Policy No.: BS009	Approved by: Mike Liberty
Title: Shipping Biological Materials and Dry Ice	Date: 12/30/2021
Revision No.: 9	Page 1 of 41
Prepared by: Sonia Rosenberger	

Personnel may use this version of the policy as a Training/User Manual. The first page includes a Table of Contents and an Executive Summary, and the Definitions section has moved toward the end, similar to a glossary. All other content is identical.

EXECUTIVE SUMMARY

Materials may be regulated for shipping because they pose a risk to persons either transporting them or taking transportation methods alongside them, or because they pose a risk to agriculture or wildlife.

- Non-compliance can result in significant penalties and fines for the University.
- A government permit or license may be required, can take weeks to get, and may require a fee.
- Packing regulated materials in checked or carry-on baggage on airplanes is prohibited.

Shipping training is required <u>every 2 years</u>, or when regulations change.

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I. PURPOSE

This procedure establishes the requirements for shipping biological materials and/or dry ice.

Non-compliance with federal shipping regulations can result in significant penalties and fines.
- Up to $250,000 and up to a year jail sentence for individuals
- Up to $500,000 per incident for organizations

II. PERSONNEL AFFECTED

1. University personnel who wish to transport or ship biological materials and/or dry ice (packing specimens, marking or labeling boxes, preparing shipping documents/forms)

2. University personnel who perform support functions for transporting or shipping biological materials and/or dry ice (ordering packaging, assigning Proper Shipping Names)

3. Supervisors of the University personnel who perform shipping functions

III. RESPONSIBILITIES

It is the responsibility of the shipper to adhere to this procedure.

It is the responsibility of the shipper's supervisor to ensure compliance of their employee with this procedure.

IV. PROCEDURES

A. Determine if the shipment is regulated and get training (IATA DGR, DOT)

Biological materials may be regulated because they pose a risk to:
- Shipping personnel who handle the packages
- Passengers or other travelers using the same transportation method,
- Animals (livestock, poultry or wildlife)
- Plants (food and endemic species)

The International Air Transport Association's Dangerous Goods Regulations (IATA DGR) protect global air transportation. Updated annually, they are based on international criteria from the United Nations (UN) and the International Civil Aviation Organization, among others.

In the United States, the Department of Transportation (DOT) harmonizes with international requirements so DOT's regulations generally conform to IATA's Dangerous Goods Regulations. However, variations may occur for ground transport.

Other federal and state government bodies regulate the transport of specific materials in line with their mission: US Departments of Agriculture (USDA), Commerce, Health and Human Services, Interior (Fish and Wildlife-USFW), and NYS Department of Environmental Conservation (DEC).

Regulated biological materials

- Viable human, animal and plant pathogens
- Any material that may contain human, animal or plant pathogens
  - Human or animal blood, body fluids, tissues or cells (including cell lines)
  - Animal products
  - Plants, plant material, plant pests, plant products, soil, and biocontrol organisms
- Genetically modified organisms and micro-organisms
- Amino acids, antibodies, DNA/RNA, enzymes, plasmids, purified proteins (if may contain an animal pathogen, or if from an endangered species)
- Animals (vertebrates or invertebrates, living or dead)
- Toxins
- Biomedical waste

Regulated chemicals and refrigerants that may be in biological shipments

- Regulated chemicals in 'excepted quantities' (e.g. formalin, ethanol, others in media)
- Dry ice
- Liquid nitrogen

Training requirements (every 2 years)

Some regulated biological materials are regulated only for import/interstate transport or export restrictions. The shipping training requirements below are for those materials regulated by the International Air Transport Association's Dangerous Goods Regulations (IATA DGR) or the US Department of Transportation (DOT) (i.e. have Proper Shipping Names, see Section III – Classify the shipment/Assign a Proper Shipping Name).

IATA DGR requires training every 2 years, or when regulations change. DOT requires training less frequently, but for air shipments, the IATA DGR requirement applies.

Per IATA DGR and 49 CFR §172.700-704, training must provide:

- General awareness/familiarity with the regulatory requirements for shipping and how to recognize hazardous materials
- Specific requirements related to a person's function (packing, marking, labeling, etc.)
- Safety, emergency response, and security: provided for research and clinical laboratory staff by EH&S's Laboratory Safety Training, and for clinical staff by hospital training programs.

To meet the regulatory training requirements:

1. Use this procedure, and

2. Take a shipping course (e.g. UR's "EHS Shipping Biological Materials and Dry Ice" and/or "EHS DOT Shipping Training for Generators of Medical Waste").

❖ For non-UR training certificates, employers are required to certify an employee is trained, therefore: 1) employee and supervisor must sign certificate, and 2) attach test score.

B. Obtain MTAs, permits or licenses

Material Transfer Agreements (MTAs) require the recipient to use care in the handling of the materials, to maintain control over the distribution of the materials, to acknowledge the provider in publications, and to follow relevant regulations. See the ORPA webpage for access to UR's online system for MTA submission - IORA Agreements (IORA = Integrated Online Research Administration). If you don't have IORA access, see the ORPA forms page.

A government permit/license may be required, can take weeks to get, and may require a fee.

Packages may be opened and inspected when entering or leaving the United States or at any time by any inspection service provided by other countries. The appropriate permits and/or licenses, along with the proper packaging and labeling, will expedite clearance through the appropriate port/Quarantine Station and release by Customs and Border Protection. Assistance with Customs is available through the Office of Counsel.

Export (USFW, DOC, OFAC)

Material shipped	Export Permit or License	Regulations	Fee
Samples from endangered or threatened species (animal, including all primates, plant)	USFW permit (animals) USDA permit (plants)	CITES-Trade in Endangered Species	$100 $70
Infectious agents (human, animal or plant) on the Export Administration Regulations' Commerce Control List (CCL)	License from the Department of Commerce (Appendix 5)	CCL: Category 1, Sections 1C351, 1C354	No
Genetic elements or genetically-modified organisms on the CCL	License from the Department of Commerce (Appendix 5)	CCL: Category 1, Section 1C353	No
Shipments to embargoed or sanctioned countries	License - Office of Foreign Assets Control (OFAC)	See embargoed/ sanctioned countries list	No
Animals	Contact Animal Resources	See all above	?

The Office of Research and Project Administration (ORPA) provides Export Controls assistance for 1) exporting biologicals, technology and materials, including equipment that can be used to grow or sequence biologicals, and 2) the 'deemed export' of information/technology.

When exporting, also ask if the importing country requires its own government permit(s).

Import (CDC, USDA, USFW, NYS DEC)

The importer, located in the US, is responsible for obtaining permit(s) and ensuring that foreign personnel pack, mark, label, and ship according to all applicable regulations.

Permits may take weeks or months to get, longer if the material requires a facility inspection. If an inspection is required, contact EH&S Laboratory Safety Unit at 275-2402 for assistance.

Once the permit is granted, the permitting agency will include instructions, shipping labels and one or more copies of the permit to send to the shipper.

Human pathogen potential	Import Permit	Purpose	Fee
Human pathogens, some human specimens, some genomic material Nonhuman primate material African rodent carcasses Animal products or vectors (snails, mosquitoes, ticks, etc.) capable of transmitting human pathogens	CDC import program - CDC import video - List of CDC regulated animals/products - e-Tool decision tree, customs language - Permits require online SAMS registration	Protect public health	No
Animal pathogen potential	**Import, Interstate Permits**	**Purpose**	**Fee**
Organisms that transmit disease to livestock or poultry (i.e. cows, sheep, goats, pigs, horses, chickens, turkeys, fish, shrimp, etc.) Organism derivatives (DNA/RNA, recombinants, inactivated/attenuated) Livestock or poultry products, cells	USDA permit, Permit assistant - Interstate permits are also required (except-ions in Guideline 1125) - Require online eFile registration	Protect United States (US) food supply	$150
Species threat	**Import Permit**	**Regulations or purpose**	**Fee**
Samples from selected endangered or threatened species (animal, including all primates, plant)	USFW permit (animals) USDA permit (plants)	CITES-Trade in Endangered Species	$100 $70
Invasive and Injurious species	**Import Permit**	**Regulations or purpose**	**Fee**
Invasive and injurious species (animals, invertebrates, eggs, plants, fungi, algae, cyanobacteria)	USFW permit NYS DEC permit	Protect US and/or New York State's (NYS) endemic populations	$100 (USFW) No (NYS)
Plant pathogen potential	**Import, Interstate Permits**	**Purpose**	**Fee**
Plant pests, plant pathogens, noxious weeds, plant products, soil, bees	USDA permit	Protect United States (US) food supply	$70

Live animals	Import Permit	Regulations or purpose	Fee
Animals	Contact Animal Resources	See all above	?

Note: CDC/USDA Select Agents and Toxins (human or animal pathogens and toxins that may be used for bioterrorism purposes) require an additional level of federal approval first, including personnel background checks, facility safeguards and security, federal inspection, etc.

Customs:

All imports are reviewed at the port of entry. If you don't want your shipment held up in Customs, follow federal guidance for biological shipments; there's overlap, so check both.

- CDC's import e-Tool gives Customs guidance if no CDC permit is required.
- USDA has over a dozen individual guidelines for 'animal products that do not require an import permit,' including pharmaceuticals, vaccines, microbially-produced materials, non-pathogenic microorganisms (and their extracts), cell lines (and their products), fixed histopathology slides, etc.

Within the US and between Hawaii or Alaska - verify recipient has permit (USDA, state-specific)

- USDA permits are required for import (for these purposes, Hawaii and Alaska are import) and interstate transport within the continental US. Blanket permits are available.
- State-specific permits may be required, e.g. for region-specific animal or plant pathogens.
- When shipping live animals, coordinate with Animal Resources.

C. Classify the shipment/Assign a Proper Shipping Name

To determine how to package and document a shipment, personnel need to be able to classify their shipments using globally-recognized descriptions and identification numbers (i.e. Proper Shipping Names, in English, the international shipping language, and UN or ID numbers corresponding to one or more Proper Shipping Names).

International Hazard Classes (IATA DGR)

Class 1 – Explosives
Class 2 – Gases
Class 3 – Flammable Liquids
Class 4 – Flammable Solids; Substances Liable to Spontaneous Combustion; Substances which, in Contact with Water, Emit Flammable Gases
Class 5 – Oxidizing Substances and Organic Peroxides
Class 6 – Toxic and Infectious Substances (Division 1 – Toxic, Division 2 – Infectious)
Class 7 – Radioactive Material

Class 8 – Corrosives
Class 9 – Misc. Dangers Substances and Articles, Incl. Environmentally Hazardous Substances

Within some of the hazard Classes, Packing Groups (I, II or III) are also assigned for the applicable degree of danger (e.g. for toxins; not applicable to other biological materials).

Internationally-recognized Proper Shipping Names (i.e. descriptions) correlate to identification numbers (e.g. UN2814) and specific, well-defined, and numbered Packing Instructions that list how to pack, mark, label and document a shipment.

