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

<table>
<thead>
<tr>
<th>UN Number and Proper Shipping Name</th>
<th>Microorganism Classified as Category A in any Form (Always Classified as Category A)</th>
<th>Microorganisms Classified as Category A only when cultured</th>
</tr>
</thead>
</table>
| 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  
Kysanur 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  
Coccidiodes 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 | *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. | 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 |
<table>
<thead>
<tr>
<th>Shipment Type</th>
<th>Proper Shipping Name</th>
<th>UN Number</th>
<th>Hazard Class</th>
<th>Packing Instruction</th>
<th>Hazard Label</th>
<th>Passenger Aircraft</th>
<th>Cargo aircraft only</th>
<th>Special Provisions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category A infectious substance, affecting humans</td>
<td>Infectious substance, affecting humans, (*)</td>
<td>UN 2814</td>
<td>6.2</td>
<td>620</td>
<td>Infectious substance</td>
<td>50ml or 50g</td>
<td>4L or 4kg</td>
<td>A81, A140</td>
</tr>
<tr>
<td>Category A infectious substance, affecting only animals</td>
<td>Infectious substance, affecting animals, (*)</td>
<td>UN 2900</td>
<td>6.2</td>
<td>620</td>
<td>Infectious substance</td>
<td>50ml or 50g</td>
<td>4L or 4kg</td>
<td>A81, A140</td>
</tr>
<tr>
<td>Category B infectious substance</td>
<td>Biological substance, category B</td>
<td>UN 3373</td>
<td>6.2</td>
<td>650</td>
<td>UN 3373</td>
<td>1L or 4kg</td>
<td>4L or 4kg</td>
<td>1L or 4kg</td>
</tr>
<tr>
<td>Dry Ice</td>
<td>Dry Ice</td>
<td>UN 1845</td>
<td>9</td>
<td>954</td>
<td>Class 9</td>
<td>200kg</td>
<td>200kg</td>
<td>A48</td>
</tr>
<tr>
<td>Genetically modified micro-organisms &amp; organisms (non-infectious)</td>
<td>Genetically modified micro-organisms</td>
<td>UN 3245</td>
<td>9</td>
<td>959</td>
<td></td>
<td>No Limit</td>
<td>No Limit</td>
<td>A47</td>
</tr>
<tr>
<td>Patient Specimens (minimal likelihood that pathogens are present)</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>See Checklist on Pg.6</td>
<td>Exempt Human Specimen or Exempt Animal Specimen</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>Non-infectious specimens (mammals, birds, amphibians, reptiles, fish, insect and other invertebrates) containing small quantities of flammable preservative</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>See Checklist on Pg. 7</td>
<td>Scientific research specimens, not restricted Special Provision A180 applies</td>
<td>(flammable preservative) 30 ml/bag 1L total/outer packaging</td>
<td>(flammable preservative) 30 ml/bag 1L total/outer packaging</td>
<td>A180</td>
</tr>
</tbody>
</table>

(*) 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)

(1) - (2) -
**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.

![UN 3245](image-url)
Completing the Top-half of a Dangerous Goods Declaration

* 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

#### 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

<table>
<thead>
<tr>
<th>UN or ID No.</th>
<th>Proper Shipping Name</th>
<th>Class or Division (Subsidiary Risk)</th>
<th>Packing Group</th>
<th>Quantity and Type of Packing</th>
<th>Packing Instructions</th>
<th>Authorization</th>
</tr>
</thead>
<tbody>
<tr>
<td>E</td>
<td>F</td>
<td>G</td>
<td>H</td>
<td>I</td>
<td>J</td>
<td>K</td>
</tr>
</tbody>
</table>

**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)

 Closure sealing tape

 Absorbent Packing Material

 PRIMARY RECEPTACLE

 Culture

 SECONDARY PACKAGING

 Cap

 Name, Address, & Telephone Number of Shipper

 OUTER PACKAGING

 Infectious substance label

 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](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/](http://www.cdc.gov/od/eaipp/)
  - Telephone: 404-498-2260; FAX: 404-498-2275

**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**
  - 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](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
- Clostrium perfringens, epsilon toxin producing types
- Enterohaemorrhagic Escherichia coli, serotype O157 and other verotoxin producing serotypes
- Francisella tularensis
- 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 (Cyanoginosin)
- 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-bourne 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 michiganennis subspecies sepedonicus
- Ralstonia solanacearum Races 2 & 3

**Viruses**
- Potato Andean latent tymovirus
- Potato spindle tuber viroid

**Fungi**
- Colletotrichum coffeana var. virulans (C. kahawae)
- Coochliobolus 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”.

