

Training Supplement Guide

Proper Shipment of Patient Specimens and Infectious Substances

**Duke University
Biological Safety Office
For questions, call 919-684-8822**

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SHIPPING CLASSIFICATION

Exempt Patient Specimens:

Definition: Specimens collected 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 or prevention.

Exempt Patient Specimens are not assigned a Proper shipping name or UN number, as they are not found on the List of Dangerous Goods. Consequently, they are not assigned specific packing instructions. HOWEVER, there are minimum requirements for packing Exempt Patient Specimens in the Dangerous Goods Regulations, and these include the use of triple packaging as detailed on page 6.

Note: If a specimen is likely or suspected to contain a human or animal pathogen, then it should be shipped as an Infectious Substance. An element of professional judgment is required when making such a decision. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, and endemic local conditions.

Infectious Substances:

Definition: 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

1. **Category A, Infectious Substances:** 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. See page 4 for a list of example agents.
 2. **Category B, Infectious Substances:** An infectious substance which does not meet the criteria for inclusion in Category A. An example includes clinical specimens containing common infectious microbiological organism(s).
-

Genetically Modified Microorganisms (GMMO) and Organisms (GMO):

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

Indicative List of Category A Infectious Substances

UN Number and Proper Shipping Name	Microorganism Classified as Category A in any Form (Always Classified as Category A)	Microorganisms Classified as Category A only when cultured
UN 2814 Infectious substance, affecting humans	Crimean-Congo hemorrhagic fever virus Ebola virus Flexal virus Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hantavirus causing pulmonary syndrome Hendra virus Herpes B virus (Cercopithecine Herpesvirus-1) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Nipah virus Omsk hemorrhagic fever virus Russian spring-summer encephalitis virus Sabia virus Variola virus	Bacillus anthracis Brucella abortus Brucella melitensis Brucella suis Burkholderia mallei-Pseudomonas mallei-Glanders Burkholderia pseudomallei- Pseudomonas pseudomallei Chlamydia psittaci- avian strains Clostridium botulinum Coccidioides immitis Coxiella burnetii Dengue virus Eastern equine encephalitis virus Escherichia coli, verotoxigenic Francisella tularensis Hepatitis B virus Herpes B virus Herpesvirus simiae Human immunodeficiency virus Human Coronavirus- Severe acute respiratory Syndrome (SARS) Highly pathogenic avian influenza virus Japanese Encephalitis virus Mycobacterium tuberculosis Monkey B virus Poliovirus Rabies virus Rickettsia prowazekii Rickettsiae rickettsia Rift Valley fever virus Russian spring-summer encephalitis virus Shigella dysenteriae type 1 Tick borne encephalitis virus Venezuelan equine encephalitis virus West Nile virus Yellow Fever virus Yersinia pestis
UN 2900 Infectious substance, affecting animals only	<i>*NOTE: The list of indicative examples of Category A Infectious substances is not exhaustive as there may be new or emerging pathogens. If a pathogen has the ability to cause permanent disability, or a life-threatening or fatal disease in otherwise healthy humans or animals, it must be classified as a Category A Infectious substance.</i>	African swine fever virus Avian paramyxovirus Type 1- Velogenic Newcastle disease virus Classical swine fever virus Foot and mouth disease virus Goatpox virus Hog Cholera virus- Classical Swine Fever Lumpy skin disease virus Mycoplasma mycoides- Contagious bovine pleuropneumonia Peste de petits ruminants virus Rinderpest virus Sheep-pox virus Swine vesicular disease virus Vesicular stomatitis virus

Shipping Information Summary

Shipment Type	Proper Shipping Name	UN Number	Hazard Class	Packing Instruction	Hazard Label	Passenger Aircraft		Cargo aircraft only		Special Provisions
						Max.net quantity per primary container	Max. net quantity per package	Max. net quantity per primary container	Max. net quantity per package	
Category A infectious substance, affecting humans	Infectious substance, affecting humans, (*)	UN 2814	6.2	620	Infectious substance		50ml or 50g		4L or 4kg	A81, A140
Category A infectious substance, affecting only animals	Infectious substance, affecting animals, (*)	UN 2900	6.2	620	Infectious substance		50mL or 50g		4L or 4kg	A81, A140
Category B infectious substance	Biological substance, category B	UN 3373	6.2	650	UN 3373	1L or 4kg	4L or 4kg	1L or 4kg	4L or 4kg	
Dry Ice	Dry Ice	UN 1845	9	954	Class 9	200kg		200kg		A48
Genetically modified micro-organisms & organisms (non-infectious)	Genetically modified micro-organisms	UN 3245	9	959		No Limit		No Limit		A47
Patient Specimens (minimal likelihood that pathogens are present)	N/A	N/A	N/A	See Checklist on Pg.6	Exempt Human Specimen or Exempt Animal Specimen	N/A		N/A		N/A
Non-infectious specimens (mammals, birds, amphibians, reptiles, fish, insect and other invertebrates) containing small quantities of flammable preservative	N/A	N/A	N/A	See Checklist on Pg. 7	Scientific research specimens, not restricted Special Provision A180 applies	(flammable preservative)30 ml/bag 1L total/outer packaging		(flammable preservative) 30 ml/bag 1L total/outer packaging		A180