Regulated biological materials and their Proper Shipping Names

Regulated biological material	Class	Category	Proper Shipping Name
Viable human pathogens, materials that may contain human pathogens	6.2	Category A (fatal or permanently disables)	Infectious substance, affecting humans (solid or liquid)
		Category B (all others)	Biological substance, Category B
Viable animal pathogens, materials that may contain animal pathogens	6.2	Category A (fatal or permanently disables)	Infectious substance, affecting animals (only; solid or liquid)
Regulated biological material	Class	Category	Proper Shipping Name
Viable animal pathogens, materials that may contain animal pathogens	6.2	Category B (all others)	Biological substance, Category B
Human or animal specimens with minimal likelihood that pathogens are present	6.2		If follow IATA DGR instructions: - Exempt human specimen - Exempt animal specimen
Biomedical waste	6.2		Biomedical waste, n.o.s.
Toxins	6.1		Toxins, extracted from living sources, liquid, n.o.s. (or solid, n.o.s.)
Genetically modified organisms and micro-organisms that are non-pathogenic to humans or animals	9		Genetically modified organisms Genetically modified micro-organisms

* n.o.s. (not otherwise specified)

Need help classifying a material/determining the Proper Shipping Name?

1. CDC's "Storing, Packaging, and Shipping Infectious Substances" https://www.cdc.gov/mmwr/pdf/other/su6101.pdf includes algorithms and guidance. (Pages 80-86 of "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories", MMWR Supplement, Vol. 61, January 6, 2012; also available in Spanish)
2. DOT's Transporting Infectious Substances Safely, 2020, includes algorithms and Category A examples. [Note: Category A lists/examples have been updated. The 2021 IATA DGR also lists hepatitis B virus (cultures only) and places vesicular stomatitis virus (cultures only) under a different Proper Shipping Name. DOT also includes 'other lyssavirus' cultures in addition to rabies virus (cultures only)].
3. UR's Biosafety Officer can also help.

Exempt or not regulated (may still require a permit or license) - materials that cannot be assigned a Proper Shipping Name do not have packaging, marking or labeling requirements for shipping, unless required by the carrier. For assistance/examples, see:

1. IATA DGR instructions for 'exempt human or animal specimens' (https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf)
2. 'Exceptions' listed in DOT's 49 CFR §173.134 'Class 6, Division 6.2—Definitions and exceptions'.
3. To hand-carry these materials on an airplane, contact the dangerous goods cargo expert for the airline and follow their instructions.

D. Contact the carrier/ transportation company

Not all carriers will transport all hazardous materials. Contact the carrier (website, phone, etc.), verify they transport the material and then follow any additional instructions they have (e.g. forms, etc.) Some of them also offer appropriate packaging materials.

For shipments sent by US Mail, see the US Postal Service's Publication 52 – Hazardous, Restricted, and Perishable Mail, including, but not limited to:

- USPS Packing Instruction 6C (Category B Infectious Substances, including COVID-19 test kits)
- USPS Packing Instruction 6G (Nonregulated Infectious materials, e.g. dried blood spots)
- USPS Packing Instruction 6H (Exempt Human or Animal Specimens)
- USPS Packing Instruction 9A (Dry ice)

For transportation in a University or personal vehicle using DOT's 'Materials of Trade Exception', see Section VI – University and personal vehicles/DOT's 'Materials of Trade Exception'. Restrictions apply.

E. Prepare, Mark, Label, Document, Pack and Secure your package

General requirements – packing, marking, labeling, media, refrigerants, documents, security

Packing, marking, and labeling

All IATA Packing Instructions start with the numeral of the hazard Class. For example, all Packing Instructions for infectious substances start with 6, and those with miscellaneous hazards (nonpathogenic genetically modified microorganisms and dry ice) start with 9.

Packaging used for air transport must be able to withstand temperature, pressure, and vibration conditions that may be encountered during air travel: per IATA DGR 5.0.4, -40°C/F to +55°C (131°F), pressure differentials of at least 95kPa (atmospheric is 100kPa or 1 bar), and vibration ranging from 5mm amplitude at 7Hz (1 g acceleration) to 0.05mm amplitude at 200 Hz (8 g).

Therefore, use all packaging products as per manufacturer instructions. Packaging systems may not be altered and packaging components may not be substituted with any other manufacturer's components.

If packaging components are re-used, they must be in good condition, have all inappropriate hazard markings and labels removed or completely obliterated, present no hazard (be disinfected or sterilized in cases of infectious substances), and the manufacturer's package assembly instructions must be available. (IATA DGR 5.0.1.4, 5.0.2.13.5.3, 6.0.1.4)

The outer packaging (i.e. box) must display specific information in either marks (printed in English, the international shipping language) or labels (internationally-recognized hazard or handling labels, uniform sizes and design).

- Some marks are pre-printed on the outer packaging to certify specific UN requirements.
- The shipper provides the others, which can generally be on any surface other than the bottom, but must be visible, legible, durable and able to withstand open weather exposure. Marks/labels cannot be folded or affixed so that the mark/label is on more than one side.
- When package size allows, all shipper-provided marks and hazard labels should be entirely on one side of the package, but not overlapping (shipper and recipient/consignee information, Proper Shipping Name, hazard labels).
- The Proper Shipping Name and UN/identification number have prescribed sizes:

Package capacity	Proper Shipping Name, UN/identification number size
< 5 L or kg	Appropriate to size of package
≥ 5 L or kg, but ≤ 30 L or kg	≥ 6 mm
> 30 L or kg	≥ 12 mm

Most materials have quantity limits allowed in a single package, and those limits may differ if transported on passenger vs. cargo aircraft. Passenger aircraft will generally allow smaller amounts – e.g. for Category A infectious agents, 50 ml (or g) on passenger aircraft vs. 4 L (or kg) on cargo aircraft. When a package is only allowed on cargo aircraft, a "Cargo Aircraft Only" label is required.

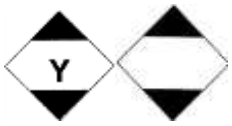
More than one completely packed, marked, and labeled package sent to the same recipient/consignee can sometimes be placed into a single box ('overpack'). This type of overpack has additional marking, labeling, and document requirements. For assistance, contact EH&S's Laboratory Safety Unit or follow carrier instructions.

Fixatives and/or media containing regulated chemicals

Regulated Hazard Classes are only allowed in infectious substance shipments if required for viability, stabilizing/preventing degradation of, or neutralizing the infectious substance.

Regulated chemicals common in biological shipments are included in some packing instructions: formaldehyde solutions, ethanol, isopropanol and some other flammable liquids, corrosives, or miscellaneous hazards - Class 3, 8, 9, respectively. When present in small quantities, they may be shipped with fewer packing, marking and labeling requirements than bulk shipments.

Note for formalin/formaldehyde: Per IATA DGR Special Provision A189, unless shipped with another regulated material, concentrations of formaldehyde solution less than 10% are not regulated for air shipment.

Regulatory Term/Section	Quantity	In addition to three layer (triple) packaging	Mark or Label on outer packaging
De minimis exceptions (IATA DGR 2.6.10, 49 CFR §173.4b)	≤ 1 ml or g per primary/ inner receptacle (≤ 100 ml or g total)	1. Primary/inner receptacle closures held in place with wire, tape, or other positive means 2. Outer packaging meets 1.8m drop test and 3m 24hour stack test*	None
Excepted quantities** (IATA DGR 2.6, 49 CFR §173.4a)	≤ 30 ml or g per primary/ inner receptacle (≤ 500 ml or g total)***	1. Primary/inner receptacle is plastic (≥ 0.2mm thick), glass or metal 2. Otherwise, same as for de minimis	 * Hazard class
Limited quantities (IATA DGR 2.7, 49 CFR §172.315)	≤ 1 liter or kg per inner receptacle	Dependent on chemical, contact EH&S	 Air Ground or Air

* Packaging for Infectious Substances exceed these requirements.
** On the Air Waybill, in the 'Nature and Quantity of Goods' box, put "Dangerous Goods in Excepted Quantities".
*** Some packing groups allow up to 1 liter or kg per package.

If the regulated chemical is proven to inactivate the infectious agent, then ship according to the chemical as the infectious agent is no longer regulated.

> Note for formalin/formaldehyde: Per IATA DGR Special Provision A189, unless shipped with another regulated material, concentrations of formaldehyde solution less than 10% are not regulated for air shipment.

For other hazardous chemicals present in media, and to determine if it can be shipped as an 'excepted quantity' or 'limited quantity', contact EH&S's Laboratory Safety Unit.

Refrigerants

Refrigerants may be used in one of two ways (pictured in Dry ice/Packing Instruction 954):

1. Overpack style - completely packed, marked, and labeled package(s) placed inside refrigerant
2. All-in-one style - packaging designed for both infectious substances and refrigerants

Irrespective of the style used, interior supports must be present to secure secondary packagings in the original position even after the refrigerant dissipates so samples don't tip.

Refrigerant	Regulations
Dry ice	1. ≤ 2.5kg (5.5 pounds) – IATA allows in baggage if airline agrees, not hazardous per DOT if comply with 49 CFR §173.217(c)(5) 2. > 2.5kg (5.5 pounds), follow Packing Instruction 954 (See "Dry ice/Packing Instruction 954 later in this Section)
Liquid nitrogen	- Use a dry shipper if possible (insulated packagings containing refrigerated liquid nitrogen fully absorbed in a porous material) – can be shipped using the fewest requirements. - For any container with free liquid nitrogen present, follow IATA Packing Instruction 202, or DOT for ground shipments. - For assistance, contact EH&S's Laboratory Safety Unit.
Cold packs	Melting cannot compromise the outer packaging.
Wet ice	Avoid, but if used, place in its own a leak-proof container or use leak-proof outer packaging.

Documents

Forms and documents tell carriers/transportation companies and everyone who handles a shipment about what's in it and how to handle it. The shipper must maintain copies – for 2 years.

1. The general Air Waybill includes a tracking number, shipper and recipient/consignee information, handling information, nature and quantity of goods/contents, etc.
2. Hazardous material shipments have a "Shipper's Declaration for Dangerous Goods" (aka DGD-Dangerous Goods Document), when required, and the shipper must print their name, sign, and date. For international shipments, the preferred date format is YYYY-MM-DD.
3. Permits or licenses also accompany the shipment, when required.
4. Keep physical or electronic copies for 2 years (DOT requirement).

Security

Personnel must also receive security awareness training and Dangerous Goods packages must be secured. In the wrong hands, hazardous materials pose a threat and can be used to cause harm or create fear in the community.

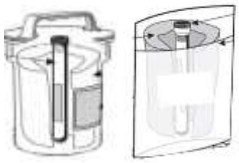
- Disclose information on a need-to-know basis.
- Secure the package until the carrier arrives.
- Immediately report to Public Safety any suspicious persons or activity in areas where hazardous material packages are kept - dial 13 from a campus phone or 275-3333 from a cell phone.
- Track the shipment. If it's not delivered when expected, notify Public Safety at 275-3333.

General requirements - three layer (triple) packaging

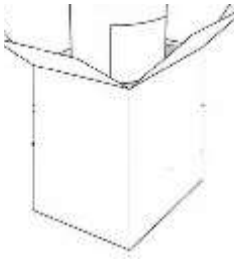
International Packing Instructions for biological materials are based on the triple packaging/three layers of protection concept. How those layers are provided and what they're composed of (i.e. what they can survive during transport) is directly proportional to the hazard of the biological material. Specimen containers (primary receptacles) and secondary packagings must have leak-proof construction and be packed to minimize leakage.

