acquire and transfer select agents and toxins. A list of select agents and toxins is provided in <u>Appendix C</u>.

If the biological material is a select agent or toxin, contact the <u>WCM Responsible Official via EHS</u> for the shipment of this substance.

7.3 INFECTIOUS SUBSTANCE, CATEGORY A

Biological materials are classified as Infectious Substance, Category A, if it is an infectious substance which is being transported in a form that, when exposure to it occurs, is capable of causing permanent disability, a life-threatening or fatal disease in otherwise healthy humans or animals. Pathogens are defined as microorganisms (including bacteria, viruses, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.

Indicative examples of substances that meet these criteria are provided in <u>Appendix D</u>. The table listed in Appendix D is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in Appendix D but meet the same criteria, must be classified as Category A. In addition, if there is doubt as to whether or not a substance meets the criteria, it must be included in Category A.

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If this classification most accurately describes the biological material, refer to <u>Section 10.0 – Infectious Substance, Category A Shipper</u> <u>Requirements</u>.

7.3.1 Infected Live Animals

Infected live animals must not be transported by air. Contact EHS if live infected animals need to be shipped.

7.4 BIOLOGICAL SUBSTANCE, CATEGORY B

Infectious substances that do <u>not</u> meet the criteria for inclusion in Category A are classified as Biological Substance, Category B. Examples of infectious substances meeting the criteria for Biological Substance, Category B include:

- Human blood, tissue, or other potentially infectious materials infected with Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), Hepatitis C Virus (HCV), or other blood-borne pathogens not otherwise considered an Infectious Substance, Category A pathogen.
- Human blood, tissue, or other potentially infectious materials being shipped for infectious disease screening. This includes
 specimens not known to be infectious but, are still being shipped for infectious disease screening.

If this classification most accurately describes the biological material, refer to <u>Section 11.0 – Biological Substance, Category B Shipper</u> <u>Requirements</u>.

7.4.1 Infected Live Animals

Infected live animals must not be transported by air. Contact EHS if live infected animals need to be shipped.

7.5 PATIENT SPECIMENS

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

7.5.1 Patient Specimens with Category A or B Pathogens

Patient specimens containing or reasonably expected to contain Category A or Category B pathogens must be classified as either an Infectious Substance, Category A, or a Biological Substance, Category B, depending on the classification of the pathogen.

7.5.2 Patient Specimens being sent for Infectious Disease Screening

Patient specimens that are being sent to screen for the presence of infectious diseases must be classified as Biological Substance, Category B.

7.5.3 Patient Specimens with Minimal Likelihood of Containing Pathogens

An element of professional judgment is required to determine if a patient specimen has a minimal likelihood of having a pathogen present. That judgment should be based on the known medical history, symptoms, and individual circumstances of the source, human or animal, and endemic local conditions.

Examples of specimens which may be transported under this classification include:

- blood or urine tests to monitor cholesterol levels
- blood glucose levels
- hormone levels or prostate-specific antigens (PSA)
- tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases
- therapeutic drug monitoring
- tests conducted for insurance or employment purposes to determine the presence of drugs or alcohol
- pregnancy tests
- biopsies to detect cancer
- antibody detection in humans or animals.

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If this classification most accurately describes the biological material, refer to Section 12.0 - Patient Specimen Shipper Requirements.

7.5.4 Patient Specimens Transported in Dedicated Vehicles

USDOT regulations do not apply to private or contract motor carriers used exclusively to transport patient (diagnostic) specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle, provided they are properly packaged and secured against exposure or contamination. Note that in order for the vehicle to be "dedicated," the vehicle cannot be utilized for other purposes at the same time (e.g., patient transport).

If this classification most accurately describes the biological material and transportation process, then no specific packing instructions are required by law. Prepare the shipment in accordance with <u>Section 9.0 – General Biological Material Packaging Requirements</u> and the carrier's specifications, if applicable.

7.6 GENETICALLY MODIFIED MICROORGANISMS AND ORGANISMS

Genetically modified microorganisms (GMMO) and organisms (GMO) are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMMOs and GMOs are divided into the following categories:

7.6.1 Infectious GMMO and GMO

GMMOs and GMOs that are infectious must be classified as either Infectious Substance, Category A, or Biological Substance, Category B, depending on the classification of the pathogen. Examples of infectious genetically modified organisms include replication competent adenoviral and lentiviral vectors. Replication competent adenoviral and lentiviral vectors would need to be classified as Biological Substance, Category B. In addition, per the NIH Appendix H-II, "*Host organisms and viruses will be shipped as etiologic agents if they contain recombinant or synthetic nucleic acid molecules when:...(ii) the recombinant or synthetic nucleic acid molecule codes for a toxin or other factor directly involved in eliciting human, animal, or plant disease or inhibiting plant growth, and is carried on an expression vector or within the host chromosome and/or when the host organism contains a conjugation proficient plasmid or a generalized transducing phage;...".*

7.6.2 Non-Infectious GMMO and GMO

This classification refers to all GMMOs and GMOs which are not infectious. Examples of non-infectious genetically modified organisms include adenoviral and lentiviral vectors, which have been rendered incapable of replication.

If this classification most accurately describes the biological material, refer to <u>Section 13.0 – Genetically Modified Microorganism</u> <u>Shipper Requirements</u>.

7.7 BIOLOGICAL PRODUCTS

Biological products are those products derived from living organisms that are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans 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. Biological products are divided into the following categories:

7.7.1 Government-Approved Biological Products

IATA does not regulate biological products that are manufactured and packaged in compliance with national governmental health authorities' approval (e.g., USDA or HHS - Food and Drug Administration) and transported for the purposes of final packaging or distribution, and used for personal health care by medical professionals or individuals.

If this classification most accurately describes the biological material, then the material must be packaged according to the approval. If the biological product is shipped with another dangerous good not associated with the approval (e.g., dry ice), then the requirements for the other dangerous goods would still apply. Furthermore, shippers must confirm if the carrier has more stringent restrictions which must be met.

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7.7.2 Non-Approved Biological Products with Category A or B Pathogens

Biological products not approved by a national governmental health authorities' approval (e.g., USDA or HHS – Food and Drug Administration) containing Category A or Category B pathogens must be classified as Infectious Substance, Category A or Biological Substance, Category B depending on the pathogen.

7.7.3 Biological Products Transported in Dedicated Vehicles

USDOT regulations do not apply to private or contract motor carriers used exclusively to transport diagnostic specimens or biological products. Medical or clinical equipment and laboratory products may be transported aboard the same vehicle, provided they are properly packaged and secured against exposure or contamination. Note that in order for the vehicle to be "dedicated," the vehicle cannot be utilized for other purposes at the same time (e.g., patient transport).

If this classification most accurately describes the biological material and transport process, then no specific packing instructions are required by law. Prepare the shipment in accordance with <u>Section 9.0 – General Biological Material Packaging Requirements</u> and the carrier's specifications, if applicable.

7.8 DNA SEQUENCING SAMPLES SENT TO CORNELL – ITHACA

This classification refers to DNA sequencing samples being shipped to the DNA Sequencing Facility at the BioResource Center of Cornell University, Ithaca, NY.

If this classification most accurately describes the biological material, refer to Section 14.0 – DNA Sequencing Sample Shipments to Cornell-Ithaca.

8.0 Chemical Classifications

This Biological Material and Dry Ice Shipments procedure and its associated training program exclude most chemicals classified as dangerous goods. Only dry ice, dangerous goods chemical preservatives shipped with infectious substances, and non-hazardous chemical preservatives may be shipped when conducted in accordance with this section. Contact EHS to review shipments of any chemicals not specifically approved in this section.

8.1 DRY ICE

Dry ice is often used when shipping samples, which must remain at low temperatures. Dry ice is regulated as a dangerous good when shipped because of its off-gassing properties. Specifically, dry ice is solidified carbon dioxide and undergoes sublimation (changes from solid to gas) at normal atmospheric conditions. The off-gassing of carbon dioxide can lead to the displacement of oxygen, resulting in asphyxiation. Additionally, if improperly packaged (i.e., not vented), the off-gassed carbon dioxide can pressurize a container, potentially resulting in the container exploding. As such, the use of dry ice in shipments is regulated by the United States Department of Transportation (USDOT), the Federal Aviation Administration (FAA), and the International Air Transport Association (IATA).

If shipping with dry ice, refer to Section 16.0 – Dry Ice Shipper Requirements.

8.2 CHEMICAL PRESERVATIVES WITH INFECTIOUS SUBSTANCES

IATA and USDOT allow **30 ml or less (per primary receptacle)** of flammable liquids (Class 3), corrosive (Class 8), or miscellaneous dangerous goods (Class 9) as long as it is necessary for maintaining the viability, stabilizing, preventing degradation, or neutralizing the hazards of the Category A and Category B infectious substances. When shipped with Category A and Category B infectious substances, these chemical preservatives are exempt.

Common dangerous good chemical preservatives include:

- Ethanol solutions
- Formaldehyde (≥10% concentration of formaldehyde)
- Acetic Acid

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8.2.1 Flammable Liquids (Class 3) Definition

Flammable Liquids (Class 3) are liquids, mixtures of liquids, or liquids containing solids in solution or in suspension, which give off a flammable vapor at temperatures of not more than 60°C (140°F) closed-cup test. Refer to the SDS or contact EHS to determine if the substance is a flammable liquid.

8.2.2 Corrosive (Class 8) Definition

Corrosive (Class 8) substances that, by chemical action can cause severe damage when in contact with living tissue or, in the case of leakage, will materially damage or even destroy other goods or the means of transport. Refer to the SDS or contact EHS to determine if the substance is corrosive.

8.2.3 Miscellaneous Dangerous Goods (Class 9) Definition

Miscellaneous Dangers Goods (Class 9) are articles and substances that may present a danger not covered by other classes during air transport. Refer to the SDS or contact EHS to determine if the substance is a miscellaneous dangerous good.

8.3 CHEMICAL PRESERVATIVES WITH NON-INFECTIOUS BIOLOGICAL MATERIALS (EXCEPTED QUANTITIES)

Some chemical preservatives may be shipped with non-infectious biological materials as **excepted quantities**. To qualify for the small quantity exception, the shipper must ensure all conditions detailing classes, quantities and containers are met.

In order to qualify, the chemical or chemical mixture must fall into one of the following hazard classes and may not exceed the maximum allowance per inner container or entire package.

Class Hazard		Maximum amount per inner container (gm solid/ml liquid)	Maximum amount per <i>entire package</i> (gm solid/ml liquid)
Class 3	Flammable	30	300
Class 8	Corrosive Material	30	500

If shipping with chemicals that qualify as excepted quantities, refer to Section 16.0.

8.4 COMMON NON-HAZARDOUS CHEMICAL PRESERVATIVES

Non-hazardous chemical preservatives used for maintaining the viability, stabilizing, preventing degradation, or neutralizing the biological material have no specific shipping restrictions when shipped in accordance with the biological material shipping requirements identified in this manual. Common non-hazardous chemical preservatives include:

- 10% Formalin (3.75% formaldehyde concentration)
- Formaldehyde (<10% concentration of formaldehyde)
- Phosphate buffered saline solutions

8.5 LIQUID NITROGEN AND DRY SHIPPER REQUIREMENTS

Liquid nitrogen is regulated as a dangerous good when shipped. This manual and the Biological Material and Dry Ice Shipments training do not cover shipments with liquid nitrogen and liquid nitrogen dry shippers. Contact EHS for assistance with shipments of liquid nitrogen.

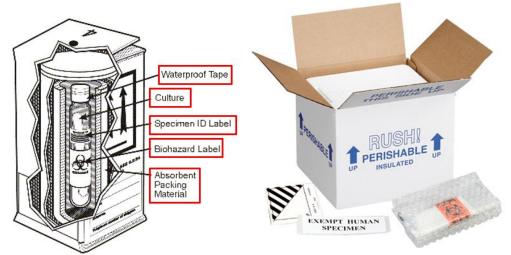
Additional information on preparing and shipping requirements is available in the <u>EHS Update – Liquid Nitrogen Dry Shippers</u> <u>Preparation and Shipping Requirements</u>.

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9.0 General Biological Material Packaging Requirements

Shippers must ensure that biological materials are prepared and packaged as specified by their classification in Section 7.0. In general, a basic triple-performance packaging strategy applies when shipping biological materials, as shown on the picture.



The following requirements represent the minimum packaging requirements for all biological materials. Additional packaging requirements may apply depending on the biological material classification and packaging requirements further identified in this Manual.

9.1 PRIMARY RECEPTACLES

Primary receptacles must be leak-proof for liquids and sift-proof for solids. "Biohazard" labels, if applicable to the material shipped, must be utilized.

9.2 SECONDARY PACKAGING

The primary receptacle(s) must be placed into secondary packaging in such a way that, under normal conditions of transport, they cannot break, be punctured or leak. Secondary packaging must be leak-proof for liquids and sift-proof for solids.

9.2.2 Liquid Specimens

An absorbent material in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) and the secondary packaging so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material

9.2.3 Fragile Primary Receptacles

If several fragile primary containers are placed into the same secondary packaging, they must be either individually wrapped or separated to prevent contact among them.

9.3 DURABLE AND RIGID OUTER PACKAGING

Secondary packaging must be secured in a **durable and rigid outer packaging** with suitable cushioning material. Outer packages must have one side with dimensions of not less than 100 mm x 100 mm when hazard class labels are required. A list of packaging suppliers is included in <u>Appendix E</u>.

9.4 DRY ICE PACKAGING REQUIREMENTS

When biological materials are shipped with dry ice, interior support must be provided to secure the secondary packaging(s) or packages in their original position after the dry ice has dissipated. The outer packaging or overpack must permit the release of carbon

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dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

9.5 ICE PACKAGING REQUIREMENTS

When biological materials are shipped with regular ice (not ice packs), interior support must be provided to secure the secondary packaging(s) or packages in their original position after the ice has melted. The outer packaging or overpack must be leak-proof. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

10.0 Infectious Substance, Category A Shipper Requirements

Infectious Substance, Category A biological materials must be shipped in compliance with IATA Packing Instruction 620. Shippers are compliant with the requirements of IATA Packing Instruction 620 when shipping as specified in this Manual and utilizing appropriate performance-tested packaging designed in compliance with Packing Instruction 620.

