Introduction to Biological Material and Dry Ice Shipments Requirements

Environmental Health and Safety

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Research Shipping Action Plan

• Recommend all WCMC-Q shipping goes through EHS until we build efficient/effective processes and trained staff

• Train EHS Specialist and select Research personnel to build shipping capacity
  – Online training Media Lab Inc.
  – EHS Training from NY or Doha

• Purchase and stock proper shipping material
  – SAFTPAC

• Assist research partners in other countries in developing compliant shipping programs
What is a Dangerous Good?

- A substance capable of **posing a risk** to health, safety, property or the environment when transported in commerce (DOT) or by air (IATA).
- Certain **Biological Materials, Chemical Preservatives** as well as **Dry Ice** are classified as Dangerous Goods when transported.
Who must receive training?

- Training required by IATA and DOT
- Employees performing any of the following functions with infectious materials:
  - Packaging and handling
  - Prepare or sign shipping documents
  - Transporting

- Refresher training is mandatory every:
  - 2 years

- 
  It is not permissible to have an untrained person complete these activities and then trained shipper sign documents
Training must include:

• General Awareness and Familiarization
• Function-Specific
  – Biological Material Shipments
  – Dry Ice Shipments
  – Hands On Demonstration
  – Competency Test
• Security Awareness
• Safety including Emergency Response
Classification of Dangerous Goods

- Non-Regulated Biological Materials
- Infectious Substance – Category A
- Biological Substance – Category B
- Patient Specimens (formerly Diagnostic Specimens)
- Genetically Modified Micro-Organisms and Organisms
- Biological Products
- Liquid Nitrogen “Dry Shippers” ONLY (see EHS Update)
- Chemical Preservatives
  - Hazardous Preservatives
    - Dry Ice
    - Class 3 (Flammable), Class 8 (Corrosive) or Class 9 (Miscellaneous) chemicals ONLY in quantities < 30 ml per vial with Category A or Category B Substances
  - Non-Hazardous Preservatives
Regulatory Agencies

The handling and transport of dangerous goods are regulated by various Federal and International Agencies.

- International Air Transportation Assoc. (IATA)
- U.S. Dept. of Transportation (DOT)
- Federal Aviation Administration (FAA)
- United States Postal Service (USPS)
- Center for Disease Control and Prevention (CDC)
- Occupational Safety and Health Administration (OSHA)
- U.S. Department of Human and Health Services (HHS)
- U.S. Department of Agriculture (USDA)
- U.S. Department of Fish and Wildlife

Note: These are **NOT optional guidelines but are LAWS**. Violations can result in:

- **Up to $250,000 and up to a year jail for the individual shipper**
- **Up to $500,000 per incident for the organization**
Passenger Plane Prohibition

Shippers are not permitted to carry dangerous goods on the plane or check in as baggage.

Best to work with a courier (like FedEx, or World Courier)
Nine Hazard Classes

1 - Explosives

2 - Gases
   - Liquid Nitrogen “Dry Shippers” ONLY (See EHS Update)

3 - Flammable Liquids
   - As preservative ONLY w/ Category A or B substances (≤ 30ml per vial)
     - Alcohols
     - Formaldehyde w/ Methanol

4 - Flammable Solids

5 - Oxidizers and Organic Peroxides

6 – Toxic (Division 6.1) & Infectious (Division 6.2) Substances
   - Division 6.2 - Infectious Substances
     - Category A Infectious
     - Category B Infectious

7 - Radioactives

8 - Corrosives
   - As preservative ONLY w/ Category A or B substances (≤ 30ml per vial)
     - Formaldehyde (37.5%)
     - Acetic Acid

9 - Miscellaneous Dangerous Goods
   - Dry Ice
   - Genetically Modified Organisms
   - As preservative ONLY w/ Category A or B substances (≤ 30ml per vial)
     - Formaldehyde (≥10%)
Biological Shipments

Biological material shipper requirements:

1. Obtain **import, export and/or interstate transport** permits
2. **Train** all persons shipping dangerous goods
3. **Classify** the biological material
4. **Determine** appropriate **packaging instructions**
5. **Select** appropriate packing materials
6. **Pack, mark and label** the package properly
7. Complete, Sign and Retain **shipping documentation**
8. **Secure packages** prior to shipment
State and Operator Variations (Country and Carrier)

- **Country examples**
  - Australia
  - China
  - Canada
  - Bahrain
- **Require permit to bring infectious agents in any quantity there**

- **Operator examples**
  - FEDEX
    - Third-Party Vendor to prepare Shipper’s Declaration form
    - 3 copies of Shipper’s Declaration form
    - No RG4 transport
  - UPS
    - No Category A infectious agents
    - International shipments of Category B Biological Substances *without* an approved *contract* with UPS are prohibited.
  - Aircrafts
    - No live infected animals
Submit form to EHS with your shipment information and EHS will help classify shipments and determine if import / export permits are required.