1. Leak-proof primary or inner receptacle(s) (i.e. specimen containers)
   - Liquids: Fill amount leaves enough space to allow for expansion (ullage)
   - Fragile (e.g. glass): individually wrapped or separated to prevent contact (bubble wrap, molded foam inserts, or other cushioning material)
   - Solids: Receptacles are siftproof/don't leak particles.

2. Leak-proof secondary or intermediate packaging (i.e. container, enclosure or bag)
   - Designed and tested to survive pressure changes during travel
   - Absorbent material added when transporting liquids (paper toweling, etc.)
   - Cushioning material (bubble wrap, etc.) or inserts (molded foam, etc.) separate fragile primary receptacles to minimize chance of breakage



3. Outer packaging of adequate strength for its intended use (i.e. box)
   Survives travel/prevents crushing of primary receptacles, large enough to bear required marks and labels:
   - Designed and tested to survive pressure changes during travel
   - Designed and tested for freight conditions (being stacked, dropped or punctured), package tolerance relative to infectious risk
   - Contains cushioning material (holds secondary packaging in place)
   - One or more surfaces is at least 10cm x 10cm (for hazard labels)



Pictures reference: Adapted from https://www.who.int/ihr/biosafety/Module_iii_packaging.pdf

Packaging systems not available from the carrier can be purchased. Options include, but are not limited to (in alphabetical order):

Berlin Packaging
CargoPak
Inmark – Exakt-Pak, Saf-T-Pak
Infekta

Source: NIH's Biological Materials Shipping website, which includes "Disclaimer: The Office of Research Services, Division of Occupational Health and Safety (DOHS) does not endorse or recommend any commercial products, processes, or services. The DOHS website provides links to other Internet sites for informational purposes."

Exempt human or animal specimens

Exempt human or animal specimens are those with minimal risk/likelihood that pathogens are present, e.g. blood submitted for routine cholesterol screening.

Therefore, exempt human or animal specimens have the most basic packing, marking, labeling, and documentation requirements.

Not sure if a specimen is exempt? IATA defers to professional judgment, but gives good guidance for how to classify a human or animal specimen as exempt. See https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf.

Note: For ground transport only, US regulations apply.

- Specimens sent for infectious disease testing, even if an infectious disease is not expected (e.g. prescreening clinical trial patients for HIV), must be sent as a 'Biological substance, Category B' (DOT interpretation 09-0065).

  Note: This does not apply to dried blood spots or other specimens that are not regulated. 173.134(b)(9) states that dried blood spots or specimens for fecal occult blood detection placed on absorbent filter paper or other material are not regulated for shipping by ground, even if procured from a person with an infectious disease such as COVID-19 or influenza (DOT interpretation 20-0077)

- Otherwise, per 49 CFR §173.134, these specimens are not regulated (i.e. no packing, marking or labeling requirements), nor are non-infectious cells, tissue cultures, DNA, RNA or other non-infectious genetic elements. OSHA labeling for Bloodborne Pathogens does still apply and many carriers will still request that you meet IATA requirements, which DOT allows (DOT interpretation 11-0314).

A. Prepare and Mark your package(s)

1. If shipping by US Mail, use USPS Packaging Instruction 6 H (in US Postal Service's Publication 52). Quantity limits apply (≤ 500 ml or g).
2. Three layer/triple packaging is still required, including leak-proof first and second layers (primary receptacles and secondary packaging). Outer packaging does not have to be a box, but must be of adequate strength for its intended use.
3. OSHA requires a biohazard label for specimens covered by the Bloodborne Pathogens standard.
4. Mark (outer package)
   a. "Exempt human specimen" or "Exempt animal specimen"
   b. For specimens using IATA DGR Special Provision A180, use "scientific research specimens, not restricted Special Provision A180 applies".

B. Document

Note: some carriers use different field/box headings on their Air Waybills.

1. Air Waybill
   - For specimens using IATA DGR Special Provision A180, in the substance description: "not restricted" and "Special Provision A180".
2. Shipper's Declaration for Dangerous Goods – not required.

C. Pack

1. Affix the biohazard label to either primary receptacles or secondary packaging (latter, if shipped by US Mail).
   - Human tears, nasal secretions, sputum, saliva (other than saliva from dental procedures), sweat, vomitus, urine and feces are excluded unless visibly contaminated with blood (OSHA interpretation 6/1/1992).
   - See OSHA interpretation 9/8/2005 for further information.
2. Refrigerants, if used, are placed between the secondary and outer packagings.
3. For air transport, per IATA DGR Special Provision A180, "non-infectious specimens" may be shipped in formaldehyde solution, ethanol, or isopropanol without additional hazard labeling (i.e. no 'excepted quantities' label required) or the packaging drop tests required for 'de minimis quantities' and 'excepted quantities' of regulated chemicals if the following additional packaging and marking requirements are met:

   Packing layers:

   a. Inner receptacle: vial or other rigid container (or heat-sealed plastic bag for specimens wrapped in towel or cheesecloth like museum specimens)
      – up to 30 ml formaldehyde solution, ethanol, or isopropanol per inner receptacle
   b. Heat-sealed plastic bag
   c. Absorbent
   d. Heat-sealed plastic bag
   e. Cushioning material
   f. Strong outer packaging
      – maximum of 1 liter of formaldehyde solution, ethanol, and/or isopropanol per package

Biological substances (Category B)/Packing Instruction 650

'Biological substances (Category B)' (Proper Shipping Name for Category B infectious substances) are those that can cause disease in people or animals (i.e. not exempt), but don't fit into other regulated categories (e.g. blood from a person that is hepatitis B positive since hepatitis B is only Category A when shipped as a culture).

Likewise, Category B infectious substances have intermediate packing, marking, labeling, and documentation requirements (between 'exempt human or animal specimens' and 'Category A infectious substances').

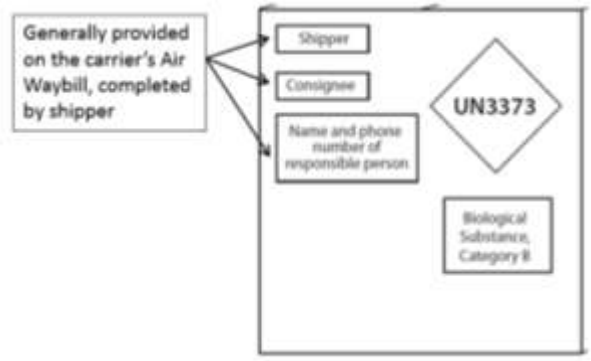
A. Prepare your packaging

Some carriers provide outer packaging (i.e. boxes) with applicable marks and labels.

1. Verify media does not contain regulated hazardous material, other than those allowed (see 'General requirements').
2. Calculate how many packaging systems to buy based on amount being shipped.
   - Each primary receptacle may contain up to 1 L.
   - The maximum quantity allowed per package is 4 L or 4 kg.
3. Use packaging approved for Packing Instruction 650, per the manufacturer. https://www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-pi650.pdf
4. OSHA requires a biohazard label for specimens covered by the Bloodborne Pathogens standard.

B. Mark and Label (outer package)

1. Proper Shipping Name – 'Biological substance, Category B'
2. Identification label (memory hint: B rhymes with 3) - 'UN 3373'
   - Prescribed orientation and label and font size – use a commercial label
3. Name and address of both the shipper and recipient/consignee
4. Name and telephone number of person responsible for shipment
   - On the package (or the Air Waybill if affixed to package)
   - If shipper or recipient/consignee, can add telephone number to step c. above.



Adapted from http://www.cdc.gov/mmwr/pdf/other/su6101.pdf

C. Document

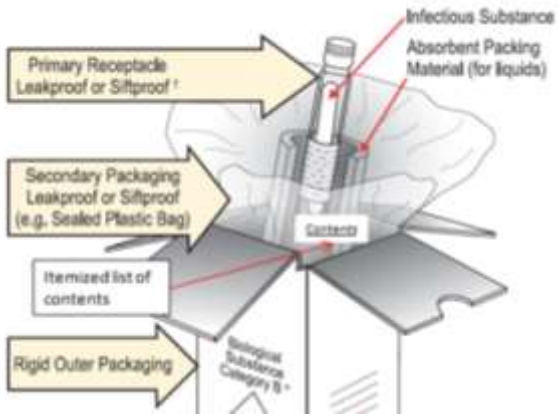
Note: some carriers use different field/box headings on their Air Waybills.

1. Air Waybill
   a. 'Handling Information' field/box – leave blank
   b. 'Nature and Quantity of Goods' field/box (if not on the Air Waybill, contact the carrier for directions/where to put the information)
      - UN 3373
      - BIOLOGICAL SUBSTANCE, CATEGORY B
      - number of packages in shipment
   c. In the US, DOT requires an "Emergency response telephone number" on the shipping paper or on the outer packaging (e.g. shipper's cell phone number).
      - Monitored during operational business hours by a person who is either
        - knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or
        - has immediate access to such a person.
      - Do not use EH&S for this number. However, if the shipper is contacted and needs assistance answering emergency response questions, have Public Safety (275-3333) page the Biosafety Officer.
2. Shipper's Declaration for Dangerous Goods – not required.

D. Pack

1. Follow the packaging manufacturer's instructions, which will include basic three layer (triple) packaging.
   - If shipping with refrigerant (e.g. dry ice), primary receptacle and secondary packaging must maintain integrity at refrigerated temperature.
   - Absorbent material added for liquids must be able to absorb the amount of liquid contained in all primary receptacles.

2. Affix a biohazard label to either primary receptacles or secondary packaging for specimens covered by the Bloodborne Pathogens standard.
   - Human tears, nasal secretions, sputum, saliva (other than saliva from dental procedures), sweat, vomitus, urine and feces are (OSHA interpretation 6/1/1992).
   - See OSHA interpretation 9/8/2005 for further information.
3. Include an itemized list of contents between the secondary and outer packagings.
   – This is for emergency responders if the package is compromised during transit.
   – This is also for the recipient so they know exactly what was packed.



Adapted from US DOT's Transporting Infectious Substances Safely, 2006 (similar in 2020 version)
For additional pictures, see Appendix 2 – CDC Job aid for Biological Substance, category B.

4. Refrigerants, if used, are placed between the secondary and outer packagings.

Category A infectious substances/Packing Instruction 620

IATA defines Category A infectious substances as capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals, if exposure to it occurs (i.e. physical contact). This definition applies to the form the substance is transported in (culture, infected bodily fluid, etc.)

Likewise, Category A infectious substances have the strictest packing, marking, labeling, and documentation requirements for all of the infectious substances.

Proper Shipping Names:

- Infectious substance, affecting humans (liquid)
- Infectious substance, affecting humans (solid)

- Infectious substance, affecting animals only (liquid)
- Infectious substance, affecting animals only (solid)

A. Prepare your packaging

Some carriers provide outer packaging (i.e. boxes) with applicable marks and labels.