(*) Identify technical name of agent

**Special Provisions:

A81 – The maximum quantity of infectious substance that can be shipped by air in one package is 4L or 4kg. The maximum quantity that may be shipped via passenger aircraft is 50mL or 50g.

The Special Provision A81 allows the shipment of body parts, organs or whole bodies to not be restricted based on quantity limits, however the shipment must still comply with Packing Instruction 620. Specimens transported in accordance with this Special Provision must be noted on the Shipper's Declaration of Dangerous Goods in the "Authorization" column of the Declaration form.

A48 – Packaging tests are not considered necessary.

A47 – Genetically modified micro-organisms and genetically modified organisms, which meet the definition of an infectious substance and the criteria for inclusion in Division 6.2 (Category A or Category B Infectious Substances), must be transported as UN 2814, UN 2900 or UN 3373, as appropriate.

A140 – For the purposes of documentation, the proper shipping name must be supplemented with the technical name. Technical names need not be shown on the package. When the Infectious Substances to be transported are unknown, but suspected of meeting the criteria of Category A, and assigned to UN 2814 or UN 2900, the words "Suspected Category A Infectious Substance" must be shown in parenthesis following the proper shipping name on the Shipper's Declaration of Dangerous Goods, but not on outer package. A180 – Small quantities of UN 1170, UN 1198, UN 1987, or UN1219 are not subject to Dangerous Goods Regulations provided certain packing and marking requirements are met.

Exempt Patient Specimens (animal or human)

(Minimal likelihood that pathogens are present)

Specimen Packaging

- ___ Specimen in leakproof primary container
- ___ Closures of primary containers are required be held securely by secondary means, such as adhesive tape, or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- ___ Primary containers are wrapped individually
- ___ Absorbent material sufficient to absorb entire contents of primary container(s)
- ___ Leakproof secondary container (**Outer containers MUST NOT be only Styrofoam**)

Labeling Outer Container

- ___ Statement: "Exempt human specimen" or "Exempt animal specimen"
- ___ Miscellaneous Class 9 label⁽²⁾ if shipment contains dry ice, "UN 1845" and amount used in kg
- ___ Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Completing the Airbill

- ___ Name and address of shipper and recipient
- ___ Check "Saturday Delivery" box if applicable
- ___ In Section 6 (Special Handling) of the airbill, indicate that the shipment is NOT a dangerous good
- ___ Check the "Dry Ice" box if applicable and indicate "UN 1845" and the quantity of dry ice in kg
- ___ Shipper's signature (optional)

Note: When determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required. That judgment should be based on the known medical history, symptoms and individual circumstances of the source and endemic local conditions.

***Non-infectious Specimens
containing small quantities of
flammable preservative in the following categories:***

*UN 1170 (Ethanol, Ethanol solution),
UN 1198 (Formalin, Formaldehyde solution),
UN 1987 (Alcohols, n.o.s. *) or
UN 1219 (Isopropyl alcohol, Isopropanol)*

Specimen Packaging

- ___ Wrapped in paper towel and/or cheesecloth moistened with alcohol or an alcohol solution and then placed in a plastic bag that is heat-sealed. Any free liquid in the bag must not exceed 30 mL **OR**
- ___ Placed in vials or other rigid containers with no more than 30 mL of alcohol or an alcohol solution

- ___ Prepared specimens are then placed in a plastic bag that is then heat-sealed
- ___ The bagged specimens are then placed inside a another plastic bag with absorbent material then heat-sealed
- ___ The finished bag is then placed in a strong outer packaging **(Styrofoam must be in an outer cardboard box)** with suitable cushioning material
- ___ The total quantity of flammable liquid per outer packaging must not exceed 1 L

Labeling Outer Container

- ___ The completed package is marked “scientific research specimens, not restricted Special Provision A180 applies”

Completing the Airbill

- ___ The words “not restricted” and the special provision number A180 must be included in the description of the substance on the Air Waybill as required by 8.2.6, when an Air Waybill is issued.