17
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

<table>
<thead>
<tr>
<th>HHS SELECT AGENTS AND TOXINS</th>
<th>OVERLAP SELECT AGENTS AND TOXINS</th>
<th>USDA SELECT AGENTS AND TOXINS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abrin</td>
<td>Bacillus anthracis</td>
<td>African horse sickness virus</td>
</tr>
<tr>
<td>Botulinum neurotoxins*</td>
<td>Bacillus anthracis Pasteur strain</td>
<td>African swine fever virus</td>
</tr>
<tr>
<td>Botulinum neurotoxin producing species of <em>Clostridium</em></td>
<td>Brucella abortus</td>
<td>Avian influenza*</td>
</tr>
<tr>
<td>Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence X-CX$_2$PCGX$_2$X$_2$X$_2$CX)</td>
<td>Brucella melitensis</td>
<td>Classical swine fever virus</td>
</tr>
<tr>
<td><em>Coxella burnetii</em></td>
<td>Brucella suis</td>
<td>Foot-and-mouth disease virus*</td>
</tr>
<tr>
<td>Crimean-Congo hemorrhagic fever virus</td>
<td><em>Burkholderia mallei</em></td>
<td>Goat pox virus</td>
</tr>
<tr>
<td><em>Diaceoxyscorpion</em></td>
<td><em>Burkholderia pseudomallei</em></td>
<td>Lumpy skin disease virus</td>
</tr>
<tr>
<td><em>Eastern Equine Encephalitis virus</em></td>
<td>Hendra virus</td>
<td>Mycoplasma capricolum</td>
</tr>
<tr>
<td><em>Ebola virus</em></td>
<td>Nipah virus</td>
<td><em>Mycoplasma mycoides</em></td>
</tr>
<tr>
<td><em>Francisella tularensis</em></td>
<td>Rital Valley fever virus</td>
<td>Newcastle disease virus*</td>
</tr>
<tr>
<td>Lassa fever virus</td>
<td>Hendra virus</td>
<td>*Peste des petits ruminants virus</td>
</tr>
<tr>
<td>Lujo virus</td>
<td>Hendra virus</td>
<td>Rinderpest virus</td>
</tr>
<tr>
<td>Marburg virus</td>
<td>Hendra virus</td>
<td>Sheep pox virus</td>
</tr>
<tr>
<td><em>Monkeypox virus</em></td>
<td>Hendra virus</td>
<td>Swine vesicular disease virus</td>
</tr>
<tr>
<td>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)</td>
<td>Hendra virus</td>
<td>USDA PLANT PROTECTION AND QUARANTINE (PPQ) SELECT AGENTS AND TOXINS</td>
</tr>
<tr>
<td><em>Ricin</em></td>
<td>Hendra virus</td>
<td><em>Peronosclerospora philippinensis</em> (Peronosclerospora sacchari)</td>
</tr>
<tr>
<td><em>Rickettsia prowazekii</em></td>
<td>Hendra virus</td>
<td><em>Phoma glycincola</em> (formerly Pyrenochaeta glycines)</td>
</tr>
<tr>
<td>SARS-associated coronavirus (SARS-CoV)</td>
<td>Hendra virus</td>
<td>*Ralessia solaniacearum</td>
</tr>
<tr>
<td>Saxitoxin</td>
<td>Hendra virus</td>
<td><em>Ratnapraraster toxocur</em></td>
</tr>
<tr>
<td><em>South American Haemorrhagic Fever viruses:</em></td>
<td>Hendra virus</td>
<td>*Sclerotiora rayssae</td>
</tr>
<tr>
<td>Chapare</td>
<td>Hendra virus</td>
<td>*Synchytrium endobioticum</td>
</tr>
<tr>
<td>Guanarito</td>
<td>Hendra virus</td>
<td>Xanthomonas oryzae</td>
</tr>
<tr>
<td>Junin</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Machupo</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Sabin</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Staphylococcal enterotoxins A,B,C,D,E subtypes</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td><em>T-2 toxin</em></td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Tetradotoxin</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td><em>Tick-borne encephalitis complex (flavi) viruses:</em></td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Far Eastern subtype</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Siberian subtype</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Kyasanur Forest disease virus</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Omok hemorragic fever virus</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Variola major virus (Smallpox virus)*</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td>Varioi minor virus (Alastrim)*</td>
<td>Hendra virus</td>
<td></td>
</tr>
<tr>
<td><em>Yersinia pestis</em></td>
<td>Hendra virus</td>
<td></td>
</tr>
</tbody>
</table>

*Denotes Tier 1 Agent

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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 caprinapneumoniae (contiguous caprine pleuropneumonia), all subspecies *Mycoplasma mycoides* except subspecies mycoides small colony (MMm SC) (contagous bovine pleuropneumonia), any subtypes of Venezuelan equine encephalitis virus except for Subtypes IA 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 disease.
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


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
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.