1. Verify media does not contain regulated hazardous material, other than those allowed (see 'General requirements').
2. Use packaging approved for Packing Instruction 620.
3. Calculate how many packaging systems to buy based on amount being shipped.
   - The maximum quantity allowed on passenger aircraft is 50 ml or 50 g.
   - The maximum quantity allowed on cargo aircraft is 4 L or 4 kg.
   - Greater quantities are allowed in body parts, organs or whole bodies, if IATA DGR special provision A81 is used (note: same for ground transport/DOT, but under a different number, DOT special provision A82).

     Note: Blood, urine and other body fluids are not considered "body parts" for this application.

B. Mark and Label your package(s)

1. Proper Shipping Name and identification number
   - Infectious substance, affecting humans (liquid), UN2814
   - Infectious substance, affecting humans (solid), UN2814
   - Infectious substance, affecting animals only (liquid), UN2900
   - Infectious substance, affecting animals only (solid), UN2900

   For security reasons, do not mark the technical name (i.e. species or virus name) on the outside of the package (IATA DGR Special Provision A140 and 49 CFR §172.203(k).) It will be on the Shipper's Declaration for Dangerous Goods (see Document, below).

2. Hazard label – Class 6 Infectious Substance
   - Prescribed orientation and label and font size
     - use a commercial label
   - Effective October 2014, does not refer to CDC
     - Picture reference: DOT 49 CFR §172.432

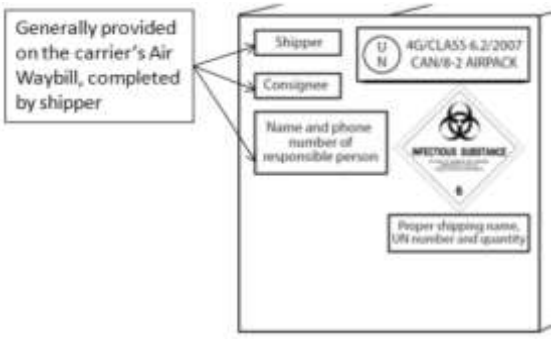
3. When shipping > 50 ml or 50 g (in primary receptacles)
   a. 

"Cargo Aircraft Only" label
   - Standard label is greater than 10cm but allowed to be half size for these shipments

b. 

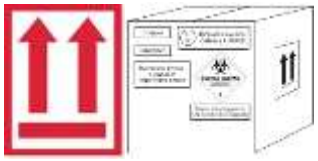
For liquids, two Package Orientation labels (red or black arrows) Affixed to opposite sides of the package pointing in the same orientation as primary receptacle closures.

4. Name and address of both the shipper and recipient/consignee
5. Name and telephone number of person responsible for shipment
   - On the package (or the Air Waybill if affixed to package)
   - If shipper or recipient/consignee, can add telephone number to step 4 above.
6. Final marks and labels (with no refrigerant):



Liquids and solids ≤ 50 ml or 50 g

\+



For liquids > 50 ml, add orientation arrows (2 opposite sides)

For liquids and solids > 50 ml or 50g, add 'Cargo Aircraft Only' (these quantities are not allowed on passenger aircraft)

Adapted from CDC's: http://www.cdc.gov/mmwr/pdf/other/su6101.pdf and CDC's "Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know" https://www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html

C. Document

Note: Some carriers use different field/box headings on their Air Waybills.

1. Air Waybill
   a. 'Handling Information' field/box
      - Dangerous Goods as per attached Shipper's Declaration (or)
      - Dangerous Goods as per attached DGD – Cargo Aircraft Only
   b. 'Nature and Quantity of Goods' field/box
      - This will be in detail on the Shipper's Declaration for Dangerous Goods; follow carrier instructions or use a general description (e.g. Infectious Substances).
   c. In the US, DOT requires an "Emergency response telephone number" on the shipping paper that is monitored at all times during package transport by a person knowledgeable about the material being shipped (e.g. shipper's cell phone number). Do not use EH&S for this number.

2. Shipper's Declaration for Dangerous Goods

   Note: CDC has additional guidance for completing the Shipper's Declaration for Dangerous Goods at http://www.selectagents.gov/guidance-shipdeclaration.html and DOT interpretation 21-0002.

   a. In the 'Nature and Quantity of Goods' section, the technical name (genus, species) must accompany the Proper Shipping Name (for this document only, do not put on the package per A140). If the technical name is unknown, use "Suspected Category A Infectious Substance" in parentheses (optional for IATA/air, required DOT/ground).

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Human immune-deficiency virus culture)	6.2		1 Fiberboard box x 25 g	620	

Fiberboard – shipping term for corrugated cardboard

Adapted from IATA DGR, 59th edition (2018)

   b. Authorization box: A140 is no longer required; use A81 if applicable (see Pack, 3.)

   c. Additional information is required if shipping with dry ice (see "Dry Ice").

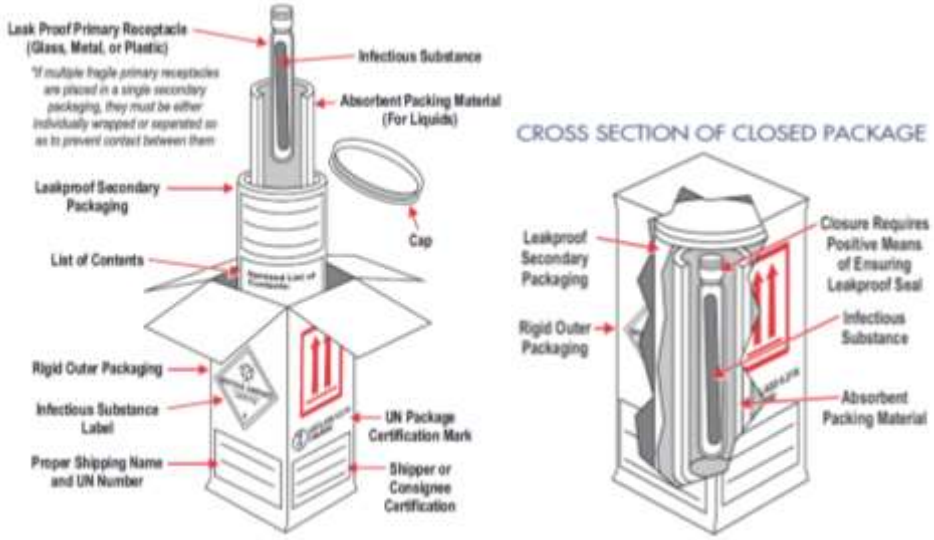
3. Emergency response information

   Per 49 CFR §172.600, 602, emergency response information must accompany all shipments that require a Shipper's Declaration for Dangerous Goods. The "Infectious Substances" section of DOT's Emergency Response Guidebook meets the requirement (see Appendix 4 – Emergency Response Information for Category A).

D. Pack

1. Follow the packaging manufacturer's instructions, which will include basic three layer (triple) packaging.
   - Additional requirements for primary receptacles:
     - If shipping at ambient or higher temperatures (i.e. no refrigerants), primary receptacles must be of glass, metal or plastic and leak-proof seal ensured (e.g. heat seal, or for screw tops: tape, paraffin or locking closure).
     - For lyophilized substances, primary receptacles must be either flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.
   - Same as for Packing Instruction 650:
     - If shipping with refrigerant (e.g. dry ice), primary receptacle and secondary packaging must maintain integrity at refrigerated temperature.
     - Absorbent material added for liquids must be able to absorb the amount of liquid contained in all primary receptacles.

2. While OSHA requires a biohazard label for specimens covered by the Bloodborne Pathogens standard, the Class 6 label on the outer packaging meets this requirement (OSHA interpretation 9/8/2005).
3. Include an itemized list of contents between the secondary and outer packagings.
   - Same reasons as for Packing Instruction 650
   - When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A, the words "Suspected Category A Infectious Substance" must be shown in parentheses following the proper shipping name on the itemized list of contents.



Adapted from US DOT's Transporting Infectious Substances Safely, 2006 and 2020
For additional pictures, see Appendix 3 – CDC Job aid for Infectious Substance, category A.

4. Refrigerants, if used, are placed between the secondary and outer packagings.

Genetically modified micro-organisms and organisms/Packing Instruction 959

GMMOs and GMOs are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. If GMMOs fit into Class 6, they are shipped according to the applicable Proper Shipping Name for infectious or biological substances. All others are shipped as a Class 9 hazard and Packing Instruction 959.

These are regulated for international shipments only. Even if shipped by air, IATA defers to DOT (IATA DGR 3.9.2.5.3), and DOT does not regulate these for shipment.

A. Prepare your packaging

1. Three layer/triple packaging is still required, including a leak-proof first layer (primary receptacle); the second layer (secondary packaging) does not have to be leak-proof.

2. There are no quantity restrictions.

B. Mark and Label (outer package)

3. Proper Shipping Name – not required
4. Identification label - 'UN 3245'
   - Prescribed orientation and label and font size – use a commercial label (if one is not available, diamond shape, and each of the following must be at least: each side 5 cm, the width of the line around the label 2 mm thick, and the numbers 6 mm high)

5. Name and address of both the shipper and recipient/consignee

C. Document

Note: some carriers use different field/box headings on their Air Waybills.

1. Air Waybill
   a. 'Handling Information' field/box – leave blank
   b. 'Nature and Quantity of Goods' field/box (if not on the Air Waybill, contact the carrier for directions/where to put the information)
      - UN 3245
      - "GMMO" or "GMO", as applicable
      - number of packages (unless these are the only packages in the shipment)
2. Shipper's Declaration for Dangerous Goods – not required.

D. Pack

1. Three layer/triple packaging is still required, including a leak-proof first layer (primary receptacle); the second layer (secondary packaging) does not have to be leak-proof.
2. There are no quantity restrictions.

Biomedical Waste

If you package Regulated Medical Waste for shipment to Stericycle or sign off on Regulated Medical Waste tracking forms, you must take specific training, e.g. "EHS DOT Shipping Training for Generators of Medical Waste" on MyPath.

Dry ice/Packing Instruction 954

Refrigerants must be placed between secondary and outer packagings. Interior supports must be present to secure secondary packagings in original position even after the refrigerant dissipates. Dry ice is a cryogenic material, a Class 9 hazard and shipped using Packing Instruction 954.

From IATA's DGR: Carbon dioxide, solid (dry ice) is used primarily for cooling and due to its very low temperature (about -79ºC) can cause severe burns to skin upon direct contact. When dry ice converts (sublimates) directly to gaseous carbon dioxide, it takes in heat from its surroundings. The resulting gas is heavier than air and can cause suffocation in confined areas.

Plan ahead and contact the carrier - proper ventilation during transport must be arranged.

A. Prepare your packaging

1. If shipping by US Mail, use USPS Packaging Instruction 9A (in US Postal Service's Publication 52). Note: the USPS sets a quantity limit for air transport of ≤ 5 pounds.
2. Maximum quantity of dry ice per package: 200 kg (passenger and cargo aircraft)
3. Dry ice may be packed in one of two ways:
   a. Overpack style outside of a completely packed outer packaging.
   b. All-in-one style already designed for packing both infectious substances and dry ice.