10.1 CONTAINER SIZE AND QUANTITY LIMITATIONS

10.1.1 Primary Receptacle Limit

There are no primary receptacle quantity limitations.

10.1.2 Outer Packaging Quantity Limit

The following outer packaging quantity limitations (totals per package) depend on the type of shipment:

- Passenger and Cargo Aircraft Shipments Must not exceed 50ml of liquid or 50g of solid infectious material.
- Cargo Aircraft Only Shipments Must not exceed 4L of liquid or 4kg of solid infectious material.
- Special Provision "A81" The outer packaging limits do not apply to body parts, organs, or whole bodies known to contain or suspected of containing infectious substances. These materials must still be packed in accordance with this Section, so as to present no hazard to persons or animals during transport. "A81" must be noted on the Shipper's Declaration when this Special Provision is utilized.

Note: blood, urine, and other body fluids are not considered "body parts" for the purposes of this special provision.

Quantity Limits	Primary Container	Outer Packag	ing
Infectious Cultotopos		Passenger and Cargo Aircraft	Cargo Aircraft Only
Infectious Substance, <i>Category A</i>	No Quantity Limits	50 ml (Liquids) 50 g (Solids)	<pre>4 L (Liquids) 4 kg (Solids)</pre>

10.2 PACKAGING REQUIREMENTS

Shippers must confirm that the packaging, including secondary packaging, has been tested and is suitable for shipping in accordance with IATA Packing Instruction 620 [e.g., stamped "UN 4G / Class 6.2" ("A" in illustration below)]. A list of packaging suppliers is provided in <u>Appendix E</u>.

Note: Special consideration for selecting appropriate packaging is required when samples are refrigerated or frozen (e.g., dry ice or prefrozen packs).

10.2.1 General Packaging Requirements

Packaging must comply with <u>Section 9.0 – General Biological Material Packaging Requirements</u> in addition to the other requirements outlined in this section.

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10.2.2 Closure Instructions

Shippers must follow the packaging manufacturer's closure instructions. Record retention information for these instructions is available in <u>Section 23.3 – Packaging Closure Instructions</u>.

10.2.3 Packaging Reuse

Packaging reuse is not recommended. Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage that reduces its structural integrity. All inappropriate dangerous goods markings and labels must be removed or completely obliterated. The closure instruction requirements described above must be satisfied.

10.2.4 Substances Shipped at Ambient Temperature or Higher

Primary receptacles must be of glass, metal, or plastic. Positive means of ensuring a leak-proof seal must be provided, such as heat seal, skirted stopper, or metal crimp seal. If screw caps are used, these must be secured by positive means (e.g., tape, paraffin sealing tape, or manufactured locking closure).

10.2.5 Lyophilized Substances

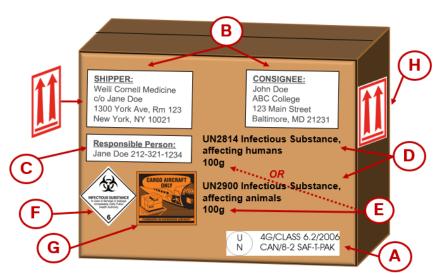
Primary receptacles must be either flame-sealed ampoules or rubber-stoppered glass vials with metal seals.

10.2.6 95 kPa Pressure-Tested Primary or Secondary Packaging

The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 13.8 lb/in2); and temperatures in the range of -40°C to 55°C (-40°F to 130°F).

Shippers must ensure that the manufacturer of either the primary receptacle or the secondary packaging has tested the container to the 95kPa pressure standard. Replacement "95 kPa" bags are available from many packaging manufacturers and must be specifically labeled as "95 kPa". *Ziplock bags or unlabeled specimen transport bags are prohibited.*

10.3 MARKINGS AND LABELS



• (A) UN Packaging Specification: Confirm that the packaging has been tested and is suitable for shipping according to IATA Packing Instruction 620 (e.g., stamped "UN 4G / Class 6.2").

For packages weighing less than 30 kg max net weight or of 30 L capacity or less, the letters must be at least <u>6 mm</u> in height.

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- (B) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package. Shipper information should start with "Weill Cornell Medicine" followed by the shipper's specific information, name, and address.
- (C) Responsible Person: The name and phone number of a person with first-hand knowledge of the materials being shipped and who has received appropriate shipper training.
- (D) "UN" Number and Proper Shipping Name: The proper shipping name is either: "UN2814, Infectious Substance, Affecting Humans", or "UN2900, Infectious Substance, Affecting Animals".
 - If the pathogen affects humans only or humans and animals, then "Infectious Substance, Affecting Humans" must be used. If the pathogen is only capable of affecting animals, then "Infectious Substance, Affecting Animals" must be used. Abbreviations or variations in spelling are violations and, therefore, prohibited.
 - **NOTE: Special Provision "A140" The technical name need not be shown on the outer package.
- (E) Net Quantity (If More Than One Package): If more than one package is shipped, then the net quantity of biological material must be marked on the package under the proper shipping name.
- (F) Class 6.2 Hazard Class Label:



- 6.2 Hazard Class label must be affixed to the side of the package.
- Labels must be 100mm x 100mm (4"x 4") in size. Use only pre-printed shipping labels. Do not print paper labels. Contact EHS if labels are needed.
- Package must be large enough for the label to fit on one side.

(G) Cargo Aircraft Only Label:



- If the outer package limits from Section 10.1.2 were used for the shipment, then a Cargo Aircraft Only label must be affixed to the side of the package.
- The label must be 120mm x 110mm in size. For small packages of Category A, these dimensions may be halved.
- Use only pre-printed shipping labels. Do not print paper labels. Contact EHS if labels are needed.
- (H) Package Orientation Arrows (≥ 50 MI Liquid): Package orientation arrows must be affixed or pre-printed on opposite sides of the package when shipping 50 ml or more of Category A liquid materials.

10.4 SHIPPING DOCUMENTS

If the infectious substance being transported is unknown, but suspected of meeting the criteria for inclusion in Category A; the words "Suspected Category A Infectious Substance" must appear on the Itemized List of Contents and the Shipper's Declaration in parenthesis after the proper shipping name.

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Documents Required	Airway Bill	Itemized List of Contents	Declaration of Dangerous Goods
Infectious Substance, Category A	Yes	Yes	Yes

10.4.1 Itemized List of Contents / Commercial Invoice

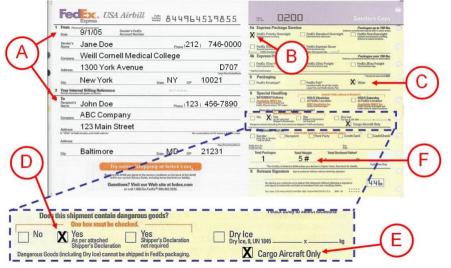
An Itemized List of Contents must be enclosed between the secondary packaging and the outer packaging. Four signed originals must be included with the shipping paperwork outside the package. An example <u>commercial invoice</u> may be utilized if an itemized list of contents is not available. The commercial invoice must be utilized for international shipments.

10.4.2 Shipper's Declaration for Dangerous Goods

A Shipper's Declaration for Dangerous Goods is required. Four signed originals must be included with the shipping paperwork outside the package. *Refer to the* Shipper's Declaration for Dangerous Goods for further instructions on completing this document.

10.4.3 Carrier's Air Waybill (e.g., FedEx Airbill)

If utilizing a paper air waybill, the following must be identified, as shown in the example FedEx Airbill below.



- (A) "To" / "From" Information: Complete "To" and "From" information.
- (B) Priority Shipping: The fastest shipping service must be selected (e.g., Priority Overnight).
- (C) Other Packaging: Select "Other" packaging. FedEx packaging cannot be used to ship these materials.
- (D) Dangerous Goods Designation: Select the "Yes As per attached Shipper's Declaration" box.
- (E) Cargo Aircraft Only Designation: Select "Cargo Aircraft Only" if the Cargo Aircraft Only outer packing limits from <u>Section 10.1.2</u> are utilized.
- (F) Number of Packages: Enter the number of packages shipped (typically "1") and the total weight.

If utilizing online system to create air waybill, ensure "Dangerous Goods" is selected, as shown in the example from the FedEx online system below.

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11.0 Biological Substance, Category B Shipper Requirements

Biological Substance, Category B must be shipped in compliance with IATA Packing Instruction 650. Shippers are compliant with the requirements of IATA Packing Instruction 650 when shipping as specified in this Manual and utilizing appropriate performance-tested packaging designed in accordance with Packing Instruction 650.

11.1 CONTAINER SIZE AND QUANTITY LIMITATIONS

11.1.1 Primary Receptacle Quantity Limitations

Must not exceed 1L of liquid or 4kg of solid biological material.

11.1.2 Outer Packaging Quantity Limitations

Must not exceed 4L of liquid or 4kg of solid biological material.

Quantity Limits	Primary Container	Outer Packaging
Biological Substance, <i>Category B</i>	1 L (Liquids) 4 kg (Solids)	4 L (Liquids)4 kg (Solids)

Exception: The packaging quantity limits do not apply to body parts, organs, or whole bodies. These materials must still be packed in accordance with Section 11.2 to present no hazard during transport.

11.2 PACKAGING REQUIREMENTS

Shippers must confirm that the packaging has been tested and is suitable for shipping in accordance with IATA Packing Instruction 650. A list of packaging suppliers is provided in <u>Appendix E</u>.

Note: Special consideration for selecting appropriate packaging is required when samples are refrigerated or frozen (e.g., dry ice or pre-frozen packs).

11.2.1 General Packaging Requirements

Packaging must comply with <u>Section 9.0 – General Biological Material Packaging Requirements</u> in addition to the other requirements in this section.

11.2.2 Closure Instructions

Shippers must follow the packaging manufacturer's closure instructions. Record retention information for these instructions is available in <u>Section 23.3 – Packaging Closure Instructions</u>.

11.2.3 Packaging Reuse

Packaging reuse is not recommended. Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage that reduces its structural integrity. All inappropriate dangerous goods markings and labels must be removed or completely obliterated. The closure instructions requirements described above must be satisfied.

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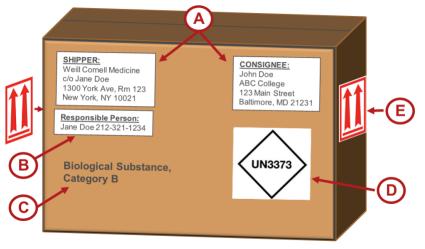


11.2.4 95 kPa Pressure-Tested Primary or Secondary Packaging

The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 13.8 lb./in2) and temperatures in the range of -40°C to 55°C (-40°F to 130°F).

Shippers must ensure that the manufacturer of either the primary receptacle or the secondary packaging has tested the container to the 95kPa pressure standard. Replacement "95 kPa" bags are available from many packaging manufacturers and must be specifically labeled as "95 kPa". *Ziplock bags or unlabeled specimen transport bags are prohibited.*

11.3 MARKING AND LABELS



11.3.1 UN Packaging Specification

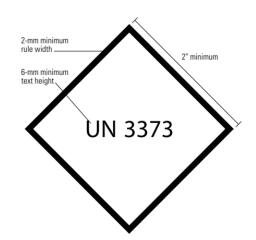
Since no UN Specification marking is required on the outside of the package, shippers must confirm that the packaging has been tested by the manufacturer and is suitable for shipping in accordance with IATA Packing Instruction 650.

Use sturdy outer packaging such as corrugated fiberboard or similar material that is strong enough to withstand normal rigors of transportation, including vibration, changes in temperature, humidity, and pressure and is capable of passing 1.2 m drop test.

- Styrofoam coolers, paperboard boxes, envelopes, and plastic bags are not suitable.
- (A) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package.
- (B) Responsible Person: The name and phone number of a person with first-hand knowledge of the materials being shipped and who has received appropriate shipper training.
- (C) Proper Shipping Name: The proper shipping name "Biological Substance, Category B" in letters at least 6 mm high must be
 marked on the outer packaging adjacent to the diamond-shaped mark. Abbreviations or variations in spelling will result in a violation.
- (D) "UN3373" Hazard Class Label:

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- "UN3373" Hazard Class label must be affixed to the side of the package
- Labels must be 50mm x 50mm (2"x 2") in size. Use only pre-printed shipping labels. Letters and numbers must be at least 6 mm tall, and the line/diamond must be 2 mm thick.
- The label must be orientated to appear in the shape of diamond, as shown here.
- Package must be large enough for the label to fit on one side.
- (E) Package Orientation Arrows: Package orientation arrows must be affixed on opposite sides of the package if 50 ml or more Category B biological liquids are shipped.

11.4 SHIPPING DOCUMENTS

Documents Required	Airway Bill	Itemized List of Contents	Declaration of Dangerous Goods
UN 3373 Biological Substance, Category B	Yes	Yes	-

11.4.1 Itemized List of Contents / Commercial Invoice

An Itemized List of Contents must be enclosed between the secondary packaging and the outer packaging. Four signed originals must be included with the shipping paperwork outside the package. An example <u>commercial invoice</u> may be used if an itemized list of contents is not available. The commercial invoice should be utilized for international shipments.