****Not otherwise specified***

Category A Infectious Substances

Packing Instruction (PI) 620

Specimen Packaging (primary or secondary is pressure and drop test approved: see PI 620)

- ___ Specimen in leakproof primary container
- ___ Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- ___ Primary containers are wrapped individually
- ___ Absorbent material sufficient to absorb entire contents of primary container(s)
- ___ Leakproof secondary container
- ___ Itemized list of contents placed between secondary and outer container

Labeling Outer Container

- ___ Infectious Substance, Class 6 label
- ___ “Infectious Substance Affecting Humans”, “UN 2814” or “Infectious Substance Affecting Animals, “UN 2900” and net quantity of infectious substance
- ___ Miscellaneous Class 9 label if shipment contains dry ice, “UN 1845” and amount used in kg
- ___ Name and telephone number of the responsible party, knowledgeable of the package contents and available 24 hours a day
- ___ If shipment includes >50mL or 50g of a Category A infectious substance, then add a “Danger, do not load in passenger aircraft” label to the outer container
- ___ Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Dangerous Goods Declaration Form*

- ___ Name, address and phone number of shipper and recipient
- ___ Mark out non-applicable “Aircraft Box”
- ___ Mark out non-applicable “Radioactive” box
- ___ 24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents in the “Handling Information” box
- ___ Name and title of signatory, place, and date
- ___ Shipper’s signature

**49 CFR 172.201 (e): The shipper MUST retain a copy of the Shipper's Declaration for a minimum of 2 years.*

“Nature and Quantity of Dangerous Goods” section of the Declaration Form

- ___ Complete this section using the information provided on Pages 5, 11 & 12 of this Guide

Category B Infectious Substances

Packing Instructions (PI) 650

Specimen Packaging (primary or secondary is pressure and drop test approved: see PI 650)

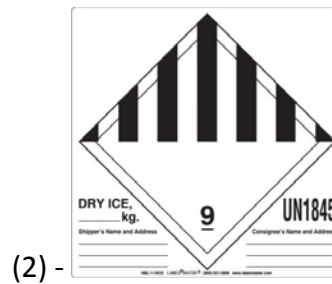
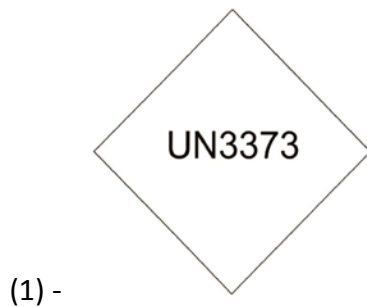
- ___ Specimen in leakproof primary container
- ___ Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- ___ Primary containers are wrapped individually
- ___ Absorbent material is sufficient to absorb entire contents of primary container(s)
- ___ Leakproof secondary container
- ___ Itemized list of contents placed between secondary and outer container

Labeling Outer Container

- ___ UN 3373 label⁽¹⁾
- ___ Statement: "Biological Substance, Category B" adjacent to UN 3373 label
- ___ Miscellaneous Class 9 label⁽²⁾ if shipment contains dry ice, "UN 1845" and amount used in kg
- ___ Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Completing the Airbill

- ___ Name and address of shipper and recipient
- ___ Check "Saturday Delivery" box if applicable
- ___ In Section 6 (Special Handling) of the airbill, indicate that the shipment is a dangerous good, which does NOT require a Shipper's Declaration
- ___ Check the "Dry Ice" box if applicable and indicate "UN 1845" and the quantity of dry ice in kg
- ___ Shipper's signature (optional)



Genetically Modified Micro-organisms & Organisms

Note: If a GMMO or GMO is a Category A or Category B Infectious Substance, package the material accordingly.

Specimen Packaging

- ___ Specimen in leakproof primary container
- ___ Closures of primary containers are required be held securely by secondary means, such as adhesive tape or friction sleeves. When it is not possible to apply a secondary means of closure a leakproof liner must be used.
- ___ Absorbent material is sufficient to absorb entire contents of primary container(s)
- ___ Primary containers are wrapped individually
- ___ Leakproof secondary container
- ___ Itemized list of contents placed between secondary and outer container

Labeling Outer Container

- ___ Miscellaneous Class 9 label
- ___ “Genetically modified micro-organism” or “Genetically modified organism”, “UN 3245⁽³⁾”
- ___ If shipment contains dry ice, “UN 1845” and amount used in kg
- ___ Shipper and consignee details should be on the same surface of the package near the proper shipping name marking, if the package dimensions are adequate.