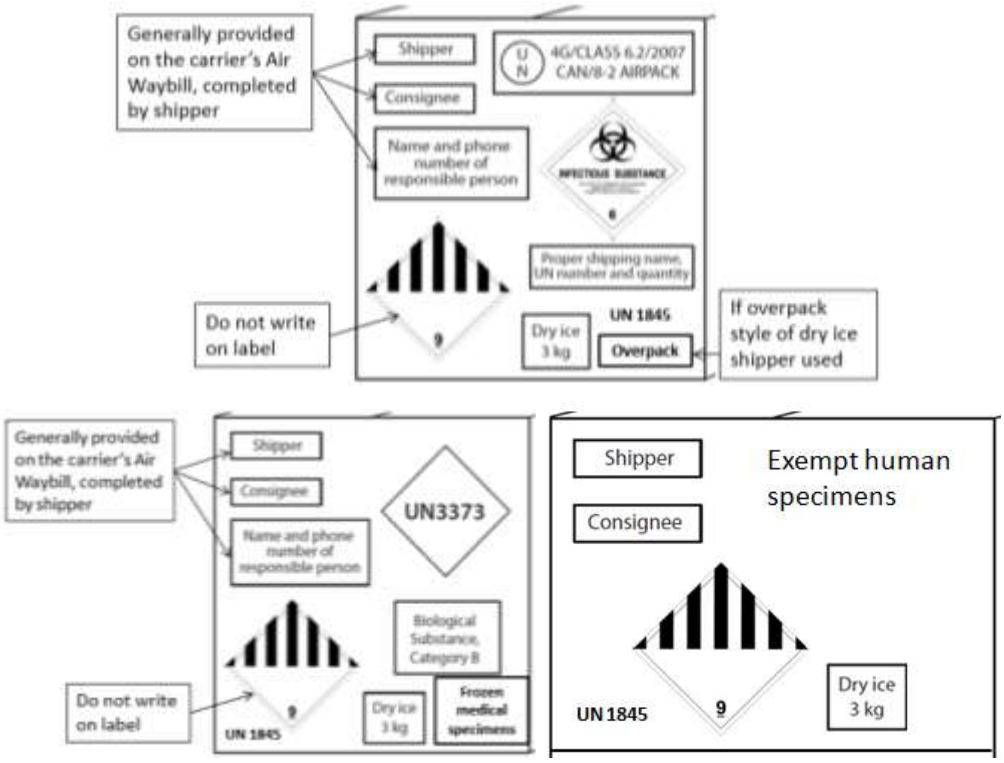
4. Irrespective of the style used, packages containing dry ice must be designed and constructed so as to prevent build-up of pressure/possible package rupture due to the release of carbon dioxide gas. A fiberboard (corrugated cardboard) box with Styrofoam insulation is generally used.

B. Mark and Label (outer package)

1. Proper Shipping Name – "Dry ice" or "Carbon dioxide, solid"
2. Identification label - UN 1845
3. Hazard label – Class 9
   – Prescribed orientation and label – use a commercial label
   – Effective October 2014, DOT uses the international Class 9 label without a horizontal line in the middle to prevent relabeling/ shipment delays outside the US. For domestic ground shipments, DOT used to allow the carrier to accept either label, however DOT interpretation 14-0165 has been deleted.

4. Quantity of dry ice (e.g. 3 kg)

5. For Category B infectious substances, if applicable, mark with "an indication that the material being refrigerated is used for diagnostic or treatment purposes (e.g., frozen medical specimens)" per DOT §173.199(d)(2) and interpretation 12-0051.
6. Per 49 CFR §173.217(c)(5) for ground shipments up to 2.5kg (5.5pounds): UN 1845 and Class 9 label not required if package marked with name of the contents being cooled. US Mail also does not require the Class 9 label if marked per USPS Packaging Instruction 9A (USPS Publication 52).
7. Name and address of both the shipper and recipient/consignee



Adapted from CDC's: http://www.cdc.gov/mmwr/pdf/other/su6101.pdf

C. Document

Note: some carriers use different field/box headings on their Air Waybills.

1. Air Waybill (if a Shipper's Declaration is not required for other materials)
   a. 'Handling Information' field/box – leave blank
   b. 'Nature and Quantity of Goods' field/box (if not on the Air Waybill, contact the carrier for directions/where to put the information)
      – UN 1845

- "Dry ice" or "Carbon dioxide, solid"
- number of packages
- Net weight of dry ice (in each package, or in overpack, as applicable)

Example:

Describe unregulated material, e.g. Frozen exempt human specimens
UN 1845
Carbon dioxide, solid
1 x 3kg

2. Air Waybill (if a Shipper's Declaration is required for other materials)
   a. 'Handling Information' field/box
      - Dangerous Goods as per attached Shipper's Declaration, or
      - Dangerous Goods as per attached DGD – Cargo Aircraft Only
   b. 'Nature and Quantity of Goods' field/box
      - This information will be given in detail on the Shipper's Declaration for Dangerous Goods. Therefore, follow carrier instructions or use a general description (e.g. Infectious Substances).
3. Shipper's Declaration for Dangerous Goods (3 copies for shipment, 1 copy for records)
   a. Dry ice with non-infectious specimens, 'exempt human specimen', or 'Biological substance, Category B' – Shipper's Declaration is not required
   b. Shipments that require a Shipper's Declaration (i.e. Category A infectious substances):

Overpack style

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Author ization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Human immunodeficiency virus culture)	6.2		1 fiberboard box x 25 g	620	
UN1845	Dry ice	9		20 kg Overpack used	954	

Fiberboard – shipping term for corrugated cardboard

All-in-one style

NATURE AND QUANTITY OF DANGEROUS GOODS

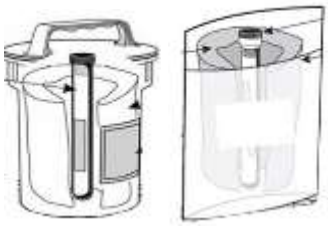
Dangerous Goods Identification				Quantity and type of packing	Packing Inst.	Author ization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary risk)	Packing Group			
UN2814	Infectious substance, affecting humans (Human immunodeficiency virus culture)	6.2		25 g	620	
UN1845	Dry ice	9		20 kg All packed in one Fiberboard box	954	

Fiberboard – shipping term for corrugated cardboard

Adapted from IATA DGR, 63th edition (2022)

D. <u>Pack</u>

- Since secondary packagings (other than for GMMOs) are leak-proof, placing dry ice inside them can cause them to explode.



<u>NO dry ice inside leak-proof containers!</u>

- Virus box explodes at Ohio FedEx site" NYTimes March 2003
- "Container with swine virus explodes in Swiss train" Reuters, April 2009

F. University and personal vehicles/DOT's 'Materials of Trade Exception'

University courier services should be used preferentially.

However, the University of Rochester does not currently have a policy forbidding the use of personal vehicles for the transport of DOT-exempt biological materials or materials that fall under DOT's 'Materials of Trade exception'.

DOT-exempt biological materials:

- Common biological materials deemed non-hazardous for shipping (similar to IATA's DGR):
  - 'exempt human specimens', 'exempt animal specimens', non-infectious DNA/RNA
  - dried blood spots, and
  - fixed pathogens (non-viable, neutralized, inactivated).
- The following materials *when* "transported by a private or contract carrier in a motor vehicle used exclusively to transport such materials"

  Note: Per DOT 49 CFR §171.8, *carrier* means a person who transports passengers or property in commerce by rail car, aircraft, motor vehicle, or vessel (i.e. University staff).

  - Human or animal specimens containing Category B infectious agents (but not wastes) *if* transported for research, diagnosis, or disease treatment or prevention
  - Medical or clinical equipment and laboratory products *if* they are "properly packaged and secured against exposure or contamination".
- For complete list, see 49 CFR §173.134(b) at www.ecfr.gov.

'Materials of Trade'

DOT allows the ground transport of selected hazardous materials when transported in small quantities as part of a non-transport business (i.e. 'Materials of Trade', 49 CFR §173.6) using fewer requirements than if they were packaged for shipping.

For example, this allows building contractors to carry acetylene, gas, paint, etc. on work or personal vehicles.

When the 'Materials of Trade' exception does not apply:

- A medical courier whose sole business is the transport of medical materials or a patient transport service if transport is their primary business,

  Note: the exception does apply to medical couriers used/operated by a non-transport business (medical labs).
- Cultures (Category A or B infectious substances), and
- Any material that may contain a Category A infectious substance (e.g., patient specimens being tested for Category A infectious substances, like Ebola virus).

When the 'Materials of Trade' exception does apply to UR medical professionals or researchers:

1. Biological 'Materials of Trade'
   - Human or animal specimens classified as 'Biological Substance, Category B' – transported for research, diagnosis, disease treatment or prevention

Note: 'exempt patient specimens' aren't 'Materials of Trade' already exempt from all DOT regulations.

- Live vaccines, toxins, and other commercial 'biological products' used for preventing or treating diseases/conditions of people or animals
- Medical waste

  Note: Medical waste generated in the home is not regulated by New York State. For home sharps disposal guidance, see https://www.dec.ny.gov/chemical/9082.html.

- Maximum quantities of biological 'Materials of Trade' per vehicle:

Biological material	Primary receptacle	Outer packaging
More than one specimen	≤ 0.5 kg or liters (1.1 pounds or 17 ounces)	≤ 4 kg or liters (8.8 pounds or 1 gallon)
One specimen	≤ 16 kg or liters (35.2 pounds or 4.2 gallons)	≤ 16 kg or liters (35.2 pounds or 4.2 gallons)
Medical waste	≤ 4 kg or liters (8.8 pounds or 1 gallon)	≤ 16 kg or liters (35.2 pounds or 4.2 gallons)

2. Class 3, 8, 9 materials (similar to Packing Instructions 620 and 650) with quantity limits
   - ≤ 30 kg or liters (66 pounds or 8 gallons) of ethanol, isopropanol, or formaldehyde solutions per vehicle
3. Dry ice

Procedure for University staff preferring to use their own vehicle:

1. During the transport operation, the vehicle cannot be used for any other purpose.
2. Contact personal insurance carrier to gather information on transporting liabilities.
   - The individual's own personal insurance would cover any damage as a result of an accident with the specimens.
   - The University does not offer insurance for this purpose.
3. Be current on applicable safety training (e.g. OSHA's Bloodborne Pathogens standard).
4. Pack 'Materials of Trade' biologicals using the appropriate packaging.
   a. Rather than the three layer/triple packaging, only two layers are required:
      - leak-proof primary receptacle, or closed sharps container for sharps
      - outer packaging
        - "strong, tight packaging securely closed and secured against shifting, including relative motion between packages, within the vehicle"

- contains absorbent material sufficient for the entire liquid contents

b. Affix a biohazard label to specimens covered by OSHA's Bloodborne Pathogens standard.
   - Human tears, nasal secretions, sputum, saliva (other than saliva from dental procedures), sweat, vomitus, urine and feces are excluded unless visibly contaminated with blood (OSHA interpretation 6/1/1992).
   - See OSHA interpretation 9/8/2005 for further information - Acceptability of DOT labeling requirements in lieu of OSHA's labeling requirements for shipments of biohazardous materials.

c. If used, place refrigerants between the primary and outer packagings.