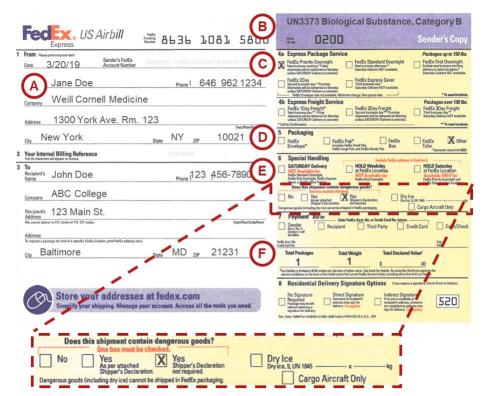
11.4.2 Shipper's Declaration for Dangerous Goods

A Shipper's Declaration for Dangerous Goods is <u>not required</u> unless shipped with Category A Infectious Substances. If shipped with materials requiring a Shipper's Declaration, the Biological Substance, Category B information must be included.

11.4.3 Carrier's Air Waybill (e.g., FedEx Airbill)

The following must be identified on the carrier's air waybill. An example FedEx Airbill is provided below.

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- (A) "To" / "From" Information: Complete "To" and "From" information.
- (B) UN3373 and Proper Shipping Name: The "Nature and Quantity of Goods" box must show "UN3373, BIOLOGICAL SUBSTANCE, CATEGORY B," and the number of packages being shipped. For FedEx USA Airbills, which do not have this box, the text may be written in any free area of the Airbill.
- (C) Priority Shipping: The fastest shipping service must be selected (e.g., Priority Overnight)
- (D) Other Packaging: Select "Other" packaging. FedEx packaging cannot be used to ship these materials
- (E) Dangerous Goods Designation: Select the "Yes. Shipper's Declaration not required" box.
- (F) Number of Packages: Enter the number of packages shipped (typically "1") and the total weight.

12.0 Patient Specimen Shipper Requirements

Patient specimens for which there is minimal likelihood that pathogens are present must be packaged as specified in this section. If the patient specimen contains or is reasonably expected to contain Category A or B pathogens, then it <u>cannot</u> be packaged in accordance with this section.

12.1 CONTAINER SIZE AND QUANTITY LIMITATIONS

There are no container size limitations for patient specimens.

12.2 PACKAGING REQUIREMENTS

Packaging must comply with <u>Section 9.0 – General Biological Material Packaging Requirements</u>. FedEx prohibits the use of their standard FedEx boxes to ship exempt human or animal specimens.

Note: Special consideration for selecting appropriate packaging is required when samples are refrigerated or frozen (e.g., dry ice or prefrozen packs).

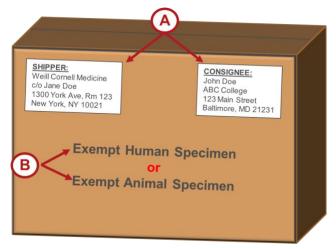
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12.2.1 Packaging Reuse

Packaging reuse is not recommended. Before reuse, each package and material must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage that reduces its structural integrity. All inappropriate dangerous goods markings and labels must be removed or completely obliterated. A list of packaging suppliers is in <u>Appendix E</u>.

12.3 MARKINGS AND LABELS



- (A) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package.
- (B) Proper Shipping Name: The package must be marked either "EXEMPT HUMAN SPECIMEN" or "EXEMPT ANIMAL SPECIMEN", as appropriate. No variations in spelling are acceptable.

12.4 SHIPPING DOCUMENTS

12.4.1 Itemized List of Contents / Commercial Invoice and Shipper's Declaration for Dangerous Goods

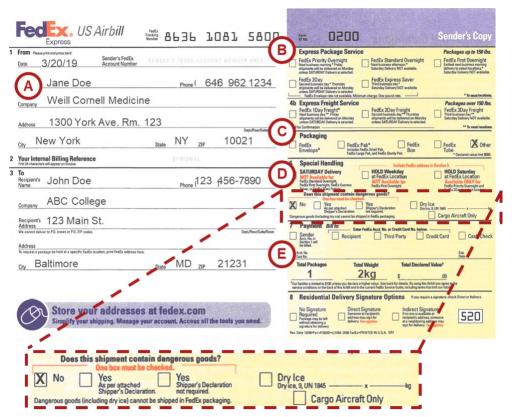
An Itemized List of Contents and Shipper's Declaration are <u>not</u> required. A <u>commercial invoice</u> should be utilized for international shipments.

Documents Required	Airway Bill	Itemized List of Contents	Declaration of Dangerous Goods
Exempt Human or Animal Specimen	Yes	International Shipments Only	-

12.4.2 Carrier's Air Waybill

The following must be identified on the carrier's air waybill, as shown in the example FedEx Airbill below.

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- (A) "To" / "From" Information: Complete "To" and "From" information.
- (B) Priority Shipping: Priority Overnight shipping is not required.
- (C) Other Packaging: Select "Other" packaging. FedEx packaging cannot be used to ship these materials.
- (D) Dangerous Goods Designation: Select the "No" box. This material does not classify as dangerous goods as long as the patient specimen is packaged and labeled in accordance with this Section.
- (E) Number of Packages: Enter the number of packages shipped (typically "1") and the total weight.

13.0 Genetically Modified Micro-Organism Shipper Requirements

Genetically modified microorganisms (GMMOs) and genetically modified organisms (GMOs) must be shipped in compliance with IATA Packing Instruction 959. Shippers are compliant with the requirements of IATA Packing Instruction 959 when shipping in accordance with this Manual and utilizing appropriate packaging. If the GMMO/GMO is <u>infectious</u>, then it <u>cannot</u> be packaged in accordance with this section. If the GMMO/GMO is infectious, it must be packaged and shipped as Biological Substance, Category B, or Infectious Substance, Category A, depending on how it is classified.

13.1 CONTAINER SIZE AND QUANTITY LIMITATIONS

There are no container size limitations for GMMOs and GMOs.

13.2 PACKAGING REQUIREMENTS

Shippers must confirm that the packaging is suitable for shipping in accordance with IATA Packing Instruction 959. GMMO / GMO packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport, including trans-shipment between transport units and between transport units and warehouses, as well as any removal from a pallet or over-pack for subsequent manual or mechanical handling. Packaging must 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.

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Note: Special consideration for selecting appropriate packaging is required when samples are refrigerated or frozen (e.g., dry ice or prefrozen packs).

A list of packaging suppliers is provided in Appendix E.

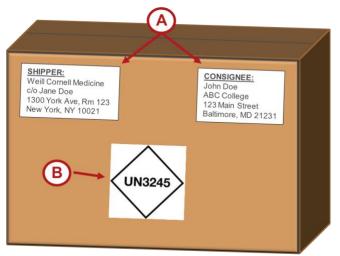
13.2.1 General Packaging Requirements

Packaging must comply with <u>Section 9.0 – General Biological Material Packaging Requirements</u> in addition to the other requirements outlined in this section.

13.2.2 Packaging Reuse

Packaging reuse is not recommended. Before reuse, each packaging must be inspected and may not be reused unless free from incompatible residue, rupture, or other damage that reduces its structural integrity. All inappropriate dangerous goods markings and labels must be removed or completely obliterated.

13.3 MARKINGS AND LABELS



- (A) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package.
- (B) "UN3245" Hazard Class Label:



- UN3245 label must be affixed to the side of the package.
- Labels must be 50mm x 50mm (2"x 2") in size.
 Use only pre-printed shipping labels. Letters and numbers must be at least 6 mm tall, and the line/diamond must be 2 mm thick.
- Label must be orientated to appear in the shape of diamond, as shown here.
- Package must be large enough for the label to fit on one side.

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13.4 SHIPPING DOCUMENTS

13.4.1 Itemized List of Contents / Commercial Invoice and Shipper's Declaration for Dangerous Goods

The Itemized List of Contents and Shipper's Declaration are <u>not</u> required unless shipped with Category A Infectious Substances. If shipped with materials requiring a Shipper's Declaration, the GMMO information must be included.

A <u>commercial invoice</u> should be utilized for international shipments.

D	ocuments Required	Airway Bill	Itemized List of Contents	Declaration of Dangerous Goods
	GMO and GMMO (UN3245)	Yes	International Shipments Only	-

13.4.2 Carrier's Air Waybill

The following must be identified on the carrier's air waybill, as shown in the example FedEx Airbill below.

	UN3245 GMO or UN3245 GMMO
Express US AIRDIN Trees BE36 1081 5800	Sender's Copy
I From Presse point and press hand Sender's FedEx Dato 3/20/19 Sender's FedEx	FedEx Priority Overnight Networks with a determined in Monday where SATINGT Oblevey and Satisfy Diskey NOT evaluation. FedEx Standard Overnight Satisfy Diskey NOT evaluation. FedEx Standard Overnight Satisfy Diskey NOT evaluation.
A Jane Doe Phone 646 962 1234 Weill Cornell Medicine	FedEx 2Day FedEx Express Saver Ther barries der Submess der, "Thurder submess and the delivered on Monday or trade Delivery not a network Submess delivery not network and Minimum charge One-pound nats
Address 1300 York Ave. Rm. 123	4b Express Freight Service Factors in the service Factors and the service for
_{city} New York _{State} NY _{ZIP} 10021	Packaging FedEx FredEx Envelope* FedEx Pak* FedEx FedEx FedEx Other Tube: FedEx Table And FedE: Box Tube * Decland wild limit \$200.
First 24 characters will appear on invoice.	Special Handling SATURDAY Delivery NOT Available for Texture Towney Art Red X Locaton MOLD Weekday af Fed X Locaton Available for fed available
Company ABC College	Dees this bit permet centain despersors goods? Deck for the method methods. No Yes Provide the method methods. Separation of the second methods. Dry Loc Dry Loc Description of the second methods. Dry Loc Dry Loc Description of the second methods. Dry Loc Dry Loc Description of the second methods. Dry Loc Dry Loc Description of the second methods. Dry Loc Dry Loc
Recipient's 123 Main St. Address We cannot deliver to PO. Dates or PO. ZP codes. Address	Payment Bill for: Enter FedEx Acct. Na. or Credit Card Na. below. Sunder Recipient Third Party Credit Card Card Card Check Static ref
To request a package to hold at a specific fortile location, prior Fortile address here. <u>City</u> Baltimore State MD _{ZIP} 21231	Total Packages Total Weight Total Declared Value! 1 2 kg s
	Tour labelity a limited to 1000 unless you declare a higher value. See back the details, by using this Archill you agree the service conditions on the back of this Archill and in the commer Field's Service Guide, including terms that limit on labelity. 8 Residential Delivery Signature Options Fyour require a signature check Direct or indirect.
Store your addresses at fedex.com Simplify Your shipping. Manage your account. Access all the tools you need.	No Signature Pequired Medurade and a second at logistic detess are signified second at logistic Rev Oats (offerent ristation closed - social sector + PlintTO RV U.S.A. Str
As per attached Shipper's Declaration)ry ice ry ice, 9, UN 1845 xkg
Shipper's Declaration. not required. Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.	Cargo Aircraft Only

• (A) "To" / "From" Information: Complete "To" and "From" information.

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- (B) UN3245 and Proper Shipping Name: The "Nature and Quantity of Goods" box must show "UN3245, GMMO" or "UN3245, GMO" and the number of packages being shipped. For FedEx USA Airbills, which do not have this box, the text may be written in any free area of the Airbill.
- (C) Priority Shipping: Priority Overnight shipping is not required.
- (D) Other Packaging: Select "Other" packaging. FedEx packaging cannot be used to ship these materials
- (E) Dangerous Goods Designation: Select the "Yes. Shipper's Declaration not required" box.
- (F) Number of Packages: Enter the number of packages shipped (typically "1") and the total weight.

14.0 DNA Sequencing Sample Shipments to Cornell-Ithaca

Laboratory personnel must appropriately package DNA sequencing samples prior to shipment by EHS. The DNA samples must be packaged as follows.

14.1 PACKAGING REQUIREMENTS

14.1.1 Primary Receptacles

DNA should be in water or Tris (not in TE) in a 500ul screw cap vial. Bacterial cell pellets should be in 15ml round bottom tubes (e.g., Falcon 2059 tube) or a deep well block that holds >1ml.

14.1.2 Secondary Packaging

Place the samples in a properly labeled envelope and seal the envelope closed. The envelope should be unpadded and the appropriate size for the quantity and size of the samples being sent.

14.2 LABELING

Write your name, phone number, laboratory location, and order number on the envelope.

14.3 SHIPPING TO CORNELL-ITHACA

Laboratory personnel must drop off the DNA sequencing samples into the drop-box located in the B-building basement corridor of 1300 York Avenue. EHS will prepare the shipments to the DNA Sequencing Facility at Cornell-Ithaca.

15.0 Campus-to-Campus (C2C) Bus Service

This service applies to biological and chemical materials that are not regulated as hazardous materials by the U.S. Department of Transportation (DOT) <u>and</u> are allowed to be transported via the Campus-To-Campus (C2C) Bus Service between WCM in New York City and Cornell University's Ithaca campus.

Permitted biological and chemical materials must be appropriately packaged, marked, and labeled and meet package terms and conditions.

15.1 PACKAGING REQUIREMENTS, MARKING & LABELING, AND QUANTITY LIMITATIONS

Contact Cornell C2C Service Hotline at 607-254-8747 or transportation@cornell.edu to see if the item can be transferred by bus and to arrange the use of this service.

16.0 Dry Ice Shipper Requirements

Dry ice must be shipped in compliance with IATA Packing Instruction 954. Shippers are compliant with the requirements of IATA Packing Instruction 954 when shipping in accordance with this Manual and utilizing appropriate packaging.

16.1 PACKAGE QUANTITY LIMITATIONS

Packaging must not contain more than 200 kg of dry ice.

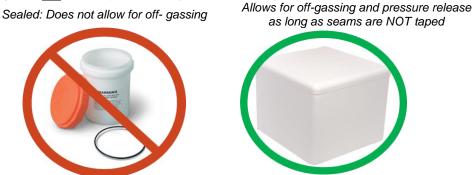
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16.2 PACKAGING REQUIREMENTS

16.2.1 Venting

Dry ice must utilize packaging designed and constructed to permit the release of carbon dioxide gas and prevent a build-up of pressure that could rupture the package. Do <u>not</u> place dry ice in airtight canisters, bags, or other containers.