Available on EHS website
Biological Material Classifications

- Non-Regulated Biological Materials
- Select Agents and Toxins
- Infectious Substance – Category A
- Biological Substance – Category B
- Patient Specimens (formerly Diagnostic Specimens)
- Genetically Modified Micro-Organisms and Organisms
- Biological Products
Biological Material and Dry Ice Flowchart

Manual - Appendix B

Training Handout

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**Dangerous Goods Characteristic**

- **Dry Ice?** (Defined in Section 8.1)
  - Yes

- **Non-Regulated Biological Material?** (Defined in Section 7.1)
  - No

- **Select Agent?** (Defined in Section 7.2)
  - Yes

- **Category A Infectious Substance?** (Defined in Section 7.3)
  - No

- **Category B Infectious Substance?** (Defined in Section 7.4)
  - No

- **Patient Specimen?** (Defined in Section 7.5)
  - Yes

- **Genetically Modified?** (Defined in Section 7.6)
  - Yes

- **Biological Product?** (Defined in Section 7.7)
  - No

- **DNA Sequencing Sample to Cornell-Ithaca?** (Defined in Section 7.8)
  - Yes

**Packaging Requirements**

- **Dry Ice (PI 554)** (refer to Section 15.0)
  - Package in accordance with Section 9.0

- **Infectious Substance Category A (PI 629)** (refer to Section 10.0)

- **Biological Substance Category B (PI 659)** (refer to Section 11.0)

- **Patient Specimen** (refer to Section 12.0)

- **Genetically Modified Micro-Organisms (PI 959)** (refer to Section 13.0)

- **DNA Sequencing** (refer to Section 14.0)

**Shipping Document Requirements**

- **1. Carrier’s Air Waybill**

- **2. Carrier’s Air Waybill**

- **3. Shipper’s Declaration**

- **1. Itemized List of Contents**

- **2. Carrier’s Air Waybill**

- **1. Carrier’s Air Waybill**

- **1. Carrier’s Air Waybill**

- **1. Carrier’s Air Waybill**

- **As specified in Approval**

- **None**

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BIOLOGICAL CLASSIFICATION

Non-Regulated Biological Materials

• Substances which do not contain infectious substances or are unlikely to cause disease in humans or animals (DNA, antibodies)
• Substances containing microorganisms which are non-pathogenic to humans or animals (E. coli K12)
• Environmental Samples (water, soil, food)
• Blood or blood components collected for transfusion
• Organs for transplantation
• Dried blood spots (newborn screening)
• Fecal occult blood tests (stool for colorectal cancer testing)
Biological agents that have a potential to pose a severe threat to public health

- Contact **EHS** for shipment of Select Agent or Toxin
- Manual - Appendix C

### HHS SELECT AGENTS AND TOXINS

<table>
<thead>
<tr>
<th>Agent</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td>ebolavirus</td>
<td>Ebola virus</td>
</tr>
<tr>
<td>hantavirus</td>
<td>Hantavirus</td>
</tr>
<tr>
<td>rickettsia</td>
<td>Rickettsia prowazekii</td>
</tr>
<tr>
<td>vibrio</td>
<td>Vibrio cholerae</td>
</tr>
</tbody>
</table>

### USDA SELECT AGENTS AND TOXINS

<table>
<thead>
<tr>
<th>Agent</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>anthrax</td>
<td>Bacillus anthracis</td>
</tr>
<tr>
<td>botulinum</td>
<td>Botulinum neurotoxins</td>
</tr>
<tr>
<td>brucella</td>
<td>Brucella abortus</td>
</tr>
<tr>
<td>brucella</td>
<td>Brucella melitensis</td>
</tr>
<tr>
<td>brucella</td>
<td>Brucella suis</td>
</tr>
<tr>
<td>burkholderia</td>
<td>Burkholderia mallei (formerly Pseudomonas mallei)</td>
</tr>
</tbody>
</table>

### OVERLAP SELECT AGENTS AND TOXINS

<table>
<thead>
<tr>
<th>Agent</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>clostridium</td>
<td>Clostridium perfringens epsilon toxin</td>
</tr>
<tr>
<td>streptococcus</td>
<td>Streptococcus pyogenes</td>
</tr>
</tbody>
</table>

### Contact EHS for shipment of Select Agent or Toxin

Manual - Appendix C
BIOLOGICAL CLASSIFICATION

Infectious Substance, Category A

An infectious substance capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.

- Category A Indicative List (Manual - Appendix D)

If in doubt whether or not a substance meets the criteria, include in Category A

- Manual - Section 10.0
- Packaging Instruction 620
BIOLOGICAL CLASSIFICATION

Biological Substance, Category B

An infectious substance which **does not** meet the criteria for inclusion in Category A is classified as Biological Substance - Category B

- Manual - Section 11.0
- Packaging Instruction 650
BIOLOGICAL CLASSIFICATION

Patient Specimens

Patient Specimens with Category A or B Pathogens
- Must be classified as Category A or B
- Packaging Instruction 620/650
- Manual - Section 10.0/11.0

Patient Specimens which are being shipped for infectious disease screening
- Includes specimens not known to be infectious, but are still be shipped for infectious disease screening
- Must be classified as Category B
- Packaging Instruction 650
- Manual – Section 11.0