5. Securely close all packages.
6. Mark all materials with a common name or Proper Shipping Name, and other labels as required by the Chemical Hygiene Program.
7. Place packages containing biologicals in the vehicle's trunk during transportation so not visible and secure to keep from moving while the vehicle is in motion.
8. Place, in the vehicle's glove box, a name and description of the material transported, the quantity, destination, the date transported, and a contact person's phone number.
9. Drive directly to the destination point. Do not make other stops during transport.
10. After delivery, discard disposable packaging and disinfect any portion of the packaging that may be reused.
    - Examples of approved disinfectants include Virex II 256 (ready to use, or diluted as per manufacturer's instructions, 10% solution of household or germicidal bleach, Oxivir TB and CaviWipes.

V. DEFINITIONS

Airway Bill: An air waybill is a document made out by or on behalf of the shipper which evidences the contract between the shipper and the carrier.

Biological Products: Products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto.

Biological substance, Category B: An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in Category B must be assigned UN 3373.

Carrier: A person who transports passengers or property in commerce by rail car, aircraft, motor vehicle, or vessel.

Centers for Disease Control and Prevention (CDC): Federal agency charged with protecting

public health and safety.

Cultures: The result of processes by which pathogens are intentionally propagated.

Dangerous Goods: Articles or substances capable of posing a risk to health, safety, property, or the environment and are shown in the list of dangerous goods in the IATA and DOT Regulations.

Dry Shipper: Insulated packaging containing refrigerated liquid nitrogen fully absorbed in a porous material and intended for transport, at low temperature, of dangerous or non-dangerous products where the design of the insulated packaging would not allow the build-up of pressure within the container and would not permit the release of any liquid nitrogen irrespective of the orientation of the insulated packaging (excerpted from IATA DGR 58th edition, unchanged for 2021).

EH&S: University of Rochester Department of Environmental Health and Safety

Genetically Modified Organisms (GMO) or Micro-organisms (GMMO): Organisms or microorganisms that have been purposely altered through genetic engineering.

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

Infectious Substance, Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

International Air Transport Association (IATA): International trade group of airlines which issues the "IATA Dangerous Goods Regulations" for shipment by air.

New York State Department of Environmental Conservation (NYSDEC): State agency responsible for the conservation, improvement, and protection of natural resources within New York State.

Overpack: an enclosure used by a single shipper to contain one or more packages and to form one handling unit for convenience of handling and stowage, or per DOT, to provide protection. Additional marking, labeling, and document requirements apply.

For example: one or more packages 1) placed in a protective outer packaging such as a box or a crate, or 2) placed and secured on a load board such as a pallet.

Transport vehicles and freight containers are not overpacks.

Packing Instruction: A set of specific packaging requirements which must be used for each article or substance offered for shipment by air.

Patient Specimens: Collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention. Includes, but not limited to, excreta, secreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (*e.g.*, transwabs, culture media, and blood culture bottles).

Shipper: An individual who does any of the following 1) Marking and labeling packages, 2)

Filling packages, 3) Accepting packages for shipment, 3) Supervising these activities, 4) Preparing shipping documentation, 5) Loading trucks, 6) Purchasing shipping supplies.

Shipper's Declaration for Dangerous Goods: A form which must be completed in conjunction with shipments containing dangerous goods.

Triple Packaging: Combination packaging consisting of a (1) leakproof primary/inner receptacle (2) leakproof secondary/intermediate packaging containing absorbent and cushioning material (3) outer packaging of adequate strength for its intended use.

UN/ID Number: A unique four digit number assigned to each Dangerous Good under the United Nations' classification system.

United States Department of Agriculture (USDA): Federal agency charged with protecting and promoting U.S. food, agriculture, natural resources and related issues.

United States Department of Transportation (DOT): National authority which regulates the shipment and transport of hazardous materials. Regulations are detailed in the Federal Code of Regulations, 49 CFR Parts 171-178.

VI. REFERENCES

Center for Disease Control and Prevention (CDC)

- Import Permit Program http://www.cdc.gov/od/eaipp/
- eTool – Do I need an import permit? https://www.cdc.gov/cpr/ipp/etool.htm
- Animals/Animal products regulated by CDC http://www.cdc.gov/importation/bringing-an-animal-into-the-united-states/index.html
- CDC's "Storing, Packaging, and Shipping Infectious Substances" http://www.cdc.gov/mmwr/pdf/other/su6101.pdf (Pages 80-86 of "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories", MMWR Supplement, Vol. 61, January 6, 2012; also available in Spanish)
- "Packing and Shipping Dangerous Goods: What the Laboratory Staff Must Know" www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html and https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_3_Packing_Category_A_and_B_and_Exempt_Human_and_Exempt_Animal_Specimens_Job_Aid_508.pdf

Department of Commerce (DOC) Bureau of Industry and Security
https://www.bis.doc.gov/index.php/licensing

Department of Transportation (DOT) 49 CFR Parts 171, 172, 173 – www.ecfr.gov

- DOT's Packaging and Shipping SARS CoV 2 Specimens, Cultures, Isolates and Waste, PHMSA https://www.phmsa.dot.gov/transporting-infectious-substances/packaging-and-shipping-sars-cov-2-specimens-cultures-isolates-and-waste
- DOT's Pipeline and Hazard Materials Safety Administration's interpretation letters https://www.phmsa.dot.gov/regulations/title49/b/2/1
- DOT's Pipeline and Hazard Materials Safety Administration's What You Should Know: A Guide To Developing a Hazardous Materials Training Program
- DOT's Pipeline and Hazard Materials Safety Administration's Emergency Response Guidebook, A Guidebook Intended for Use by First Responders During the Initial Phase of a

Transportation Incident Involving Dangerous Goods/Hazardous Materials, 2016

- DOT's Safety Advisory Notice for the Transportation of COVID-19 Diagnostic Samples https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2020-06/UN3373%20COVID%2019%20Safety%20Advisory.pdf
- DOT's Transporting Infectious Substances Safely, 2020 www.phmsa.dot.gov/transporting-infectious-substances/transporting-infectious-substances-safely

Federal Select Agent Program (FSAP) www.selectagents.gov

International Air Transport Association Dangerous Goods Regulations (IATA DGR), 62st ed. 2021

- IATA DGR 6.2, including instructions for 'exempt human or animal specimens' www.iata.org/contentassets/b08040a138dc4442a4f066e6fb99fe2a/dgr-62-en-3.6.2.pdf

New York State Department of Environmental Conservation (NYS DEC)

- Fish, Wildlife & Plant Permits http://www.dec.ny.gov/permits/96308.html
- Household Sharps-Dispose of Them Safely https://www.dec.ny.gov/chemical/9082.html

NIH's Division of Occupational Health and Safety - Biological Materials Shipping website www.ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/shipping_biological_material.aspx

Occupational Safety and Health Association's (OSHA) Bloodborne Pathogens Standard

- interpretations (for Part 1910.1030): https://www.osha.gov/laws-regs/standardinterpretations/standardnumber (use browser other than Internet Explorer)

Office of Foreign Assets Control (OFAC) http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx

Office of Research and Project Administration (ORPA)
https://www.rochester.edu/orpa/compliance/#export

World Health Organization – Packaging of Infectious Substances, Shippers' Programme 2015-2016
https://www.who.int/ihr/biosafety/Module_iii_packaging.pdf

United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS)

- Imports and Exports https://www.aphis.usda.gov/aphis/ourfocus/importexport
- Animal and Animal Product Import Information https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/
- No import permit required https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/import-live-animals/no-import-permit-req
- Veterinary Services Permitting Assistant https://efile.aphis.usda.gov/s/vs-permitting-assistant

US Fish and Wildlife (USFW)

- Permits https://fwsepermits.servicenowservices.com/fws

- Injurious Wildlife, list of species https://www.fws.gov/injuriouswildlife/

US Postal Service US Postal Service's Publication 52 - Hazardous, Restricted, and Perishable Mail – http://pe.usps.com/text/pub52/welcome.htm (see USPS Packing Instruction 6C and 6H)

VII. REVISION HISTORY

Date	Revision	Description
12/29/2009	New	Establish written procedure for shipping biological materials
05/01/2011	1	Update section references
07/07/2011	2	Update to reflect regulatory changes
01/13/2014	3	Updated to update website link and correct typos
09/17/2014	4	Updated Dry Ice label
04/27/2016	5	Reformatted and updated to match UR's revised Shipping Biological Materials and Dry Ice training
01/17/2019	6	Clarified USDA permit requirements, updated web links, updated Appendix 4, added Appendix 5 (Commerce Control List)
2/21/2020	7	Annual regulatory review (one IATA add – IATA DGR 2.6.7.1.3., no DOT changes), updated or deleted unavailable web links, updated Import section, added fee column to import and export tables, added MTA paragraph, added reference to EHS RMW training
3/11/2021	8	Annual regulatory review – update Category B emergency number, dried blood spot exception; web link updates; revise task order in each Proper Shipping Name instruction so that documents are prepared in advance; Appendix 1 - add second page for export, import
12/30/2021	9	Annual regulatory review and web link updates

APPENDIX 1 – IMPORT, EXPORT AND SHIPMENT CHECKLISTS

IMPORTS (biologicals from other countries including Canada; USDA – transfer between states too)

☐ CDC's e-Tool decision tree determines if a CDC import permit is required.

- Permits are free, but require online federal Secure Asset Management System (SAMS) registration (restricts access to permit holder) – this should be the Principal Investigator.
- If a permit is not required, the tool provides certification statements for help with Customs. Put these on letterhead and provide to the sender for inclusion with the shipment.

☐ USDA's Veterinary Services Permitting Assistant determines if a USDA import permit is required (e.g. for animal products such as bovine serum albumin and fetal bovine serum.)

- USDA requires permit if from other another country e.g. Canada (transfer between states too).
- Permits are $150 and require registration with USDA's eFile system.
- If a permit is not required, follow the instructions in the appropriate guideline for help with Customs (e.g. a written statement supplied on foreign producer/shipper letterhead).

☐ USDA's Plant Health Permits website lists when a USDA permit is required for plants, plant products, plant pests, plant pathogens, biological control agents, bees, soil, etc.

☐ CITES permit - samples from endangered or threatened animals (see USFW), plants (see USDA); e.g. a CITES permit is required for all nonhuman primate material, including cell lines (Vero).

☐ Lists of invasive and injurious species (eggs, invertebrates, plants, fungi, algae, cyanobacteria) help determine when a USFW permit or NYS DEC permit is required.

EXPORTS (sending biologicals to other countries including Canada)

The US DOC's Commerce Control List (CCL) changes. Always check www.bis.doc.gov/index.php/regulations/export-administration-regulations-ear for the current CCL. Human and animal pathogens and toxins; plant pathogens; and genetic elements and genetically modified organisms appear in Category 1 of the CCL.

Any export compliance questions may be submitted to: export@rochester.edu

☐ Material Transfer Agreements (MTA) implemented through ORPA help with export compliance (submit MTA requests through IORA). ORPA will also take the lead for DOC export licenses.