16.2.2 Package Integrity

The package must be free from damage and 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. Styrofoam coolers are not suitable outer containers. They must be shipped inside a sturdy cardboard box.

Examples include commercially available packaging systems consisting of a Styrofoam container within a durable and rigid cardboard box.

16.2.3 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.

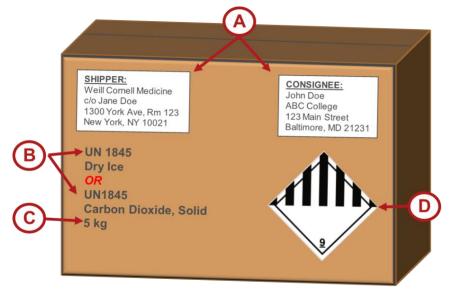
16.2.4 Packaging Vendors

A list of packaging vendors is provided in <u>Appendix E</u>. FedEx boxes are <u>not</u> acceptable for shipping dry ice.

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16.3 MARKINGS AND LABELS

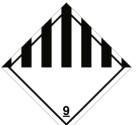


- (A) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package.
- (B) "UN1845" and Proper Shipping Name: One of the following proper shipping names and UN1845 identification number for dry ice must be marked on the package. No spelling variations are acceptable.

"UN1845, Dry Ice", or

"UN1845, Carbon Dioxide, Solid".

- (C) Net Weight of Dry Ice: The net weight of dry ice placed in the package <u>must</u> be marked on the package adjacent to the proper shipping name and UN number. The net weight <u>must</u> be in kilograms.
- (D) Class 9 Hazard Class Label:



- Class 9 hazard class label must be affixed to the side of the package.
- Labels must be at least 100mm x 100mm (4"x 4") in size. Use only pre-printed shipping labels.
 - Package must be large enough for the label to fit on one side.

As of **October 1, 2014**, shippers can no longer utilize Class 9 Hazard Class labels containing a horizontal line through the midpoint. Above is an image of the revised Class 9 Hazard class label.

16.4 SHIPPING DOCUMENTATION

16.4.1 Itemized List of Contents / Commercial Invoice and Shipper's Declaration for Dangerous Goods

An Itemized List of Contents and Shipper's Declaration are <u>not</u> required. If a Shipper's Declaration is required for another dangerous good (e.g., Category A infectious substance), then the information pertaining to dry ice must be included.

A commercial invoice should be utilized for international shipments.

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Documents Required	Airway Bill	Itemized List of Contents	Declaration of Dangerous Goods
UN 1845, Dry Ice	Yes	International Shipments Only	-

16.4.2 Carrier's Air Waybill

The following must be identified on the carrier's air waybill, as shown in the example FedEx Airbill below.

Fedex, US Airbill	🐘 🛛 😂 D200 Sender's Copy
I FTOIL Please print and press hard. Sondar's EadEv	Express Package Service Packages up to 150 lbs.
Date 3/20/19 Sender's FEDEX SEMDER'S FEDEX ACCOUNT NUMBER ONLY	FedEx Priority Overnight FedEx Standard Overnight Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard Standard
A Jane Doe 646 962 1234	FedEx 2Day Second Subsets day: "Thursday: Jedend Subsets of Monday windex STURDAY Collever's instructul. FedEx Express Saver That Subsets day. That Subsets
Company Weill Cornell Medicine	4b Express Freight Service Packages over 150 lbs.
Address 1300 York Ave. Rm. 123	FedEx 1Day Freight* Second basis of the finance of the fi
City New York State NY ZIP 10021	Packaging FedEx FedEx Pak* FedEx FedEx X Other Envelope* FedEx Law PA & FedEx Tube FedEx Law PA & effects Sum PA FedEx FedEx Pak* FedEx Complexity FedEx FedEx FedEx Complexity FedEx
2 Your Internal Billing Reference BPTIONAL	FedEx Large Pak, and FedEx Startly Pak. *Declared value timt 2000. Special Handling Include FedEx address in Section 3.
3 To Recipient's John Doe phone (123 (456-7890	SATURDAY Delivery NOT Available for FedS booked benefits FedS b
ABC College	Does this shipment contain dangerous goods?
company	No Ves statched Spiper's Declaration Acregate Carlos Declaration Ref packaging. Cargo Aircraft Only
Recipient's 123 Main St.	Payment Bill to: Enter FedEx Acct. No. or Credit Card No. below.
We cannot deriver to PD bases or PD ZPP codes. Dept/PoorSube/Room Address	Sender Recipient Third Party Credit Card Card/Check
To request a package to held at a specific FedEx location, print FedEx address here.	r Acet No. Exp.
_{City} Baltimore _{State} MD _{ZIP} 21231	Total Packages Total Weight Total Declared Value*
	¹ Our fability is limited to \$100 unless you declare a higher value. See back for details. By using this Arbitility as greaters the service conditions on the back of this Arbitilit and the uncerner fields service (backs, including terms that limit can will be approximately as a service of the service of the arbitility of the service
-	8 Residential Delivery Signature Options #you require a signature, check Direct or Indirect.
Store your addresses at fedex.com Simplify your shipping. Manage your account. Access all the tools you need.	No Signature Direct Signature Segurad in Segurad Methods with the segurad frequency and the seguration of the segura
1	Nex. Uses indeman analyzing-2008 Hebberrini LD IN U.S.A. Shi
Does this shipment contain dangerous goods?	
One box must be checked.	
No Yes As per estached Shipper's Declaration	Dry Icexkg
Dangerous goods (including dry ice) cannot be shipped in FedEx packaging.	Cargo Aircraft Only

- (A) "To" / "From" Information: Complete "To" and "From" information.
- (B) Priority Shipping: It is highly recommended that all packages with dry ice be shipped priority overnight whenever possible. Insulated containers will still sublimate an estimated 5 to 10 pounds of dry ice in a 24-hour period. Actual timeframes will vary depending on the package used and volume and density of dry ice.
- (C) Other Packaging: Select "Other" packaging. FedEx packaging cannot be used to ship these materials.
- (D) Dangerous Goods Designation: Select the "Yes Shipper's Declaration not required" box.
- (E) Nature and Quantity of Goods: The proper shipping name, hazard class, UN identification number, number of packages, and net weight must be entered on the carrier's air waybill.
 - Pre-Printed (e.g., FedEx Airbills): FedEx pre-prints this information in Section 6 of their FedEx USA Airbill for domestic service. Complete the following:
 - 1. Check the Dry Ice box.
 - 2. Enter the total number of packages and net weight of dry ice per package in kilograms.
 - Not Pre-Printed Information: If the information is <u>not</u> pre-printed, the following information must be entered in the Nature and Quantity of Goods section of the carrier's air waybill:

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- 1. Enter "UN1845, Dry Ice, 9" or "UN1845, Carbon Dioxide, Solid, 9".
- 2. (Enter # of packages) x (Enter net weight per package, in kilograms). For example package: 1 x 5 kg.
- (F) Number of Packages: Enter the number of packages shipped (typically "1") and the total weight.

17.0 Excepted Quantities

Excepted quantities of chemicals and chemical solutions must meet the following shipping requirements in addition to the shipping requirements of the non-infectious biological being shipped. Please note this section applies only to shipping as a preservative with non-infectious biological material. Contact EHS to review shipments of any chemicals not specifically approved in this section.

17.1 CONTAINER SIZE AND QUALITY LIMITATION

Class	Hazard	Maximum amount per <i>inner container</i> (gm solid/ml liquid)	Maximum amount per <i>entire package</i> (gm solid/ml liquid)
Class 3	Flammable	30	300
Class 8	Corrosive Material	30	500

17.2 PACKAGING REQUIREMENTS

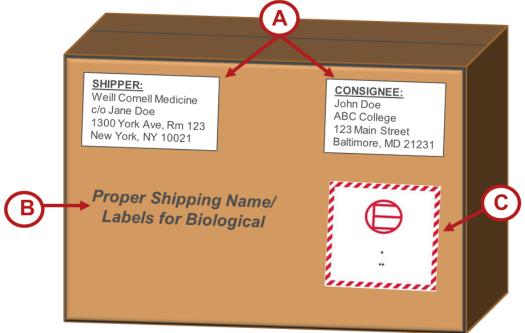
Packaging must comply with packaging requirements of the non-infectious biological and

- Each inner container must be closed (capped) and its cap is secured with tape or other positive means
- Chemically compatible absorbent/cushioning material must be added around the inner container capable of absorbing the entire liquid contents of the inner container(s)
- The inner containers must be packaged in a strong, rigid outer packaging
- Outside packaging must be capable of sustaining drops on all sides and edges from a height of 1.8 m (5.9) ft onto a solid surface.

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17.3 MARKINGS AND LABELS



- (A) Ship "From" and "To" Information: The full name and address of the shipper ("From") and consignee ("To") must be clearly labeled or marked on the package.
- (B) Proper Shipping Name and/or Label of Biological Material: The package must be marked with the proper shipping name (or hazard label if shipping GMO/GMMO) of the non-infectious biological substance.
- (C) Excepted Quantity Label:



- Excepted Quantity label must be affixed to the side of the package.
- Labels must be at least 100mm x 100mm (4"x 4") in size. Use only pre-printed shipping labels.
- Package must be large enough for the label to fit on one side.
- *Place for class or, when assigned, the division number(s).
- **Place for name of shipper or consignee, if not shown elsewhere on the package.

17.4 SHIPPING DOCUMENTATION

17.4.1 Itemized List of Contents / Commercial Invoice and Shipper's Declaration for Dangerous Goods

Excepted quantities do not need to be noted on the Itemized List of Contents and Shipper's Declaration.

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17.4.2 Carrier's Air Waybill

When shipping Excepted Quantities, the Air Waybill selection "Dangerous goods as per attached Shipper's Declaration" or "Dangerous goods as per attached DGD" does not apply as long as the chemicals meet the excepted quantities requirements AND are not shipped with other dangerous goods.

The following endorsement is required in the "Nature and Quantity of Goods" box on the Air Waybill:

- "Dangerous Goods in Excepted Quantities"
- The number of packages (unless these are the only packages within the consignment).

18.0 Itemized List of Contents/ Commercial Invoice

An itemized list of contents (also called a commercial invoice) is always required for the shipment of Category A Infectious Substances and Category B Biological Substances. A commercial invoice must be utilized for international shipments of any biological.

18.1 ITEMIZED LIST OF CONTENTS/ COMMERCIAL INVOICE

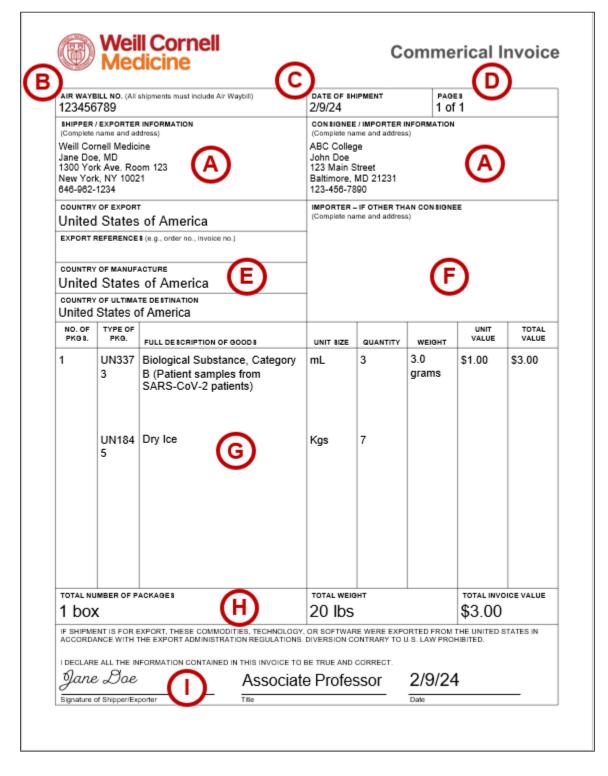
An example <u>commercial invoice</u> may be utilized if an itemized list of contents is not available

18.2 GENERAL REQUIREMENTS

- The person completing the form must have received Biological Material and Dry Ice Shipments training within the past two years (refer to <u>Section 20.0</u> of this manual).
- The Itemized List of Contents/ Commercial Invoice must be completed in English.
- A copy of the finalized form must be enclosed between the secondary packaging and the outer packaging.

18.3 ITEMIZED LIST OF CONTENTS/ COMMERCIAL INVOICE INSTRUCTIONS

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• (A) Shipper and Consignee Information: Enter the full name, address, and contact number of the shipper and consignee.

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Weill Cornell Medicine c/o (Shipper name or Principal Investigator) Street Address Phone Number

- (B) Air Waybill Number: Enter the carrier's air waybill unique tracking number.
- (C) Date of Shipment: enter the date the shipment will take place
- (D) Page Number(s): Enter the page number(s), typically "1 of 1".
- (E) Export Control:
 - Country of Export: Enter "United States of America"
 - **Export References**: Optional. May enter order or invoice number if available.
 - Country of Manufacture: Enter the country your product was made in.
 - **Country of Ultimate Destination:** Enter the recipient country
- (F) Importer- If Other Than Consignee:
- (G) Content Information:
 - No. of Packages: Enter the number of packages
 - **Type of Package**: Enter the UN number of the dangerous good being shipped.
 - Full Description of Goods:
 - Utilize the following table to assist in completing the Full Description of Goods portion. Select the appropriate proper shipping name(s), which identify the dangerous goods being shipped, and fill in the related information onto the Itemized List of Contents.