Dangerous Goods Declaration Form (if required)

- ___ Name, address and phone number of shipper and recipient
- ___ Mark out non-applicable “Aircraft Box”
- ___ Mark out non-applicable “Radioactive” box
- ___ 24-hour emergency response telephone number for the responsible party, knowledgeable of the package contents
- ___ Name and title of signatory, place, and date
- ___ Shipper’s signature

“Nature and Quantity of Dangerous Goods” section of the Declaration Form

- ___ Complete this section using the information provided on Pages 5, 11 & 12 of this guide.



(3) -

Completing the Top-half of a Dangerous Goods Declaration

SHIPPER'S DECLARATION FOR DANGEROUS GOODS					
<p style="font-size: 24px; text-align: center; margin: 0;">A</p> <p style="font-size: 12px; margin: 0;">Shipper</p>	<p style="font-size: 10px; margin: 0;">Air Waybill No.</p> <p style="font-size: 10px; margin: 0;">Page of Pages</p> <p style="font-size: 10px; margin: 0;">Shipper's Reference Number (optional)</p>				
<p style="font-size: 24px; text-align: center; margin: 0;">B</p> <p style="font-size: 10px; margin: 0;">Consignee</p>					
<p style="font-size: 10px; margin: 0;">Two completed and signed copies of this Declaration must be handed to the operator.</p>		<p style="font-size: 10px; margin: 0;">WARNING</p> <p style="font-size: 10px; margin: 0;">Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.</p>			
<p style="font-size: 10px; margin: 0;">TRANSPORT DETAILS</p>					
<p style="font-size: 10px; margin: 0;">This shipment is within the limitations prescribed for: <i>(delete non-applicable)</i></p>		<p style="font-size: 10px; margin: 0;">Airport of Departure</p>			
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="font-size: 8px; padding: 2px;">PASSENGER AND CARGO AIRCRAFT</td> <td style="font-size: 8px; padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	<p style="font-size: 24px; text-align: center; margin: 0;">C</p>		
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY				
<p style="font-size: 10px; margin: 0;">Airport of Destination</p>		<p style="font-size: 24px; text-align: center; margin: 0;">D</p> <p style="font-size: 10px; margin: 0;">Shipment Type <i>(delete non-applicable)</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="font-size: 8px; padding: 2px;">NON-RADIOACTIVE</td> <td style="font-size: 8px; padding: 2px;">RADIOACTIVE</td> </tr> </table>		NON-RADIOACTIVE	RADIOACTIVE
NON-RADIOACTIVE	RADIOACTIVE				

* FedEx Express® dangerous goods shipments originating in the U.S. must have the Shippers' Declarations prepared using one of the following methods:

- FedEx-approved vendor software application
- Pre-approved shipper proprietary software
- FedEx Express Automated Shipping Solutions that have dangerous goods error checks

A – Shipper: Enter your full name, address and telephone number.

B – Consignee: Enter full name and address of recipient. When shipping infectious substances, include the text, "Person responsible:" plus his/her name and phone number at the bottom of "Consignee" box.

C – Transport Details: Indicate here if your shipment is restricted to cargo aircraft only (if it is > 50ml or 50g of an infectious substance). Airport of departure and airport of destination will be filled out by the carrier, leave blank.

D – Shipment Type: Cross out "radioactive" to indicate you are shipping a non-radioactive substance.

Completing the Bottom-half of a Dangerous Goods Declaration

NATURE AND QUANTITY OF DANGEROUS GOODS							
Dangerous Goods Identification							
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization	
E	F	G	H	I	J	K	
Additional Handling Information							
L							
Emergency Telephone Number							
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory			
				M			
				Place and Date			
				Signature <i>(see warning above)</i>			

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

E – UN or ID Number: Enter appropriate UN number (i.e. UN 2814 or UN 2900).

F – Proper Shipping Name: Enter the proper shipping name with the technical name in parentheses – i.e. “Infectious substance, affecting humans (Hepatitis B virus)”. UN 2814 or UN 2900 that is suspected to contain an unknown Category A infectious substance must have the words “suspected Category A infectious substance” next to the Proper Shipping Name.

G – Class or Division: Enter appropriate hazard class (i.e. 6.2 or 9).

H – Packing Group: For dry ice, enter “III” in this column. Biological materials are not assigned packing groups.

I – Quantity and Type of Packaging: Enter the net quantity for each material here. Use only metric units. At the bottom of this column, indicate the number and type of packages. If multiple packages are packed in one overpak state (“All packed in one fibreboard box.”). Do not spell like “fiberboard.” If using an overpack, indicate here with “Overpack Used.”