* See Appendix 5 of BS009 for complete list. A subset of the CCL, of particular note for UR:

Organism (1C351)	Genes* (1C353)	Rationale (Australia Group, CCL Handbook, Federal Register)
LCMV	All	All *Arenavirus* genus spp. that cause human disease are listed
MERS	All	Homology with SARS-CoV
Pseudorabies	All	Potential for socioeconomic harm
Rabies	All	Some countries are rabies-free
SARS-CoV (not 2)	All	No effective vaccine, limited post-exposure treatment options
Vibrio cholerae	Some	Potential to damage the environment
VSV	All (e.g. VSV-G)	Potential for socioeconomic harm (mimics Foot and Mouth disease in livestock)

* For more on 'genes', see Technical Note 2 at the end of ECCN 1C353 in the Commerce Control List (CCL).

☐ CITES permit - samples from endangered or threatened animals (see USFW), plants (see USDA); e.g. a CITES permit is required for all nonhuman primate material, including cell lines (Vero).

☐ Import permit for recipient's country – the recipient should get the permit. If not required, recommend you include the same certification statement used for US imports, on UR letterhead. When serum-free media is used, that's helpful information to include.

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Personnel may use this version of the policy as a Training/User Manual. The first page includes a Table of Contents and an Executive Summary, and the Definitions section has moved toward the end, similar to a glossary. All other content is identical.

Date	*Keep shipping documents for 2 years past ship date
Person shipping	Last trained (within previous 2 years):
Recipient/Consignee	
Material(s) shipped	
Permit or License	☐ None or 3 copies with shipment: ☐ Import or Interstate ☐ Export
Proper Shipping Name	☐ Not applicable for biological component (exempt specimen, etc.) ☐ Biological substance, Category B ☐ Infectious substance, affecting humans (liquid, solid) ☐ affecting animals ☐ Dry ice ☐ Genetically modified micro-organism
Chemicals included	☐ De minimis (≤ 1 ml per primary/inner receptacle, ≤ 100 ml total) ☐ Excepted quantities (≤ 30 ml per primary/inner receptacle, ≤ 500 ml total) ☐ Limited quantities ☐ "non-infectious" in formaldehyde, ethanol or isopropanol (A180) ☐ None
Refrigerant	☐ Dry ice ☐ Cold Pack ☐ Liquid nitrogen ☐ Dry shipper ☐ None
Carrier	☐ UPS ☐ FedEx ☐ World Courier ☐ US Mail ☐ Self/MOT ☐ Other
Document	☐ Air Waybill ☐ Emergency response telephone number ☐ Substance description: "not restricted, Special Provision A180" ☐ Handling Information ☐ "Dangerous Goods as per attached Shipper's Declaration" ☐ "Dangerous Goods as per attached DGD-Cargo Aircraft Only" ☐ Nature and Quantity of Goods ☐ UN 3373, "Biological Substance, Category B", number of packages ☐ UN 3245, "GMMO" or "GMO", number of packages ☐ UN 1845, "Dry ice" or "Carbon dioxide, solid", number of packages, net weight of dry ice in kg ☐ Shipper's Declaration for Dangerous Goods and Emergency Response Info (3 copies with shipment, 1 copy for records)
Mark and Label Outer Packaging	Circle:  ☐ Exempt human specimen or Exempt animal specimen ☐ Biological substance, Category B ☐ Infectious substance, affecting humans, UN2814 (…animals, UN2900) ☐ Dry ice (or "Carbon dioxide, solid"), net weight of dry ice in kg, and "frozen medical specimens" for Category B specimens ☐ Overpack ☐ Other:
Pack	☐ Packaging per manufacturer instructions; not altered or substituted ☐ Biohazard label on primary or secondary packaging (latter for US Mail) ☐ List of contents between secondary and outer packaging ☐ Exempt human or animal specimen – basic three layer/triple packaging ☐ Biological substance, Category B/Packing Instruction 650 (+ biohazard symbol) ☐ Infectious substance, Category A/Packing Instruction 620 ☐ Genetically modified micro-organism/Packing Instruction 959 ☐ Dry ice/Packing Instruction 954

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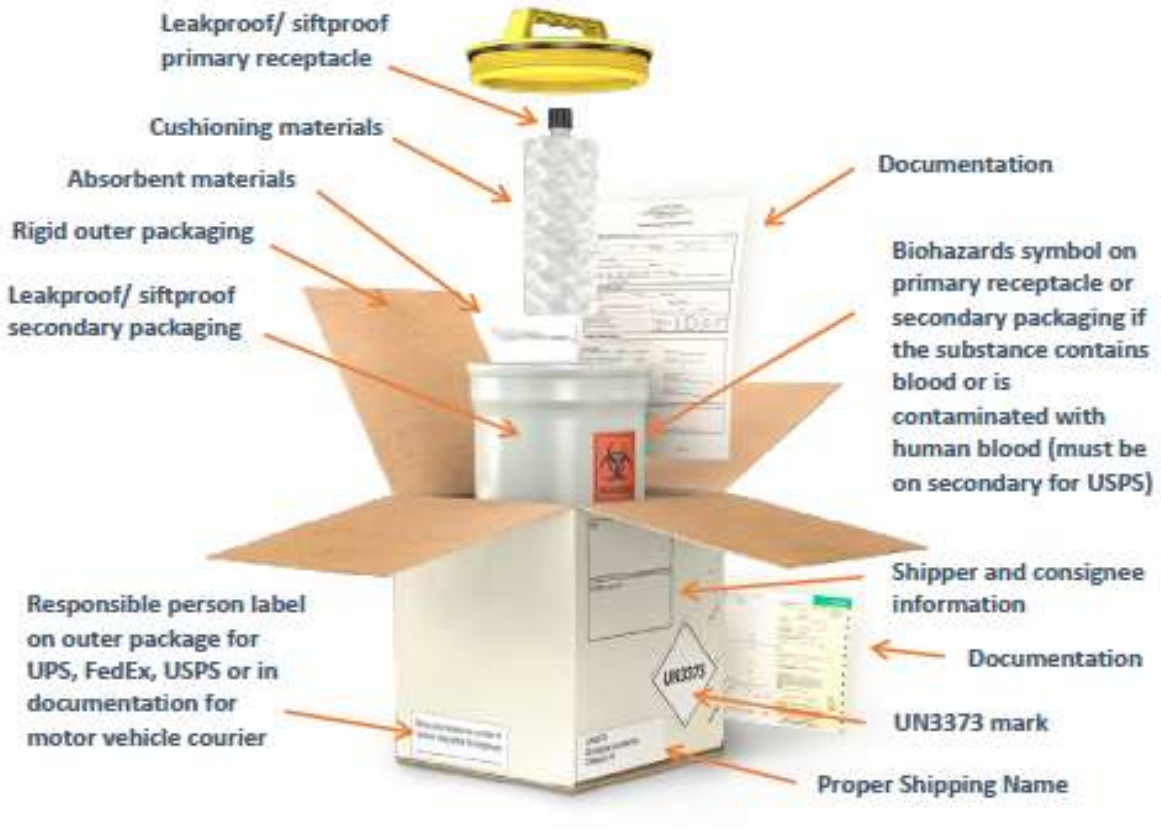
APPENDIX 2 – CDC JOB AID FOR BIOLOGICAL SUBSTANCE, CATEGORY B

Category B Substance Packaging



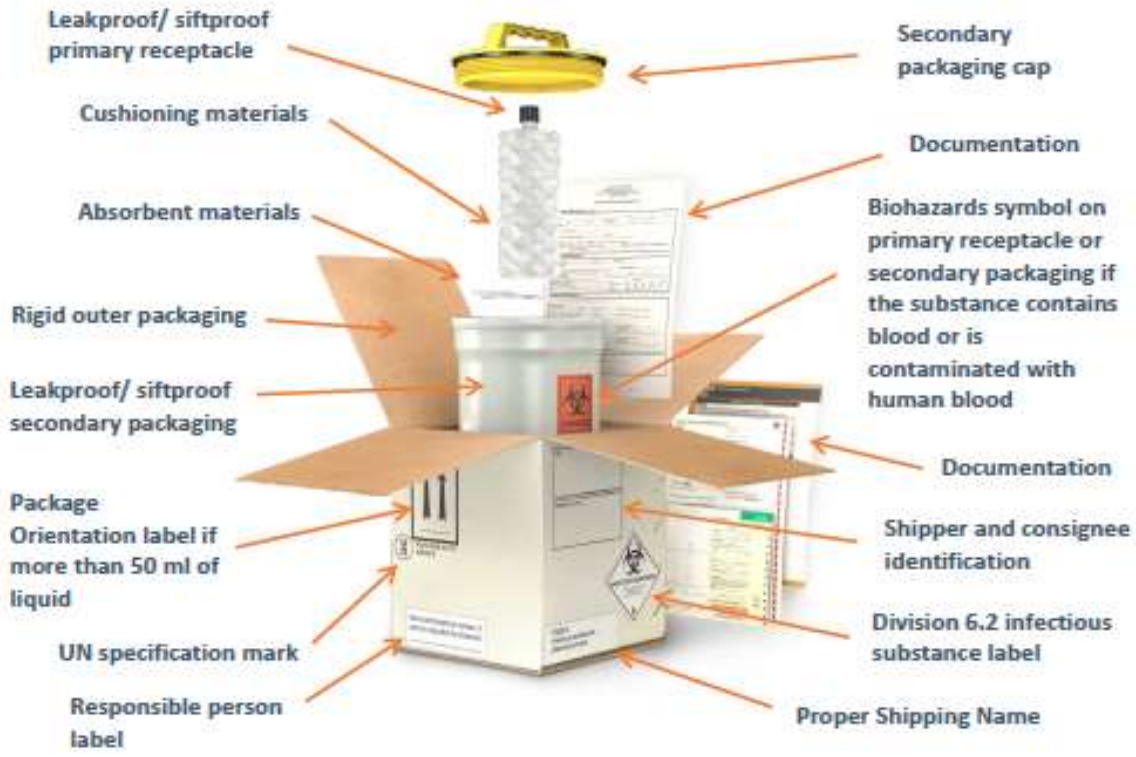
Category B Substance Packaging with Dry Ice

https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_3_Packing_Category_A_and_B_and_Exempt_Human_and_Exempt_Animal_Specimens_Job_Aid_508.pdf

APPENDIX 3 – CDC JOB AID FOR INFECTIOUS SUBSTANCE, CATEGORY A

Category A Substance Packaging

NOTE: The packaging is the same for both types (UN 2814 and UN2900) of Category A packaging, only the UN mark and Proper Shipping Names change.