UN No.	Proper Shipping Name
UN2814	Infectious Substance, Affecting Humans
	(Insert Technical Name of Infectious Substance)
UN2900	Infectious Substance, Affecting Animals
	(Insert Technical Name of Infectious Substance)
UN3245	Genetically Modified Micro-Organisms
	(Insert Technical Name Substance)
UN3245	Genetically Modified Organisms
	(Insert Technical Name Substance)
UN3373	Biological Substance, Category B
	(Insert Technical Name Substance)
UN1845	Dry Ice or
	Carbon Dioxide, Solid

- Unit Size, Quantity, Weight: Unit of measurement (ex: mL, kg), the number of samples, the total weight of samples
- Unit Value and Total Value: value of each unit and total value of line item.
- (H) Totals:
 - Total Number of Packages: Enter the total number of packages being shipped
 - Total Weight: Enter the total weight of the entire shipping box once packed
 - **Total Invoice Value:** Total the value of all line items in the shipment and put the total here.
- (I) Signature of Shipper: The person signing the Shipper's Declaration must be properly trained and have first-hand knowledge of the shipment. While it is acceptable to have an untrained Principle Investigator, Doctor, or Manager's name listed in the Shipper Section, the Certification Section must identify and be signed by only the trained shipper.
 - Each copy of the Itemized List of Contents/ Commercial Invoice must be signed either by hand or using approved signature software. A typed signature is not allowed.

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19.0 Shipper's Declaration for Dangerous Goods

A Shipper's Declaration for Dangerous Goods is always required for the shipment of Category A Infectious Substances.

A completed example of a Shipper's Declaration for **one** dangerous good shipped (e.g., Category A Infectious Substance, ambient or ice packs, without Dry Ice) is provided in <u>Appendix F.</u> A completed example of a Shipper's Declaration for **two** dangerous goods shipped (e.g., Category A Infectious Substance with Dry Ice) is provided in <u>Appendix G</u> and used as an example in Section 19.4 Shippers Declaration Instructions.

19.1 SHIPPER'S DECLARATION - FEDEX APPROVED VENDOR SOFTWARE

Fed-Ex requires all Shippers Declarations to be prepared using FedEx-approved third-party software with error checking capabilities. In past years, shippers could use fillable PDF documents to prepare Shippers Declarations. This is no longer allowed. **Contact EHS for** access to FedEx-approved Shipper's Declaration software.

19.2 GENERAL REQUIREMENTS

- The person completing the form must have received Biological Material and Dry Ice Shipments <u>and</u> Infectious Substance, Category A training within the past two years (refer to <u>Section 20.0</u> of this manual).
- The Shipper's Declaration must be completed in English using the online Shipper Declaration software to prepare the document. The use of historical, fillable PDFs is no longer accepted by FedEx.
- Three (3) color copies with vertical red hatchings must accompany the shipment. Each copy must be identical and comply with all the requirements.
- The Shipper's Declaration form must fit on one page. If the declaration form does not contain sufficient space, additional Shipper's Declaration forms may be used and must show:
 - A page number and the total number of pages,
 - The Air Waybill number, and
 - Aircraft limitation and shipment type must be the same on all pages.
- Alterations and amendments made to the Shipper's Declaration must be signed with the same signature used to sign the document (refer to <u>Section 14.2</u>).

19.3 24-HOUR EMERGENCY RESPONSE INFORMATION

IATA and USDOT require that the Shipper's Declaration identify an emergency response contact that is immediately available 24-hours to provide technical information and emergency response guidance. To satisfy this requirement, Weill Cornell Medical College retains the services of ChemTel (VelocityEHS) and utilizes their 24-hour emergency telephone number.

In order to utilize this service, shippers must complete the following steps:

- Complete the Shipper's Declaration and provide the ChemTel emergency contact information outlined in the Shipper's Declaration Instructions.
 - Shipments <u>within</u> the United States, Canada, Puerto Rico, and the U.S. Virgin Islands should reference ChemTel's toll free phone number: +1-800-255-3924
 - Shipments <u>outside</u> of the U.S., Canada, Puerto Rico, and the U.S. Virgin Islands must use ChemTel's international phone number: +1-813-248-0585
 - o Collect calls are accepted.
 - Shipments originating in the U.S. and going oversees <u>must use both numbers</u>. Shipment originating overseas and destined for the U.S., Canada, Puerto Rico, or the Virgin Islands <u>must also use both numbers</u>.
- On the Shipper's Declaration of Dangerous Goods include WCM's ChemTel (VelocityEHS) Contract# (Contact EHS for contract number)

Submit the following to CHEMTEL at <u>ERSSDS@ehs.com</u> prior to the shipment:

 An appropriate Pathogen Safety Data Sheet (PSDS) for an infectious substance being shipped (excellent options can be found here).

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A copy of the completed Shipper's Declaration of Dangerous Goods

For large data transmissions, please contact a customer service representative to obtain access to a secure FTP (file transfer protocol) site.

- Christina Arroyo Manager, ERS Services carroyo@ehs.com
- Kristine Flowers Accounts Receivable & Customer Support kflowers@ehs.com

19.4 SHIPPER'S DECLARATION INSTRUCTIONS

Example shown is for one Category A dangerous good being shipped with dry ice within the United States. See completed form in Appendix G.

(A) Shipper and Consignee Information: Enter the full name and address of the shipper and consignee. Shipper information must be as follows in order to comply with ChemTel 24-Hour Emergency Contact Information.

Weill Cornell Medicine

c/o (Shipper name or Principal Investigator)

Street Address

- (B) Air Waybill Number: Enter the carrier's air waybill unique tracking number.
- (C) Page Number(s): Enter the page number(s), typically "1 of 1."
- (D) Transport Details / Limitations:

DA

- For shipments of Infectious Substances Category A utilizing the Cargo Aircraft Only outer packing limits in accordance with Section 10.1.2, cross-out or XXX-out "Passenger and Cargo Aircraft."
 - For all other shipments packaged in accordance with this procedure cross-out or XXX-out "Cargo Aircraft Only".
- (E) Airport of Departure and Destination: If this is unknown, enter in the city, state, and country associated with the Shipper and Consignee in the respective Departure and Destination boxes.
- (F) Shipment Type: Cross-out or XXX-out the word "Radioactive."

Shipper	Weill Cornell Medicin	ne	Air Waybill No. 123456789	90	
	Jane Doe, MD 1300 York Ave Roor	n 123	Page 1 of 1 Pages		
New York, NY 10021		1	Shipper's Reference Number (optional)		
Consign	 John Doe ABC College 123 Main Street Baltimore, MD 23237 	1	G	JREAU OF ANGEROUS OODS	
	Two completed and signed copies of this Declaration must be handed to the operator		WARNING		
	ORT DETAILS		Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of		
limitation	s prescribed for n-applicable) Ne	ew York City	the applicable law, subject to		
Airport o	f Destination Baltimore		Shipment Type (delete non-	-applicable)	
				RADIOAETIKEXXX	
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19.5 NATURE AND QUANTITY OF DANGEROUS GOODS:

Utilize the following table to assist in completing the Nature and Quantity of the Dangerous Goods portion of the Shipper's Declaration. Select the appropriate proper shipping name(s), which identify the dangerous goods being shipped, and fill in the related information onto the Shipper's Declaration.

UN or ID No. "G"	Proper Shipping Name " H "	Class or Division " "	Packing Group "J "	Packing Inst. "L"
UN2814	Infectious Substance, Affecting Humans (Insert Technical Name of Infectious Substance)	6.2		620
UN2900	Infectious Substance, Affecting Animals (Insert Technical Name of Infectious Substance)	6.2		620
UN3245	Genetically Modified Micro-Organisms	9		959
UN3245	Genetically Modified Organisms	9		959
UN3373	Biological Substance, Category B	6.2		650
UN1845	Dry Ice <i>or</i> Carbon Dioxide, Solid	9		954

- Technical Names must be recognized microbiological names currently used in scientific and technical handbooks, journals, and texts. Do not use abbreviations. Spell-out the full name of the infectious substance/disease.
- Unknown but Suspected Category A Infectious Substance (Special Provision "A140") If the infectious substance being transported as UN2814 or UN2900 is unknown but suspected of meeting the criteria for inclusion in Category A the words "Suspected Category A Infectious Substance" must be listed as the technical name.

19.5.1 Quantity and Type of Packaging

• (K) One Dangerous Good Shipped: Identify the number and type of packages and net quantity of the dangerous goods. The unit of measure for the net quantity must be the same as indicated in the "Container Size Limitations" for the dangerous goods specific shipper requirements. Examples include:

- "1 fiberboard box x 25 g" where 1 package contains 25 total grams of the solid biological material.
- "2 fiberboard boxes x 25 ml" where 2 packages contain 25 total milliliters per package of liquid biological material.
- (K) Two or More Dangerous Goods Shipped: When two or more different dangerous goods are packed into the same outer package (i.e., multiple types of biological materials and/or dry ice), only indicate the net quantity of the dangerous goods on the corresponding line of the Shipper's Declaration. The unit of measure for the net quantity must be the same as indicated in the "Container Size Limitations" for the dangerous goods specific shipper requirements.
 - Underneath the last dangerous good in this package, write "ALL PACKED IN ONE" and then the type of package (e.g., "All packed in one fiberboard box").
- (M) Authorization: If the special provision referred to in <u>Section 10.1.2</u> was utilized for this shipment, then "A81" must be listed in this portion of the Shipper's Declaration. Otherwise, leave this area blank.

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	Dangerous Goods Identification					
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Hazard)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization
	Infectious substance, affecting humans (Mycobacterium tuberculosis)	6.2		3.0 mL	620	
UN1845	Dry Ice	9		7 kg	954	
G	H	\bigcirc		All packed in one Fibreboard box		M

19.6 ADDITIONAL HANDLING INFORMATION:

(N) Additional Handling Information:

<u>Responsible Person Contact Information</u>: The name and telephone number of a responsible person must be included on the Shipper's Declaration for infectious substances in Category A (UN 2814 and UN 2900). This contact should be the shipper or someone else familiar with the contents of the shipment but is not the 24-hour Emergency Contact. Provide the following Responsible Person Contact Information in the Additional Handling section:

"Responsible Person: (Insert Shipper Name and Phone Number)"

<u>24-Hour Emergency Contact</u>: EHS has contracted the services of ChemTel to serve as the 24-hour emergency contact for WCM shipments. As such, "Weill Cornell Medical College" must appear on the first line of the "Shipper" information on the Shipper's Declaration. Provide the following 24-Hour Emergency Contact information in the "Emergency Telephone Number" and "Emergency Response Contract Name" and this will auto populate the information into the Additional Handling section:

- <u>US / Domestic Shipments</u>: "Emergency Contact: ChemTel: +1-800-255-3924 (Weill Cornell Medical College Customer Code – Contact EHS for code)"
- International Shipments: "Emergency Contact: ChemTel: +1-813-248-0585 (Weill Cornell Medical College Customer Code – Contact EHS for code)"

Additional Handling Information 24-Hour Emergency Contact Telephone Number: CHEMTEL 1-800-255-392 Weill Cornell Medicine Contract#Contact EHS for Code CHEMTEL Within US/Canada/Puerto Rico/ US Virgin Islands: 1-800-255-3924 Outside US/Canada/Puerto Rico/ US Virgin Islands: 1-813-248-0585	-3924	
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.	Name of Signatory Jane Doe Date December 22, 2021 Signature (see warning above)	

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19.7 CERTIFICATION STATEMENT AND SIGNATURE:

Enter the name of the signatory. The person signing the Shipper's Declaration must be properly trained and have first-hand knowledge of the shipment. While it is acceptable to have an untrained Principle Investigator, Doctor, or Manager's name listed in the Shipper Section, **the Certification Section must be identified and signed by only the trained shipper.**

Each copy of the Declaration of Dangerous Goods must be signed by the signatory. A typed signature is not acceptable.

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.	Name of Signatory Jane Doe Date February 23, 2021 Signature (see warning above) Jane Doe	
--	--	--

20.0 Additional Carrier Requirements (Airway Bills)

In addition to the requirements established by IATA for the transport of dangerous goods by air, specific carriers may have more stringent requirements. The shipper must contact their intended carrier and verify if the carrier has any additional requirements from those specified in this Manual. The following are additional limitations for a few common carriers that relate to shipment of biological materials.

20.1 FEDERAL EXPRESS (FEDEX)

The following are the additional requirements and limitations for FedEx.

- Risk Group 4 Infectious Substances FedEx will not accept Risk Group 4 infectious substances for shipment.
- Shipper's Declaration FedEx Approved Vendor Software: FedEx requires all Shippers Declarations to be prepared using FedExapproved third-party software with error-checking capabilities. In past years, shippers could use fillable PDF documents to prepare Shippers Declarations. This is no longer allowed.
 - Contact EHS for access to FedEx-approved Shipper's Declaration software.
- Shipper's Declaration Three Copies: When a Shipper's Declaration is required, three (3) color copies must be provided with each shipment at the origin location.

20.2 UNITED PARCEL SERVICE (UPS)

The following are the additional requirements and limitations for UPS.

- Category A Infectious Substances: UPS will not accept shipments of Category A Infectious Substances. UPS will only accept shipments of:
 - Category B Biological Substances
 - Exempt Patient Specimens
 - Non-Regulated Specimens
- Contracted Services: International shipments of Category B Biological Substances without an approved contract with UPS are
 prohibited. Shippers must establish contracted services with UPS in order to ship Category B substances.

21.0 Pre-Shipment Storage and Security

All packages of dangerous goods prepared in accordance with this Manual <u>must</u> remain in the possession of and under the supervision of the Shipper, until collected by the transport company. <u>The use of drop box locations is prohibited</u>. Additionally, any concerns regarding unauthorized personnel representing a possible security threat must be reported to NYP Security (212-746-0911) and EHS immediately.

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22.0 Training

All Weill Cornell Medical College employees who prepare shipments and/or complete the shipping documents (i.e., "shippers") in accordance with this procedure must satisfactorily complete Biological Material and Dry Ice Shipper Training; and related safety training <u>before</u> conducting a shipping activity. Shippers who will be shipping Infectious Substances, Category A are required to additionally complete a specialized Category A training.

Training must be recurrent at least once every two years.