Completing the Bottom-half of a Dangerous Goods Declaration

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
E	F	G	H	I	J	K
Additional Handling Information						
L						
Emergency Telephone Number						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory		
				M		
				Place and Date		
				Signature <small>(see warning above)</small>		

J – Packing Instructions: Enter appropriate packing instruction number. The Packing Instruction for infectious substances is 620. The Packing Instruction for dry ice is 954.

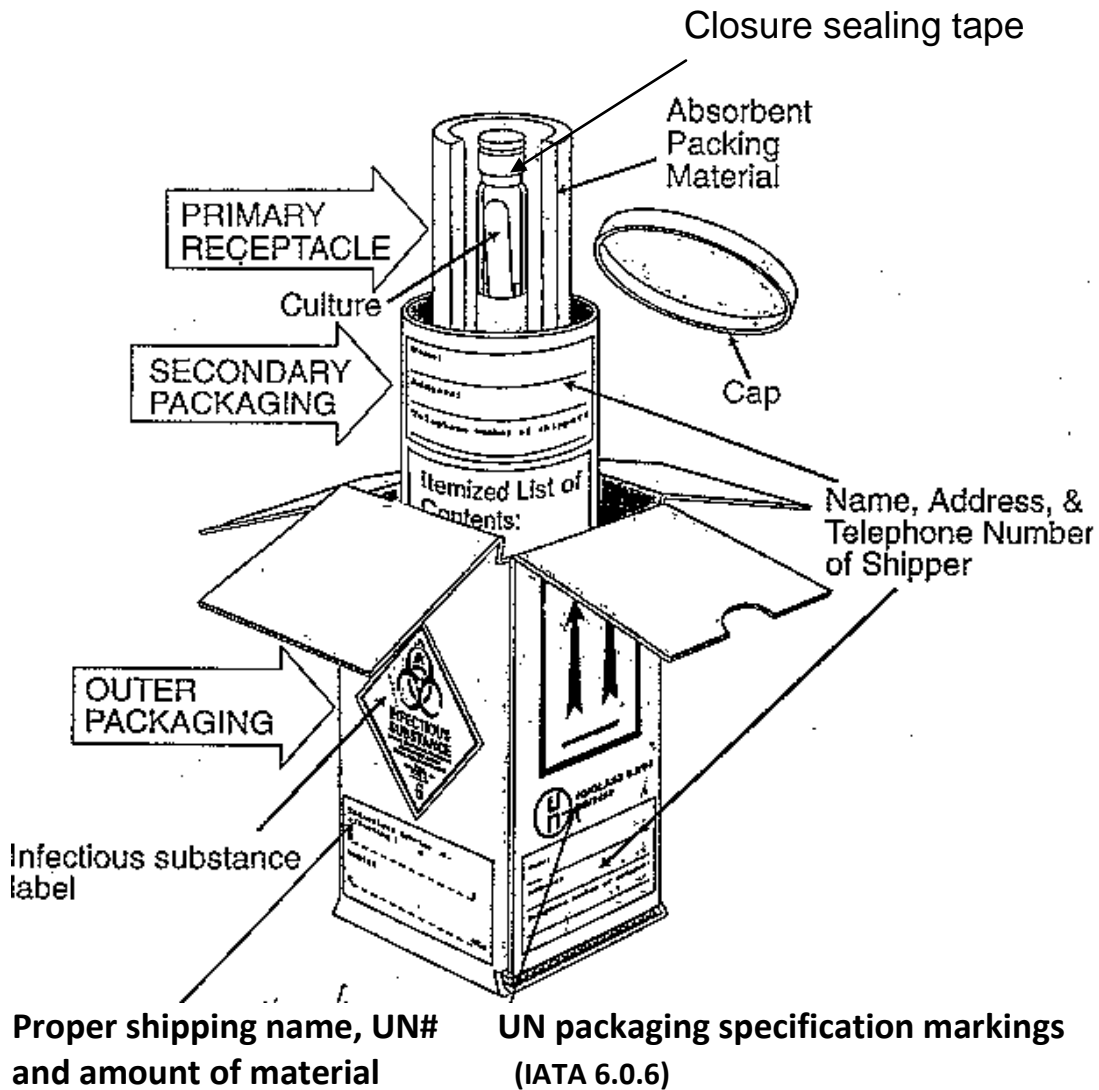
K – Authorization: Note any Special Provisions, if applicable (i.e. if you choose to not include the technical name on outer package, you must list A140 in this column).

L – Additional Handling Instructions: The statement “Emergency Contact:” followed by a 24-hour emergency telephone response number where the shipper can be reached.

M – Sign and date each copy of your Shipper’s Declaration.