Category A Substance Packaging with Dry Ice

https://www.cdc.gov/labtraining/docs/job_aids/packing_and_shipping/Step_3_Packing_Category_A_and_B_and_Exempt_Human_and_Exempt_Animal_Specimens_Job_Aid_508.pdf

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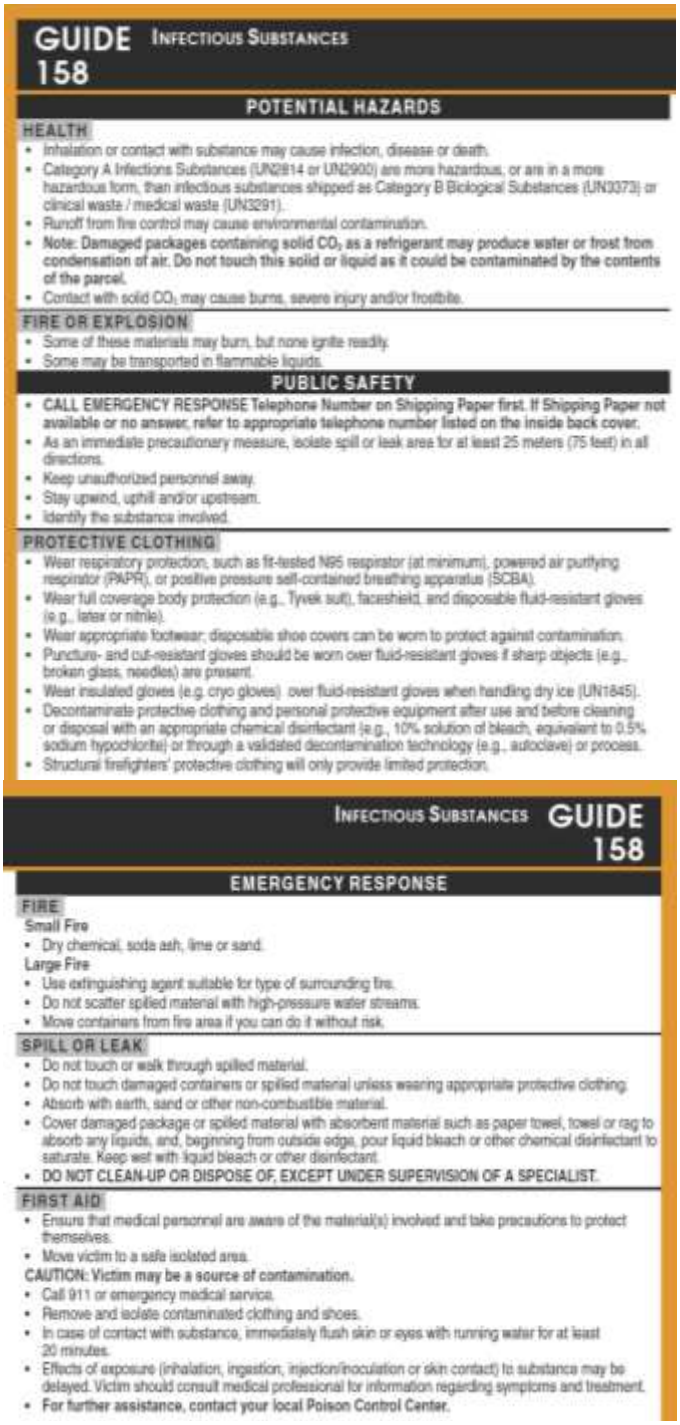
APPENDIX 4 – EMERGENCY RESPONSE INFORMATION FOR CATEGORY A



GUIDE 158 INFECTIOUS SUBSTANCES

POTENTIAL HAZARDS

HEALTH

- Inhalation or contact with substance may cause infection, disease or death.
- Category A Infectious Substances (UN2814 or UN2900) are more hazardous, or are in a more hazardous form, than infectious substances shipped as Category B Biological Substances (UN3373) or clinical waste / medical waste (UN3291).
- Runoff from fire control may cause environmental contamination.
- **Note: Damaged packages containing solid CO_2 as a refrigerant may produce water or frost from condensation of air. Do not touch this solid or liquid as it could be contaminated by the contents of the parcel.**
- Contact with solid CO_2 may cause burns, severe injury and/or frostbite.

FIRE OR EXPLOSION

- Some of these materials may burn, but none ignite readily.
- Some may be transported in flammable liquids.

PUBLIC SAFETY

- **CALL EMERGENCY RESPONSE Telephone Number on Shipping Paper first. If Shipping Paper not available or no answer, refer to appropriate telephone number listed on the inside back cover.**
- As an immediate precautionary measure, isolate spill or leak area for at least 25 meters (75 feet) in all directions.
- Keep unauthorized personnel away.
- Stay upwind, uphill and/or upstream.
- Identify the substance involved.

PROTECTIVE CLOTHING

- Wear respiratory protection, such as fit-tested N95 respirator (at minimum), powered air purifying respirator (PAPR), or positive pressure self-contained breathing apparatus (SCBA).
- Wear full coverage body protection (e.g., Tyvek suit), faceshield, and disposable fluid-resistant gloves (e.g., latex or nitrile).
- Wear appropriate footwear; disposable shoe covers can be worn to protect against contamination.
- Puncture- and cut-resistant gloves should be worn over fluid-resistant gloves if sharp objects (e.g., broken glass, needles) are present.
- Wear insulated gloves (e.g. cryo gloves) over fluid-resistant gloves when handling dry ice (UN1845).
- Decontaminate protective clothing and personal protective equipment after use and before cleaning or disposal with an appropriate chemical disinfectant (e.g., 10% solution of bleach, equivalent to 0.5% sodium hypochlorite) or through a validated decontamination technology (e.g., autoclave) or process.
- Structural firefighters' protective clothing will only provide limited protection.

INFECTIOUS SUBSTANCES GUIDE 158

EMERGENCY RESPONSE

FIRE

Small Fire

- Dry chemical, soda ash, lime or sand.

Large Fire

- Use extinguishing agent suitable for type of surrounding fire.
- Do not scatter spilled material with high-pressure water streams.
- Move containers from fire area if you can do it without risk.

SPILL OR LEAK

- Do not touch or walk through spilled material.
- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
- Absorb with earth, sand or other non-combustible material.
- Cover damaged package or spilled material with absorbent material such as paper towel, towel or rag to absorb any liquids, and, beginning from outside edge, pour liquid bleach or other chemical disinfectant to saturate. Keep wet with liquid bleach or other disinfectant.
- **DO NOT CLEAN-UP OR DISPOSE OF, EXCEPT UNDER SUPERVISION OF A SPECIALIST.**

FIRST AID

- Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
- Move victim to a safe isolated area.

CAUTION: Victim may be a source of contamination.

- Call 911 or emergency medical service.
- Remove and isolate contaminated clothing and shoes.
- In case of contact with substance, immediately flush skin or eyes with running water for at least 20 minutes.
- Effects of exposure (inhalation, ingestion, injection/inoculation or skin contact) to substance may be delayed. Victim should consult medical professional for information regarding symptoms and treatment.
- **For further assistance, contact your local Poison Control Center.**

Excerpted from DOT's Pipeline and Hazard Materials Safety Administration's Emergency Response Guidebook, A Guidebook Intended for Use by First Responders During the Initial Phase of a Transportation Incident Involving Dangerous Goods/ Hazardous Materials, 2016

APPENDIX 5 -EXCERPTS FROM THE COMMERCE CONTROL LIST (12/6/2021)

(Notes: The US DOC's Commerce Control List (CCL) changes. Always check www.bis.doc.gov/ for the current CCL.)

The US is a member of international groups that develop harmonized export controls for biologicals and related equipment (Australia Group, Wassenaar Arrangement). Export licenses are required for:

- CDC/USDA's Select Agents and Toxins (including Select Toxin subunits)
- Additional Bacteria, Fungi, Viruses, and Plant pathogens; additional Toxins and subunits
- Genetic elements: all genes-CCL Viruses; some genes from Bacteria, Fungi, Toxins and subunits

CDC/USDA's Select Agents and Toxins (and subunits of Select Toxins), 1C351, 353, 354:

These are potential bioterror agents, listed at www.selectagents.gov/SelectAgentsandToxinsList.html. For Select Toxins, even 'permissible amounts' and subunits have export controls.

Bacteria (in addition to those on the Select Agents list), 1C351:

Chlamydia psittaci (Chlamyodophila psittaci)
Clostridium perfringens, epsilon toxin producing types
Salmonella enterica subspecies *enterica* serovar Typhi (*Salmonella typhi*)
Shiga toxin producing *Escherichia coli* (STEC) (see serogroups on the Commerce Control List)
Shigella dysenteriae
Vibrio cholerae

Fungi (in addition to those on the Select Agents list), 1C351:

Coccidioides immitis
Coccidioides posadasii

Viruses (in addition to those on the Select Agents list), 1C351:

Andes virus
Bluetongue virus
Chikungunya virus
Choclo virus
Dobrava-Belgrade virus
Hantaan virus
Japanese encephalitis virus
Laguna Negra virus
Louping ill virus
Lymphocytic choriomeningitis virus
Lyssaviruses (including rabies)
Murray Valley encephalitis virus
Oropouche virus
Porcine Teschovirus
Powassan virus
Rabies virus (and all other members of the Lyssavirus genus)
Rocio virus
Seoul virus
Sin Nombre virus

St. Louis encephalitis virus
Suid herpesvirus 1 (Pseudorabies virus; Aujeszky's disease)
Vesicular stomatitis virus
Western equine encephalitis virus
Yellow fever virus

Plant Pathogens (in addition to those on the Select Agents list; not by kingdom), 1C354:

Andean potato latent virus (Potato Andean latent tymovirus)
Clavibacter michiganensis subspecies *sepedonicus* (see syn. on the Commerce Control List)
Cochliobolus miyabeanus (Helminthosporium oryzae)
Colletotrichum kahawae (*Colletotrichum coffeanum* var. *virulans*)
Magnaporthe oryzae (Pyricularia oryzae)
Microcyclus ulei (syn. *Dothidella ulei*)
Potato spindle tuber viroid
Puccinnia graminis (see specific subspecies and variants on the Commerce Control List)
Puccinia striiformis (syn. *Puccinia glumarum*)
Tilletia indica
Thecaphora solani
Xanthomonas albilineans
Xanthomonas axonopodis pv. *citri* (*Xanthomonas campestris* pv. *citri*, *X. campestris* pv. *citri* A)

Toxins and subunits (in addition to those on the Select Toxins list), 1C351:

Aflatoxins
Cholera toxin
Clostridium perfringens alpha, beta1, beta2, epsilon and iota toxins
HT-2 toxin
Microcystins (Cyanginosins)
Modeccin
Shiga toxins (shiga-like toxins, verotoxins, and verocytotoxins)
Viscumin (Viscum album lectin 1)
Volkensin

Genetic elements, 1C353:

Any genetically modified organism that contains, or any genetic element that codes for:
1) genes specific to any virus on the CCL, 2) any toxin (or its subunit) on the CCL, or
3) any genes specific to any bacteria or fungus on the CCL that:

- In itself or through its transcribed or translated products represents a significant hazard to human, animal or plant health; *or*
- Could endow or enhance pathogenicity*.

Exception: Shiga toxin producing *Escherichia coli* (STEC) genes other than toxins or subunits

**'Endow or enhance pathogenicity' is defined as when the insertion or integration of the nucleic acid sequence or sequences is/are likely to enable or increase a recipient organism's ability to be used to deliberately cause disease or death. This might include alterations to, inter alia: virulence, transmissibility, stability, route of infection, host range, reproducibility, ability to evade or suppress host immunity, resistance to medical countermeasures, or detectability.*