22.1 SAFETY TRAINING

Safety training is a required component for dangerous goods shipment training. This requirement is satisfied with the completion of either (1) Laboratory Safety or (2) Clinical and General Safety training.

- Laboratory Safety Training is required for shippers working in laboratories that handle or use biological materials and chemicals (e.g., dry ice or chemical preservatives).
- Clinical and General Safety Training is required for shippers working in clinical areas that handle clinical specimens and chemicals (e.g., dry ice, formalin).

22.2 BIOLOGICAL MATERIAL AND DRY ICE SHIPMENTS TRAINING

Biological Material and Dry Ice Shipments training consists of two components:

- Biological Material and Dry Ice Shipments Training Course: Shippers must attend the Biological Material and Dry Ice Shipment Training course once every two years and successfully pass the Biological Material and Dry Ice Shipment competency test. Upon successful completion of the training course and competency test, the shipper will be provided a certificate of training. Only upon receipt of this certificate is the training attendee authorized to act as the shipper of biological materials or dry ice.
 - Infectious Substance, Category A Shipments Training Course: Shippers who will be packaging, shipping, or preparing the paperwork for Infectious Substances, Category A must additionally complete the Category A Training course once every two years and successfully pass the competency test. Upon successful completion of the training course and competency test, the shipper will be provided a certificate of training. Only upon receipt of this certificate is the training attendee authorized to act as the shipper of Infectious Substances, Category A.
- Prior to Shipping Biological Materials and Dry Ice: Shippers must have read and be familiar with the requirements identified in the most current version of this procedure prior to each shipment.
- Note: that IATA re-issues its regulations on an annual basis and may revise the shipper requirements throughout the course of the year. All necessary revisions will be made accordingly by EHS to this Manual; it is the shipper's responsibility to ensure they are using the most up-to-date version of the manual which will be posted on the EHS website.

23.0 Record Retention, Availability, and Revisions

23.1 TRAINING RECORDS

Once training has been completed, Certificates of Training will be provided to shippers who have successfully completed the training requirements. A printed copy of the training certificate must be centrally filed for a minimum of <u>3 years</u> and be readily available for inspection. If training is conducted by a training entity other than EHS, then it is the responsibility of the shipper to obtain and maintain copies of their training records and training materials.

23.2 SHIPPING DOCUMENTS

Shipping documents, (e.g. Shipper's Declaration for Dangerous Goods, Airbills, and Commercial Invoices) must be retained by the Shipper for a minimum of <u>5 years</u> from the date of shipment and made available upon request by EHS or a governing agency.

23.3 PACKAGING CLOSURE INSTRUCTIONS

Packaging closure instructions for DOT Specification or UN standard packaging subject to federal and international shipping regulations must be retained for a minimum of <u>90 days</u>.

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23.4 REVISIONS

IATA revises the Dangerous Goods Regulations on an annual basis and/or throughout the course of the year. This procedure will be updated by EHS accordingly. Shippers must ensure that all shipments of biological materials are in accordance with the most current version of this procedure. The most current version of this procedure will be posted on the <u>EHS website</u>.

24.0 Definitions

Biological products are those products derived from living organisms, which are manufactured and distributed in accordance with the requirements of appropriate national authorities. These products may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans 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.

Carrier(s) means a person or entity engaged in the transportation of passengers or property by:

- Land or water, as a common, contract, or private carrier, or
- Civil aircraft.

Corrosives (Class 8) are substances that, by chemical action, can cause severe damage when in contact with living tissue or, in the case of leakage, will materially damage or even destroy, other goods or the means of transport. Refer to the MSDS or contact EHS to determine if the substance is corrosive.

Cultures are the result of a process by which pathogens are intentionally propagated. This definition does <u>not</u> include patient specimens.

Dangerous goods are articles or substances that are capable of posing a risk to health, safety, property, or the environment. General classifications of dangerous goods include explosives, gases, flammable liquids, flammable solids, spontaneously combustibles, water-reactives, oxidizers, organic peroxides, toxic and infectious substances, radioactive material, corrosives, and miscellaneous.

Flammable liquid (Class 3) comprises liquids or mixtures of liquids or liquids containing solids in solution or in suspension, which give off a flammable vapor at temperatures of not more than 60°C (140°F) closed-cup test. Refer to the MSDS or contact EHS to determine if the substance is a flammable liquid.

Foreign national is any person other than a U.S. citizen, U.S. permanent or temporary legal resident alien, or person in U.S. custody.

Genetically modified micro-organisms and organisms are micro-organisms (GMMO) and organisms (GMO) in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Infectious substances are substances that are known or are reasonably expected to contain pathogens.

Miscellaneous Dangerous Goods (Class 9) are articles and substances, which during air transport, present a danger not covered by other classes. Refer to the MSDS or contact EHS to determine if the substance is a miscellaneous dangerous good.

Net quantity is the weight or volume of the dangerous goods contained in a package, excluding the weight or volume of any packaging material. **Note:** only International System units of measure (e.g., kg, g, L, ml, etc.) may be used when shipping dangerous goods by air.

Pathogens are micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) and other agents, such as prions, which can cause disease in humans or animals.

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.

Select agents and toxins are viruses, bacteria, rickettsia, fungi, and toxins that, according to U.S. Department of Human Health Services and the U.S. Department of Agriculture, have the potential to cause substantial harm to public health, animal or plant health, or to animal or plant products. *The shipment of select agents can only be conducted by the WCM Responsible Official*. Contact EHS for further assistance in shipping Select Agents.

Shipper(s) refers to WCM faculty, staff, employees, or students who perform any of the activities in steps 3 through 9 of the shipment process identified in Section 3.0 – Objective.

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World Health Organization (WHO) Risk Group is characterized by the pathogenicity of the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventative agents and treatment. The Risk Group criteria are developed and published in the *World Health Organization Laboratory Biosafety Manual (third edition, 2004).*

Risk Group 4 (high individual and community risk): a pathogen 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 treatment and preventative measures are not usually available.

25.0 References

- 49 CFR Subchapter C Hazardous Materials Regulations
- American Biological Safety Association (<u>https://my.absa.org/tiki-index.php?page=Riskgroups</u>)
- Federal Express Dangerous Goods Shipping
- IATA Dangerous Goods Regulations (65th Edition, 2024)
- National Select Agent Registry (http://www.selectagents.gov/)
- University of New Hampshire Shipment of Biological Material Manual
- UPS Guide to Shipping International Dangerous Goods
- UPS Guide to Shipping Ground and Air Hazardous Materials

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Appendix A: IATA Provisions for Dangerous Goods Carried by Passengers or Crew 65th Ed. 2024

TABLE 2.3.A Provisions for Dangerous Goods Carried by Passengers or Crew (Subsection 2.3)

Dangerous goods must not be carried in or as passengers or crew, checked or carry-on baggage, except as otherwise provided below. Dangerous goods permitted in carry-on baggage are also permitted "on one's person", except where otherwise specified.

The pilot-in-con	nmand mu	st be infor	med of the	location
Permit	ted in or a	s carry-on	baggage	
Permitted in or a	s checked	baggage		
The approval of the operator is	required			
Alcoholic beverages, when in retail packagings, containing more than 24% but not more than 70% alcohol by volume, in receptacles not exceeding 5 L, with a total net quantity per person of 5 L.	NO	YES	YES	NO
Note: Alcoholic beverages containing 24% or less alcohol by volume are not subject to any restrictions.				
Ammunition, securely packaged (in Div. 1.4S, UN 0012 or UN 0014 only), in quantities not exceeding 5 kg gross weight per person for that person's own use. Allowances for more than one person must not be combined into one or more packages.	YES	YES	NO	NO
Avalanche rescue backpack, one (1) per person, containing cartridges of compressed gas in Div. 2.2. May also be equipped with a pyrotechnic trigger mechanism containing no more than 200 mg net of Div. 1.4S. The backpack must be packed in such a manner that it cannot be accidentally activated. The airbags within the backpacks must be fitted with pressure relief valves.	YES	YES	YES	NO
Baggage with installed lithium batteries non-removable batteries exceeding=0.3 g lithium metal or 2.7 Wh.		FORB	IDDEN	I
Baggage with installed lithium batteries:	NO	YES	YES	NO
 non-removable batteries. Batteries must contain no more than 0.3 g lithium metal or for lithium ion must not exceed 2.7 Wh; 				
 removable batteries. Batteries must be removed if baggage is to be checked in. Removed batteries must be carried in the cabin. 				
Batteries, spare/loose, including lithium batteries, non-spillable batteries, nickel-metal hydride batteries and dry batteries (see 2.3.5.8) for portable electronic devices must be carried in carry-on baggage only. Articles which have the primary purpose as a power source, e.g. power banks are considered as spare batteries. These batteries must be individually protected to prevent short circuits. Lithium metal batteries: the lithium metal content must not exceed 2 g (see 2.3.5.8.4). Lithium ion batteries: the Watt-hour rating must not exceed 100 Wh (see 2.3.5.8.4). Each person is limited to a maximum of 20 spare batteries. "The operator may approve the carriage of more than 20 batteries. Non-spillable batteries: must be 12 V or less and 100 Wh or less. Each person is limited to a maximum of 2 spare batteries (see 2.3.5.8.5).	NO*	NO	YES	NO
Camping stoves and fuel containers that have contained a flammable liquid fuel, with empty fuel tank and/or fuel container (see 2.3.2.5 for details).	YES	YES	NO	NO
Chemical Agent Monitoring Equipment, when carried by staff members of the Organization for the Prohibition of Chemical Weapons on official travel (see 2.3.4.4).	YES	YES	YES	NO
Disabling devices such as mace, pepper spray, etc. containing an irritant or incapacitating substance are forbidden on the person, in checked and carry-on baggage.		FORB	IDDEN	
Dry ice (carbon dioxide, solid), in quantities not exceeding 2.5 kg per person when used to pack perishables not subject to these Regulations in checked or carry-on baggage, provided the baggage (package) permits the release of carbon dioxide gas. Checked baggage must be marked "dry ice" or "carbon dioxide, solid" and with the net weight of dry ice or an indication that there is 2.5 kg or less dry ice.	YES	YES	YES	NO
e-cigarettes (including e-cigars, e-pipes, other personal vaporizers) containing batteries must be individually protected to prevent accidental activation (see 2.3.5.8.2).	NO	NO	YES	NO
Electro shock weapons (e.g. Tasers) containing dangerous goods such as explosives, compressed gases, lithium batteries, etc. are forbidden in carry-on baggage or checked baggage or on the person.		FORB	IDDEN	
Fuel cells containing fuel, powering portable electronic devices (e.g. cameras, cellular phones, laptop computers and camcorders), see 2.3.5.9 for details.	NO	NO	YES	NO
Fuel cell cartridges, spare for portable electronic devices, see 2.3.5.9 for details.	NO	YES	YES	NO
Gas cartridges, small, non-flammable containing carbon dioxide or other suitable gas in Division 2.2. Up to two (2) small cartridges fitted into a self-inflating personal safety device, intended to be worn by a person, such as a life jacket or vest. Not more than two (2) devices per passenger and up to two (2) spare small cartridges per device, not more than four (4) cartridges up to 50 mL water capacity for other devices (see 2.3.4.2).	YES	YES	YES	NO
Gas cylinders, non-flammable, non-toxic worn for the operation of mechanical limbs. Also, spare cylinders of a similar size if required to ensure an adequate supply for the duration of the journey.	NO	YES	YES	NO
Hair styling equipment containing a hydrocarbon gas cartridge, up to one (1) per passenger or crew- member, provided that the safety cover is securely fitted over the heating element. This hair styling equipment must not be used on board the aircraft. Spare gas cartridges for such hair styling equipment are not permitted in checked or carry-on baggage.	NO	YES	YES	NO

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TABLE 2.3.A Provisions for Dangerous Goods Carried by Passengers or Crew (Subsection 2.3) (continued)