**** A statement must appear on the Shipper’s Declaration. The statement reads as follows: “I declare that all of the applicable air transport requirements have been met.”** This statement is often pre-printed on the form (see above). If this statement does not appear on the form then it should be typed in the “Additional Handling” section of the form.

**Packed in Compliance with IATA Packing Instruction 620
(Category A Infectious Substances)**



Proper shipping name, UN# and amount of material

UN packaging specification markings (IATA 6.0.6)



Note: Shipments that include > 50mL or 50g of Category A Infectious Substances, must have this label attached to the outer container.

Does your shipment need a permit?

If yes or you are unsure, contact the Duke University Office of Export Controls <http://ors.duke.edu/export-controls> (919-668-2711). Import Permit assistance is also provided.

CDC Import Permit:

- Is required if you import:
 - any etiologic agent
 - any arthropod or other animal host or vector of human disease
 - any exotic living arthropod or other animal capable of being a host or vector of human disease
- **CDC: Etiologic Agent Import Permit Program**
 - Website: <http://www.cdc.gov/od/eaipp/>
 - Telephone: 404-498-2260; FAX: 404-498-2275
 - Permit Application: <http://www.cdc.gov/od/eaipp/importApplicationForms.htm>

USDA/ APHIS Permit:

- May be required for all imports/ exports, **and** inter-state transport of:
 - animal or plant pathogens
 - specimens reasonably believed to contain animal or plant pathogens
 - any pest or vector of animal or plant disease
 - potentially hazardous animal or plant products
- **APHIS: Import and Export**
 - http://www.aphis.usda.gov/import_export/index.shtml
 - Telephone: 301-734-0841(plants), 301-734-3277 (animals)

Department of Commerce (DOC) Export License:

- May be required when exporting:
 - infectious agents of human, plant and animal diseases
 - genetic material, and products which might be used for culture of large amounts of agents
- **DOC: Bureau of Industry and Security (BIS):**
 - Website: <http://www.bis.doc.gov/index.htm>
 - Telephone: 202-482-4811
- Review list of biological materials which may require an export license on pages 16 and 17 of this guide.

List of Biological Materials that MAY Require a DOC Export License

HUMAN PATHOGENS AND TOXINS

Bacteria

- Bacillus anthracis
- Brucella abortus
- Brucella melitensis
- Brucella suis
- Burkholderia mallei (Pseudomonas mallei)
- Burkholderia pseudomallei (Pseudomonas pseudomallei)
- Chlamydia psittaci
- Clostridium botulinum
- Clostridium perfringens, epsilon toxin producing types
- Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes
- Francisella tuarensis
- Salmonella typhi
- Shigella dysenteriae
- Vibrio cholerae
- Yersinia pestis

Toxins

- Abrin
- Aflatoxins
- Botulinum toxins
- Cholera toxin
- Clostridium perfringens toxin
- Conotoxin
- Diacetoxyscirpenol toxin
- HT-2 toxin
- Microcystin (Cyanginosin)
- Modeccin toxin
- Ricin
- Saxitoxin
- Shiga toxin
- Staphylococcal aureus toxins
- T-2 toxin
- Tetrodotoxin
- Verotoxin
- Volkensin toxin
- Viscum albumin lectin 1 (Viscumin)

Viruses

- Chikungunya virus
- Congo-Crimean haemorrhagic fever virus
- Dengue fever virus
- Eastern equine encephalitis virus
- Ebola virus
- Hantaan virus
- Hendra virus (Equine morbillivirus)
- Japanese encephalitis virus
- Junin virus
- Kyasanur forest virus
- Lassa fever virus
- Louping ill virus
- Lymphocytic choriomeningitis virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- Murray Valley encephalitis virus
- Nipah Virus
- Omsk haemorrhagic fever virus
- Oropouche virus
- Powassan virus
- Pulmonary and renal syndrome-haemorrhagic fever viruses (Seoul, Dobrava, Puumala, Sin Nombre)
- Rabies virus cultures
- Rift Valley fever virus cultures
- Rocio virus
- South American haemorrhagic fever virus (Sabia, Flexal, Guanarito)
- St. Louis encephalitis virus
- Tick-borne encephalitis virus (Russian Spring-Summer encephalitis virus)
- Variola virus
- Venezuelan equine encephalitis virus cultures
- Western equine encephalitis virus
- White pox virus
- Yellow fever virus

Rickettsiae

- Bartonella quintana (Rochalimea quintana, Rickettsia quintana)
- Coxiella burnetii
- Rickettsia prowasecki
- Rickettsia rickettsii