Patient Specimens w. Minimum Likelihood of Pathogens (eg., blood or urine sample to test cholesterol levels)
- Manual - Section 12.0
- ‘Exempt’ Human Specimen / Animal Specimen
BIOLOGICAL CLASSIFICATION
Genetically Modified Microorganisms and Organisms

GMMOs and GMOs are those in which genetic material has been purposely altered through genetic engineering

• Infectious GMMO and GMO
  – Must be classified as Category A or B

• Non-Infectious GMMO and GMO
  – Manual - Section 13.0
  – Packaging Instruction 959
BIOLOGICAL CLASSIFICATION

Biological Products

Biological products are those products derived from living organisms which are used for the prevention, treatment, or diagnosis of disease in humans or animals (e.g., vaccines)

- Government approved Biological Products (e.g., USDA, HHS-FDA) are not regulated by IATA. Material must be packaged in accordance with the approval.

- Non-Approved Biological Products known or reasonably believed to contain a Category A or B Infectious Substance must be classified as Category A or B Infectious Substance.
### BIOLOGICAL CLASSIFICATIONS

#### Examples

<table>
<thead>
<tr>
<th><strong>Biological Material</strong></th>
<th><strong>Classification</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Human blood specimen</td>
<td>Exempt patient Specimen</td>
</tr>
<tr>
<td>Human blood for ID screening</td>
<td>Biological Substance, Category B</td>
</tr>
<tr>
<td>Human blood w/ HIV</td>
<td>Biological Substance, Category B</td>
</tr>
<tr>
<td>HIV Cultures</td>
<td>Infectious Substance, Category A</td>
</tr>
<tr>
<td>Ebola Virus</td>
<td>Select Agent and Toxin</td>
</tr>
</tbody>
</table>
CHEMICAL CLASSIFICATION

Dry Ice

• Over-pressurization hazard
  – If packaged in a sealed container, the gas cannot be released and the package will “explode”.

• Suffocation hazard
  – Carbon dioxide will displace the oxygen

• Contact hazard
  – It will cause severe frostbite on contact with skin.

Manual - Section 15.0
Packaging Instruction 954
Preservatives used for maintaining the viability, stabilizing, or preventing degradation of the Category A or B infectious substance.

- Flammable Liquid (Class 3)
  - e.g. ethyl alcohol, formaldehyde in methanol
- Corrosive (Class 8)
  - e.g. acetic acid, formaldehyde solution (20-37.5%)
- Miscellaneous dangerous goods (Class 9)
  - e.g. formaldehyde solution (10-20%)

Manual - Section 8.2 / 8.3
CHEMICAL CLASSIFICATION

Chemical Preservatives

1. Hazardous Preservatives with Infectious Substances Manual - Section 8.2
   - ≤ 30 ml (per vial) with Category A/B exempt
   - > 30 ml – Contact EHS

2. Hazardous Preservatives with Non-Infectious Substances Manual - Section 8.3
   - Preservative more hazardous - Contact EHS

3. Common Non-Hazardous Preservatives Manual - Section 8.4
   - Formaldehyde (<10%)
   - 10% Formalin (3.75% formaldehyde concentration)
   - Phosphate buffered salines

No Shipping Restrictions; Refer to MSDS for Preservative or Contact EHS
General Packaging Requirements

- **Primary Receptacle**
  - Leakproof (No petri plates)
  - Labeled with the name of the contents (Specimen ID Label)
  - Use Biohazard label when necessary

- **Leakproof Secondary Container**
  - Leakproof
  - Itemized list of package contents
  - Absorbent material enough to absorb **ALL** of the liquid from the primary receptacle(s).
  - Wrap multiple primary containers to prevent contact between them and prevent breakage

- **Durable Outer Container**
Selecting and Purchasing Appropriate Packaging

- Confirm packaging is designed for appropriate Packing Instruction. Special consideration for **Dry Ice**
- Packing Instruction 620 box can be used for all biological materials
- Appendix E in Shipper Manual has list of packaging suppliers.
  - SAFTPAC
  - VWR, Fisher Scientific, Lab Safety Supply
  - Search for “infectious substance”

DO NOT REUSE OLD PACKAGING UNLESS CONFIRMED TO MEET PACKING INSTRUCTION

<table>
<thead>
<tr>
<th>Category</th>
<th>UN Code</th>
<th>Packing Instruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>2814 or 2900</td>
<td>620</td>
</tr>
<tr>
<td>B</td>
<td>3373</td>
<td>650</td>
</tr>
<tr>
<td>Patient Specimens</td>
<td></td>
<td>Manual Section 12.0 (Durable/Rigid)</td>
</tr>
<tr>
<td>Non-Regulated Biologicals</td>
<td>3245</td>
<td>Manual Section 9.0 (Durable/Rigid)</td>
</tr>
<tr>
<td>GMMO and GMO</td>
<td>3245</td>
<td>Packing Instruction 959</td>
</tr>
<tr>
<td>Dry Ice</td>
<td>1845</td>
<td>Packing Instruction 954</td>
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</table>
Questions?