The pilot-in-command must be informed of the			location	
Permitted in or as carry-on baggage			baggage	
Permitted in or a	s checked	baggage		
The approval of the operator is	required			
Insulated packagings containing refrigerated liquid nitrogen (dry shipper), fully absorbed in a porous material containing only non-dangerous goods.	NO	YES	YES	NO
Internal combustion or fuel cell engines, must meet A70 (see 2.3.5.12 for details).	NO	YES	NO	NO
Lithium Batteries: Portable electronic devices (PED) containing lithium metal or lithium ion cells or batteries, including medical devices such as portable oxygen concentrators (POC) and consumer electronics such as cameras, mobile phones, laptops and tablets (see 2.3.5.8). For lithium metal batteries the lithium metal content must not exceed 2 g and for lithium ion batteries the Watt-hour rating must not exceed 100 Wh. Devices in checked baggage must be completely switched off and must be protected from damage. Each person is limited to a maximum of 15 PED. *The operator may approve the carriage of more than 15 PED.	NO*	YES	YES	NO
Lithium batteries, spare/loose, including power banks, see Batteries, spare/loose	VED	MEG	VEC	
Lithium battery-powered electronic devices. Lithium ion batteries for portable (including medical) electronic devices, a Wh rating exceeding 100 Wh but not exceeding 160 Wh. For portable medical electronic devices only, lithium metal batteries with a lithium metal content exceeding 2 g but not exceeding 8 g. Devices in checked baggage must be completely switched off and must be protected from damage.	YES	YES	YES	NO
Lithium batteries, spare/loose with a Watt-hour rating exceeding 100 Wh but not exceeding 160 Wh for consumer electronic devices and PMED or with a lithium metal content exceeding 2 g but not exceeding 8 g for PMED only. Maximum of two spare batteries in carry-on baggage only. These batteries must be individually protected to prevent short circuits.	YES	NO	YES	NO
Matches, safety (one small packet) or a small cigarette lighter that does not contain unabsorbed liquid fuel, other than liquefied gas, intended for use by an individual when carried on the person. Lighter fuel and lighter refills are not permitted on one's person or in checked or carry-on baggage.	NO	ON O PER		NO
Note: "Strike anywhere" matches, "Blue flame" or "Cigar" lighters or lighters powered by a lithium battery without a safety cap or means of protection against unintentional activation are forbidden (see 2.3.5.8.4(e)).				
Mobility Aids: Battery-powered wheelchairs or other similar mobility devices with non-spillable wet batteries, nickel-metal hydride batteries or dry batteries, (see 2.3.2.2).	YES	YES	NO	YES
Mobility Aids: Battery-powered wheelchairs or other similar mobility devices with spillable batteries or with lithium ion batteries (see 2.3.2.3 and 2.3.2.4 for details).	YES	YES	NO	YES
Mobility Aids: Battery-powered wheelchairs or other similar mobility devices with lithium ion batteries where the design of the mobility aid does not provide adequate protection for the battery(ies) (see 2.3.2.4.3 for details).	YES	NO	YES	YES
Non-radioactive medicinal or toiletry articles (including aerosols) such as hair sprays, perfumes, colognes and medicines containing alcohol; and Non-flammable, non-toxic (Division 2.2) aerosols, with no subsidiary hazard, for sporting or home use (see 2.3.5.1).	NO	YES	YES	NO
The total net quantity of non-radioactive medicinal or toiletry articles and non-flammable, non-toxic (Division 2.2) aerosols must not exceed 2 kg or 2 L and the net quantity of each single article must not exceed 0.5 kg or 0.5 L. Release valves on aerosols must be protected by a cap or other suitable means to prevent inadvertent release of the contents.				
Oxygen or air, gaseous, cylinders required for medical use. The cylinder must not exceed 5 kg gross weight.	YES	YES	YES	YES
Note: Liquid oxygen systems are forbidden for transport.				
Permeation devices, must meet A41 (see 2.3.5.13 for details).	NO	YES	NO	NO
Radioisotopic cardiac pacemakers or other devices, including those powered by lithium batteries, implanted into a person or fitted externally.	NO	ON O PER	SON	NO
Security-type equipment (see 2.3.2.6 for details).	YES	YES	NO	NO
Security-type attaché cases, cash boxes, cash bags, etc. incorporating dangerous goods, such as lithium batteries and/or pyrotechnic material, except as provided in 2.3.2.6 are totally forbidden. See entry in 4.2-List of Dangerous Goods.		FORBI	DDEN	
Specimens, non-infectious packed with small quantities of flammable liquid, must meet A180 (see 2.3.5.11 for details).	NO	YES	YES	NO
Thermometer, medical or clinical, which contains mercury, one (1) per person for personal use, when in its protective case.	NO	YES	NO	NO
Thermometer or barometer, mercury filled carried by a representative of a government weather bureau or similar official agency (see 2.3.3.1 for details).	YES	NO	YES	YES

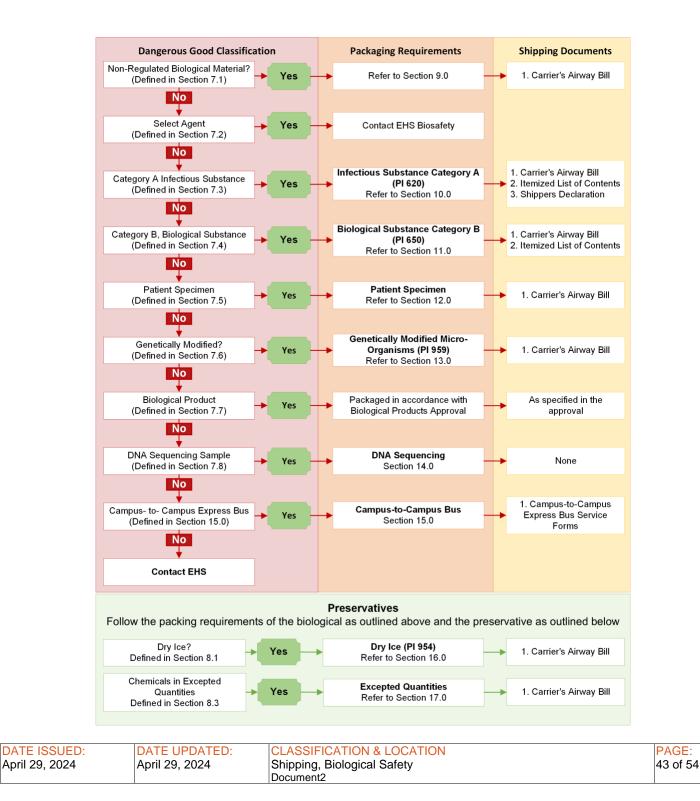
Note:

The provisions of Subsection 2.3 and Table 2.3.A may be limited by State or operator variations. Passengers should check with their airline for the current provisions.

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Appendix B – Biological Materials Classification Flowchart





Appendix C – HSS and USDA Select Agents and Toxins Select Agents and Toxins List

The following biological agents and toxins have been determined to have the potential to pose a severe threat to both human and animal health, to plant health, or to animal and plant products. An attenuated strain of a select agent or an inactive form of a select toxin may be excluded from the requirements of the Select Agent Regulations. Here is a list of <u>excluded agents and toxins</u>.

HHS and USDA Select Agents and Toxins 7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73

HHS Select Agents and Toxins

- 1. Abrin [<u>6]</u>
- 2. Bacillus cereus Biovar anthracis [1]
- 3. Botulinum neurotoxins [1][6]
- 4. Botulinum neurotoxin producing species of Clostridium [1]
- Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇) [6]
- 6. Coxiella burnetii
- 7. Crimean-Congo haemorrhagic fever virus
- 8. Diacetoxyscirpenol [6]
- 9. Eastern Equine Encephalitis virus [4][5]
- 10. Ebola virus [1]
- 11. Francisella tularensis [1]
- 12. Lassa fever virus
- 13. Lujo virus
- 14. Marburg virus [<u>1</u>]
- 15. Monkeypox virus [4]
- Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
- 17. Ricin [6]
- 18. Rickettsia prowazekii
- 19. SARS-associated coronavirus (SARS-CoV) [5]
- 20. Saxitoxin [6]

Overlap Select Agents and Toxins

- 36. Bacillus anthracis [1]
- 37. Bacillus anthracis Pasteur strain
- 38. Brucella abortus
- 39. Brucella melitensis
- 40. Brucella suis
- 41. Burkholderia mallei [1]
- 42. Burkholderia pseudomallei [1]
- 43. Hendra virus
- 44. Nipah virus
- 45. Rift Valley fever virus
- 46. Venezuelan equine encephalitis virus [4][5]

USDA Select Agents and Toxins

- 47. African horse sickness virus
- 48. African swine fever virus
- 49. Avian influenza virus [<u>4</u>]
- 50. Classical swine fever virus [5]
- 51. Foot-and-mouth disease virus [1][5]
- 52. Goat pox virus
- 53. Lumpy skin disease virus
- 54. Mycoplasma capricolum [4]
- 55. Mycoplasma mycoides [4]

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South American Haemorrhagic Fever viruses:

- 21. Chapare
- 22. Guanarito
- 23. Junin
- 24. Machupo
- 25. Sabia
- 26. Staphylococcal enterotoxins (subtypes A,B,C,D,E) [6]
- 27. T-2 toxin [6]
- 28. Tetrodotoxin [6]

Tick-borne encephalitis complex (flavi) viruses:

- 29. Far Eastern subtype [5]
- 30. Siberian subtype [5]
- 31. Kyasanur Forest disease virus [5]
- 32. Omsk hemorrhagic fever virus [5]
- 33. Variola major virus (Smallpox virus) [1]
- 34. Variola minor virus (Alastrim) [1]
- 35. Yersinia pestis [1]

[1] Denotes Tier 1 Agent

- 56. Newcastle disease virus [<u>3][4]</u>
- 57. Peste des petits ruminants virus
- 58. Rinderpest virus [1]
- 59. Sheep pox virus
- 60. Swine vesicular disease virus [5]

USDA Plant Protection And Quarantine (PPQ) Select Agents and Toxins

- 61. Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)
- 62. Peronosclerospora philippinensis (Peronosclerospora sacchari)
- 63. Ralstonia solanacearum
- 64. Rathayibacter toxicus
- 65. Sclerophthora rayssiae
- 66. Synchytrium endobioticum
- 67. Xanthomonas oryzae

[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; "Des X" = "an amino acid does not have to be present at this position." For example if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

[3] A virulent Newcastle disease virus (avian paramyxovirus serotype 1) has an intracerebral pathogenicity index in day-old chicks (Gallus gallus) of 0.7 or greater or has an amino acid sequence at the fusion (F) protein cleavage site that is consistent with virulent strains of Newcastle disease virus. A failure to detect a cleavage site that is consistent with virulent strains does not confirm the absence of a virulent virus.

[4] Select agents that meet any of the following criteria are excluded from the requirements of this part: Any low pathogenic strains of avian influenza virus, South American genotype of eastern equine encephalitis virus, west African clade of Monkeypox viruses, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumoniae (contagious caprine pleuropneumonia), all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), and any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, provided that the individual or entity can verify that the agent is within the exclusion category.

[5] For determining the regulatory status of nucleic acids that are capable of producing infectious forms of select agent viruses, please reference guidance <u>here</u>.

[6] For determining the regulatory status of Recombinant and/or Synthetic nucleic acids that encode for the toxic form(s) of any select toxins if the nucleic acids (i) can be expressed in vivo or in vitro, or (ii) are in a vector or recombinant host genome and can be expressed in vivo or in vitro; please reference guidance <u>here</u>.

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Appendix D – Indicative List of Category A Infectious Substances

From the **2024 IATA Dangerous Goods Regulations** TABLE 3.6.D Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated. The table listed here is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in Appendix D but meet the same criteria, must be classified as Category A. In addition, if there is doubt as to whether a substance meets the criteria, it must be included in Category A.

UN Number and Prope Shipping Name	r Micro-organism	
UN 2814	Bacillus anthracis (cultures only)	
Infectious substance	Brucella abortus (cultures only)	
affecting humans	Brucella melitensis (cultures only)	
	Brucella suis (cultures only)	
	Burkholderia mallei-Pseudomonas mallei-Glanders (cultures only)	
	Burkholderia pseudomallei–Pseudomonas pseudomallei (cultures only)	
	Chlamydia psittaci-avian strains (cultures only)	
	Clostridium botulinum (cultures only)	
	Coccidioides immitis (cultures only)	
	Coxiella burnetii (cultures only)	
	Crimean-Congo haemorrhagic fever virus	
	Dengue virus (cultures only)	
	Eastern equine encephalitis virus (cultures only)	
	Escherichia coli, verotoxigenic (cultures only)	
	Ebola virus	
	Flexal virus	
	Francisella tularensis (cultures only)	
	Guanarito virus	
	Hantaan virus	
	Hantavirus causing hemorrhagic fever with renal syndrome	
	Hendra virus	
	Hepatitis B virus (cultures only)	
	Herpes B virus (cultures only)	
	Human immunodeficiency virus (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 haemorrhagic fever virus	
	Poliovirus (cultures only)	
	Rabies virus (cultures only)	
	Rickettsia prowazekii (cultures only)	
	Rickettsia rickettsii (cultures only)	
	Rift Valley fever virus (cultures only)	
	Russian spring-summer encephalitis virus (cultures only)	
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TABLE 3.6.D Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (continued)

UN Number and Proper Shipping Name	Micro-organism
	Sabia virus
	Shigella dysenteriae type 1 (cultures only)
	Tick-borne encephalitis virus (cultures only)
	Variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	Yellow fever virus (cultures only)
	Yersinia pestis (cultures only)
UN 2900	African swine fever virus (cultures only)
Infectious substances	Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only)
affecting animals	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)

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Appendix E – Packaging Supplier List

Inmark Life Sciences, Inc. Phone: (800) 646-6275 <u>http://www.lifescience.inmarkinc.com</u> / Grainger

Phone: (800) 472-4643 http://www.grainger.com/

VWR Scientific Phone: (800) 932-5000 http://www.us.vwr.com/store Berlin Packaging Phone: (800) 363-9822 http://www.berlinpackaging.com

Avantor Clinical Services. Phone: (909) 267-2000 http://www.therapak.com

HAZMATPAC, Inc. Phone: (800) 923-9123 http://www.hazmatpac.com ThermoSafe Brands Phone: (800) 323-7442 http://www.thermosafe.com/

Fisher Scientific Phone: (800) 766-7000 http://www.fishersci.com

Saf-T-Pak, Inc. Phone: (800) 814-7484 <u>https://us.shop.lifescience.inmarkinc.com/collections/ne</u> w-specimen-transport-packaging

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Appendix F – Commercial Invoice Example

Commercial Invoice, available on the EHS website:

	0	Weil Mec	l Corne licine	211		C	Com	me	rical lı	nvoice	
	AIR WAYB	ILL NO. (AI	shipments must inclu	de Air Waybill)	DATE OF SH	IPMENT		PAGE	S		
		EXPORTER	INFORMATION		CONSIGNEE (Complete na			ATION			
	COUNTRY	OF EXPOR	r		IMPORTER - (Complete na			ISIGNE	E		
	EXPORT F	REFERENCE	S (e.g., order no., inv	oice no.)							
	COUNTRY	OF MANUE	ACTURE								
	COUNTRY	OF ULTIMA	TE DESTINATION								
	NO. OF PKGS.	TYPE OF PKG.	FULL DESCRIPTIC	ON OF GOODS	UNIT SIZE	QUANTIT	Y WEI	GHT	UNIT VALUE	TOTAL VALUE	
	TOTAL NU	MBER OF P	ACKAGES		TOTAL WEIG	ант			TOTAL INVO	ICE VALUE	
	ACCORDA	NCE WITH 1	THE EXPORT ADMIN	MMODITIES, TECHNOLO	IS. DIVERSION C	ONTRARY T	0 U.S. LA	W PROP	HE UNITED S	STATES IN	
	IDECLAR	E ALL THE IN	IFORMATION CONT	AINED IN THIS INVOICE T	O BE TRUE AND	CORRECT.					
	Signature of	of Shipper/Ex	porter	Title			Date				
ED: 24		<mark>ATE UP</mark> pril 29, 2	DATED: 024	CLASSIFICATI Shipping, Biolog Document2							