List of Biological Materials that MAY Require a DOC Export License – Continued

ANIMAL PATHOGENS AND TOXINS

Bacteria

- *Mycoplasma mycoides*

Viruses

- African horse sickness virus
- African swine fever virus
- Avian influenza virus (highly pathogenic strains)
- Bluetongue virus
- Foot and mouth disease virus
- Goat pox virus
- Lumpy skin disease virus
- Lyssa virus

Viruses continued

- Newcastle disease virus
- Peste des petis ruminants virus
- Porine enterovirus type 9 (Swine vesicular disease virus)
- Porcine herpes virus (Aujeszky's disease)
- Rinderpest virus
- Sheep pox virus
- Swine fever virus (Hog cholera virus)
- Teschen disease virus
- Vesicular stomatitis virus

PLANT PATHOGENS

Bacteria

- *Xanthomonas albilineans*
- *Xanthomonas campestris* pv. *citri* types A, B, C, D, E or otherwise classified as *X. citri*, *X. campestris* pv. *aurantifolia* or *X. campestris* pv. *Citrumelo*
- *Xanthomonas oryzae*
- *Clavibacter michiganensis* subspecies *sepedonicus*
- *Ralstonia solanacearum* Races 2 & 3

Viruses

- Potato Andean latent tymovirus
- Potato spindle tuber viroid

Fungi

- *Colletotrichum coffeanum* var. *virulans* (C. *kahawae*)
- *Cochliobolus miyabeanus* (*Helminthosporium oryzae*)
- *Magnaporthe grisea* (*pyricularia grisea*/*pyricularia oryzae*)
- *Microcyclus ulei* (*Dothidella ulet*)
- *Puccinia graminis* (*Puccinia graminis* f. sp. *tritici*)
- *Puccinia striformis* (*Puccinia glumarum*)

GENETIC ELEMENTS/GENETICALLY MODIFIED ORGANISMS

- Genetic elements that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetic elements that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins".
- **Technical Note:** Genetic elements include, inter alia, chromosomes, genomes, plasmids, transposons, and vectors, whether genetically modified or unmodified.
- Genetically modified organisms that contain nucleic acid sequences associated with the pathogenicity of controlled microorganisms.
- Genetically modified organisms that contain nucleic acid sequences coding for any controlled "toxins" or "sub-units of toxins".

Contact Biological Safety at 919-684-8822 prior to Shipment or Receipt of the following:

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

HHS SELECT AGENTS AND TOXINS

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X₁CCX₂PACGX₃X₄X₅X₆CX₇)
Coxiella burnetii
Crimean-Congo haemorrhagic fever virus
Diacetoxyscirpenol
Eastern Equine Encephalitis virus¹
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus¹
Reconstructed replication competent forms of the 1918 pandemic influenza virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 Influenza virus)
Ricin
Rickettsia prowazekii
SARS-associated coronavirus (SARS-CoV)
Saxitoxin
South American Haemorrhagic Fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins A,B,C,D,E subtypes
T-2 toxin
Tetrodotoxin
Tick-borne encephalitis complex (flavi) viruses:
Far Eastern subtype
Siberian subtype
Kysanur Forest disease virus
Omsk hemorrhagic fever virus
Variola major virus (Smallpox virus)*
Variola minor virus (Alastrim)*
*Yersinia pestis**

OVERLAP SELECT AGENTS AND TOXINS

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

USDA SELECT AGENTS AND TOXINS

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

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

Peronosclerospora philippinensis (*Peronosclerospora sacchari*)
Phoma glycinicola (formerly *Pyrenochaeta glycines*)
Ralstonia solanacearum
Rathayibacter toxicus
Sclerophthora rayssiae
Synchytrium endobioticum
Xanthomonas oryzae

*Denotes Tier 1 Agent

¹ 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), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IAB or IC, and Vesicular stomatitis virus (exotic): Indiana subtypes VSV-IN2, VSV-IN3, provided that the individual or entity can verify that the agent is within the exclusion category.

² 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.