Appendix G – Example Shipper's Declaration Form – One Dangerous Good

	SHIPPE	ER'S DECLARATION FO	R DANGEROUS GOO				(Provide a	t least two	copies to the airline	.)
	Shipper	Weill Cornell M	edicine	— (B	Air Waybi	II No. 12345	67890			
		Jane Doe, MD		ē	Page 1 o	of 1 Pages				
		1300 York Ave		(C		11 10800				
		New York, NY 1	10021	\sim	Shipper's	Reference Numbe	r ional)			
(A)	Consign	John Doe				loba	ionaly			
	Consign	ABC College					BUREA	OF		
		123 Main Street	t			*	DANGE	ROUS		
		Baltimore, MD 2	23231			*	GOODS			
						•	powered by Shipi	Hazmat.NET		
		npleted and signed copies	s of this Declaration		WARNING	;				
		handed to the operator ORT DETAILS				e to comply in all r				
		ment is within the	Airport of Departure			rous Goods Regulati oplicable law, subj				
		s prescribed for on-applicable)	New York City				• •			
	PASSE	NGER XXXGARGOX								
(D	AND C/		(E)							
Ĭ	Airport	of Destination Baltir	more		Shipment	Type (dele	te non-applicable)			
		Data				-RADIOACTIVE	XEXARDOXADEXU	KKXXX		
	NATURE	AND QUANTITY OF DAN	GEROUS GOODS		ワ					
		Dangerous (Goods Identification							
	UN			Class or Division	Pack- ing	Quantit type of p		Packing Inst.	Authorization	
	ID	Proper St	hipping Name	(Subsidiary	Group	1994 of p	and a second sec			
	No.			Hazard)						
	UN	2814 Infectious subst	· · · ·	6.2		1 fiberboard bo	x x 25 g	620		
		humans (Mycol tuberculosis)	pacterium							
						~				
	G		U		5	U U	ソ	E	\mathbf{W}	
	Additio	nal Handling Information								
	24-Ho	ur Emergency Contac	ct Telephone Numbe	r: CHEMTREC	+1-800-42	24-9300	N			
	Weill C	Cornell Medicine- Co	ntact EHS for Code							
	Respo	onsible Person: Jane I	Doe							
	Teleph	hone: 1-123-456-7890)							
	1 hereit	w dealars that the sector	of this considerment are full	hand						
	accura	by declare that the contents of ately described above by the	proper shipping name, and	d are		Name of Signa Jane Doe	atory			
		fied, packaged, marked and la cts in proper condition for tr				Date				
	spec	in proper condition for u	and a second state of the second seco			February 23	3, 2021			
	interna	ational and national governme		hat all				m Or		
	interna	ational and national governme applicable air transport requir		hat all		Signature (see warning ab		ine Doe		
TE ISSUED.	interna of the s	applicable air transport requir	rements have been met.		18100	Signature (see warning ab		ine Doe		
TE ISSUED: il 29, 2024	interna of the a		CLASS	SIFICATION ng, Biologic		Signature (see warning at		ine Doe		PAGE 50 of 5



Appendix H – Example Shipper's Declaration Form – Two or More Dangerous Goods

	SHIPPER	'S DECLARATION FO	R DANGEROUS GOOD	\$		(Provi	de at least two	copies to the airline)	
	Shipper	Weill Cornell M	edicine		Air Wayb	ill No. 1234567890			
		Jane Doe, MD 1300 York Ave New York, NY 1			Page 1				
		New TOIK, NT	10021		Shipper's	s Reference Number (optional)			
	Consigned	ABC College 123 Main Street Baltimore, MD 2				GOOI	EROU		
		leted and signed copies	s of this Declaration		WARNIN		Smpriezmacive i		
		anded to the operator RT DETAILS			Failu	re to comply in all respects with	the applicable		
	This shipm	ent is within the prescribed for	Airport of Departure New York City		-	erous Goods Regulations may be in pplicable law, subject to legal pe			
	PASSENG AND CAR AIRCRAE	GO XXAIRCRAFT							
	Airport of	Destination Baltir	nore		Shipment				
					NO	N-RADIOACTIVE	KXXXXXXXX		
	NATURE A	ND QUANTITY OF DAN							
	UN or ID No.		Soods Identification	Class or Division (Subsidiary Hazard)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization	
	UN28	14 Infectious subst humans (Mycol tuberculosis)	· · · · · · · · · · · · · · · · · · ·	6.2		3.0 mL	620		
	UN18	45 Dry Ice		9		7 kg All packed in one Fibreboard box	954		
	24-Hour <u>Weill Cor</u> Respon	• •		CHEMTREC	+1-800-4	24-9300	<u> </u>		
	accurate classified respects internatio	ly described above by the I, packaged, marked and la in proper condition for tr	of this consignment are fully a proper shipping name, and belled/placarded, and are in al ansport according to applical ntal regulations. I declare that ements have been met.	are I ble		Name of Signatory Jane Doe Date February 23, 2021 Signature (see warning above)	Jane Do	0	
TE ISSUED: il 29, 2024		DATE UPDATE April 29, 2024		SIFICATIOI ng, Biologic ent2					PAGE: 51 of 54



Appendix I – Shipping Assessment Form

Shipping Assessment Form, available on the EHS website:

Weill Cornell Medicine	Shipping Assessment Form
WCM). This includes and is not limited to any TS equipment, patient specimens, reagents, s	n for all items to be shipped to/from Weill Cornell Medicine shipments containing batteries, biological products, chemicals, amples, hand-carry items, etc. If more than 5 items need y times as necessary and e-mail all forms compiled to
ackaging, labeling, permitting, and documenta	at will allow the shipping team to accurately assess shipping, ation requirements for your shipment. This includes a copy of the chemicals or preservatives that may impact your shipment, py of MTA, product manuals, etc.
ead times for assessment. Some items require locumentation for government regulatory ager complete. The shipping timeline is dependent to	the expected ship date. Note, some items may require longer e government agency permits. This process requires additional iccies, transporters, and airlines, which can take several weeks to upon the nature of the material and complexity of the shipment. ling requirements for export due to value restrictions.
	eements (MTA's), please contact the Office of Sponsored shipments (osra-contracts@med.cornell.edu) and Center for
echnology Licensing (CTL) for outgoing shipr	nents (mta-ctl@cornell.edu).
dditional information regarding shipping can t	
Additional information regarding shipping can the strength of	be found on the EHS website:
Additional information regarding shipping can b https://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te locordance with the export administration regu	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited.
Additional information regarding shipping can b https://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te locordance with the export administration regu	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited.
Additional information regarding shipping can b https://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te accordance with the export administration regu NOTE: Radioactive substances are NOT inc ehs@med.cornell.edu or 646-962-7233) for ra	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited.
Additional information regarding shipping can hittps://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te accordance with the export administration regu- NOTE: Radioactive substances are NOT inc ehs@med.cornell.edu or 646-962-7233) for ra- SECTION 1: CONTACT INFORMATION Principal Investigator / Lab	be found on the EHS website: echnology, or software were exported from the U.S. in illations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS idioactive substance shipment instructions.
Additional information regarding shipping can be https://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te accordance with the export administration regu- NOTE: Radioactive substances are NOT inco- ehs@med.cornell.edu or 646-962-7233) for ra SECTION 1: CONTACT INFORMATION	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited. cluded on this form; if applicable, please contact EHS indioactive substance shipment instructions.
Additional information regarding shipping can hittps://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te accordance with the export administration regu- NOTE: Radioactive substances are NOT inc ehs@med.cornell.edu or 646-962-7233) for ra- SECTION 1: CONTACT INFORMATION Principal Investigator / Lab	be found on the EHS website: echnology, or software were exported from the U.S. in illations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS idioactive substance shipment instructions.
Additional information regarding shipping can be https://ehs.weill.cornell.edu/shipping. f shipment is for export, these commodities, te accordance with the export administration regu- NOTE: Radioactive substances are NOT inco- ehs@med.cornell.edu or 646-962-7233) for ra- SECTION 1: CONTACT INFORMATION Principal Investigator / Lab Name of WCM Contact to Discuss Shipment:	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS indicactive substance shipment instructions. Fund# for supplies or freight services WCM Contact's Email and Telephone#
Additional information regarding shipping can be https://ehs.weill.cornell.edu/shipping. If shipment is for export, these commodities, te accordance with the export administration regu- NOTE: Radioactive substances are NOT inco- ehs@med.cornell.edu or 646-962-7233) for ra- SECTION 1: CONTACT INFORMATION Principal Investigator / Lab Name of WCM Contact to Discuss Shipment: Name of Courier / Airline to be Used:	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS idioactive substance shipment instructions. Fund# for supplies or freight services WCM Contact's Email and Telephone# Expected Ship / Travel Date:
Additional information regarding shipping can be ttps://ehs.weill.cornell.edu/shipping. If shipment is for export, these commodities, te accordance with the export administration regu- IOTE: Radioactive substances are NOT inc ehs@med.cornell.edu or 646-962-7233) for ra SECTION 1: CONTACT INFORMATION Principal Investigator / Lab Name of WCM Contact to Discuss Shipment: Name of Courier / Airline to be Used: SHIPPER / TRAVELER INFORMATION	be found on the EHS website: echnology, or software were exported from the U.S. in lations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS indicactive substance shipment instructions. Fund# for supplies or freight services WCM Contact's Email and Telephone# Expected Ship / Travel Date: END USER INFORMATION
Additional information regarding shipping can be ttps://ehs.weill.cornell.edu/shipping. If shipment is for export, these commodities, te accordance with the export administration regu- IOTE: Radioactive substances are NOT ince ehs@med.cornell.edu or 646-962-7233) for rance SECTION 1: CONTACT INFORMATION Principal Investigator / Lab Name of WCM Contact to Discuss Shipment: Name of Courier / Airline to be Used: SHIPPER / TRAVELER INFORMATION Shipper's Company name and Address	be found on the EHS website: echnology, or software were exported from the U.S. in ilations. Diversion contrary to the U.S. Law is prohibited. Educed on this form; if applicable, please contact EHS indicactive substance shipment instructions. Fund# for supplies or freight services WCM Contact's Email and Telephone# Expected Ship / Travel Date: END USER INFORMATION End User's Company name and Address
dditional information regarding shipping can be ttps://ehs.weill.cornell.edu/shipping. shipment is for export, these commodities, te ccordance with the export administration regu- lOTE: Radioactive substances are NOT inco- ehs@med.cornell.edu or 646-962-7233) for ra- SECTION 1: CONTACT INFORMATION Principal Investigator / Lab Name of WCM Contact to Discuss Shipment: Name of Courier / Airline to be Used: SHIPPER / TRAVELER INFORMATION Shipper's Company name and Address Shipper's Information (Full Name)	be found on the EHS website: echnology, or software were exported from the U.S. in llations. Diversion contrary to the U.S. Law is prohibited. Eluded on this form; if applicable, please contact EHS indicactive substance shipment instructions. Fund# for supplies or freight services WCM Contact's Email and Telephone# Expected Ship / Travel Date: END USER INFORMATION End User's Company name and Address End User's Information (Full Name)

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SECTION 2: MATERIAL	DESCRIPTION A	ND SHIPMENT INF	ORMATION		
	Item 1	Item 2	Item 3	Item 4	Item 5
What type of shipment is this? Please select.	Please Select				
f answer is other than biological, please skip section 3.					
f answer is chemical, please provide SDS.					
Material name:					
Catalog/NDC/CAS Number (if applicable):					
Manufacturer:					
Country of Manufacture:					
Number of Units:					
Volume / Weight per Unit:					
Value per Unit (US\$):	\$	\$	\$	s	s
Shipping Temperature:	Please Select If Other, specify here:				
Item ECCN (if known):					
MTA/CTA in Place*	Please Select				
Is medical license required for purchase or use?**	Please Select				
SECTION 3: BIOLOGIC	AL MATERIALS O	NLY	1	1	1
	Item 1	Item 2	Item 3	Item 4	Item 5
Which description best fits this item?	Please Select If Other, specify here:	Please Select It Other, specify here:	Please Select It Other, specify here:	Please Select It Other, specify here:	Please Select If Other, specify here:
Is the item likely to contain an infectious agent?	Please Select If Yes, specify here:				
Does this item contain a	Please Select				

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What is the preservative type and quantity per container?					
Is the item contained in leak-proof container?	Please Select	Please Select	Please Select	Please Select	Please Select
SECTION 4: PACKAGI	NG & SHIPPING				
Need Assistance with Purchasing a Shipping Box/Container?	Please Select	Please Select	Please Select	Please Select	Please Select
Quantity of Dry Ice to be Use (if applicable):	kg	kg	kg	kg	k
Who is preparing the shipment?	Please Select If Other, specify here:	Please Select If Other, specify here:	Please Select If Other, specify here:	Please Select If Other, specify here:	Please Select If Other, specify here
Date of bio. material and dry ice shipments, training of person preparing package					
SECTION 5: SUBMIT T	HE COMPLETED F	ORM TO SHIPPING	S VIA EMAIL: SHIP	PING@MED.CORN	ELL.EDU
*If MTA is in place, ple not required. If you do Administration (OSRA) **If a medical license is	ase send a copy. It not have an MTA t).	but need one, plea	ise contact the Off	ice of Sponsored	ials, then it is
*If MTA is in place, ple not required. If you do Administration (OSRA)	ase send a copy. It not have an MTA t).	but need one, plea	ise contact the Off	rering these mater ice of Sponsored I	ials, then it is
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