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

Air Sea Atlanta
1234 Logan Circle
Atlanta, GA 30318
Phone: 404-351-8600
www.airseaatlanta.com

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

CARGOPak Corporation
PO Box 98686
Raleigh, NC 27615
Phone: 800-266-0652
www.cargopak.com

Inmark, Inc.
675 Hartman Road, Suite 100
Austell, GA 30168
Phone: 800-646-6275
www.inmarkinc.com

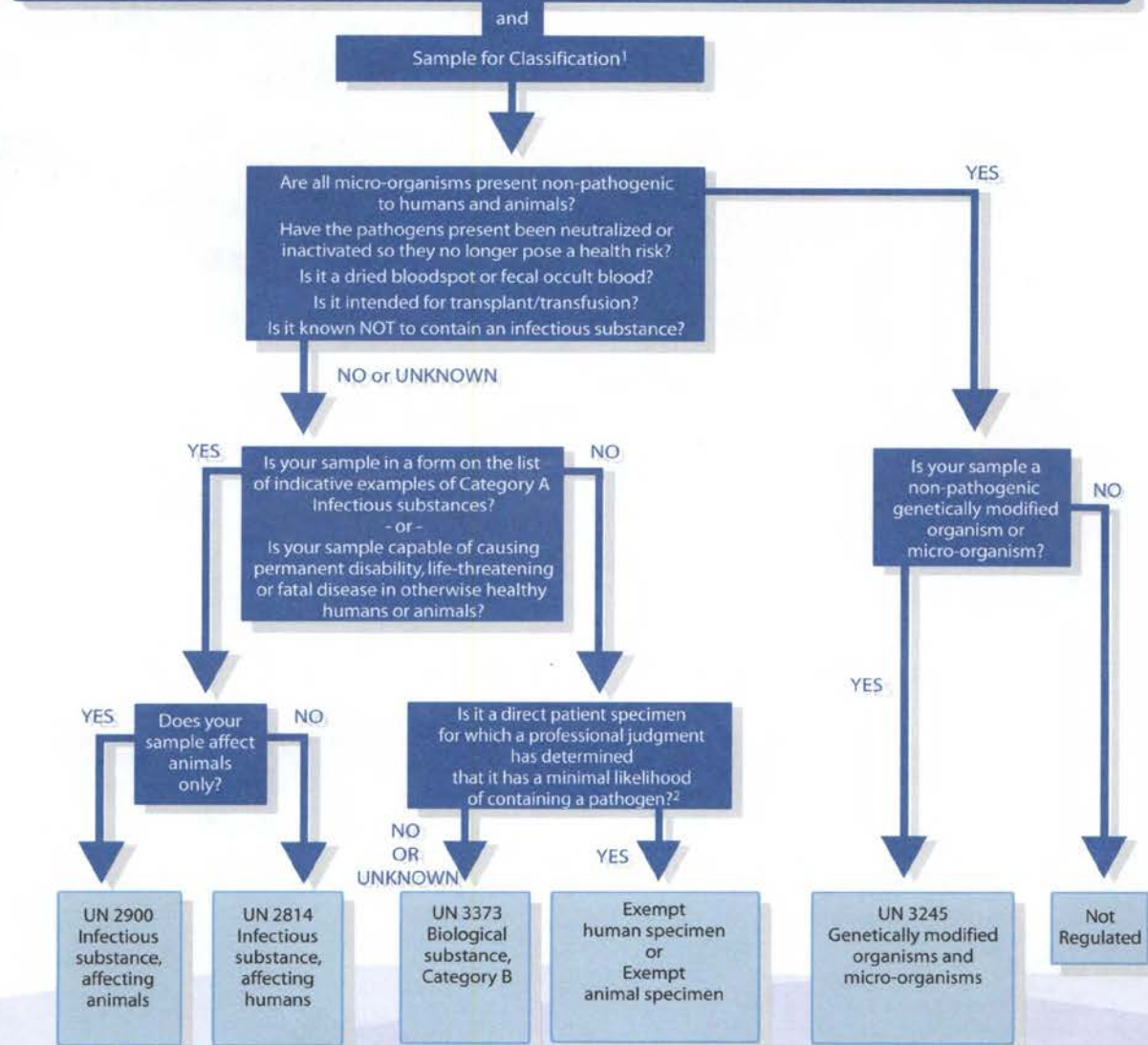
SAF-T-PAK, Inc.
899 Airport Park Rd Ste A
Glen Burnie, MD
21061-2557
Phone: 800-814-7484
www.saftpak.com.

Therapak Corporation
4305 Hamilton Mill Road
Suite 200
Buford, Georgia 30518
Phone: 888-505-7377
www.therapak.com

ThermoSafe
3930 N. Ventura Drive
Arlington Heights, IL 60004
Phone: 800-323-7442
www.thermosafe.com

FedEx-recognized shipper's
declaration available at the
"On-line Forms/Shipper's
Declaration" link:
(<http://www.saftpak.com/Support/Support.aspx>).

Classification Flow Chart



1. Anyone classifying an infectious substance must be trained and certified.

2. In determining if a patient specimen has a minimal likelihood that a pathogen is present, an element of professional judgment is required. This judgment should be based on known patient medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions.

Disclaimer - This flow chart is provided as guidance only.

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