Shipping Infectious Substances Category A and B

DHEC Bureau of Laboratories
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South Carolina Department of Health and Environmental Control
Promoting and Protecting the Health of the Public and the Environment  www.scdhec.gov
What Regulations Apply When Shipping Infectious Substances?

It Depends…..
If the package will travel by air, most airlines belong to the International Air Transporters Association (IATA) and will use IATA Dangerous Goods Regulations. The IATA regulations are updated annually on January 1.

The US Dept. of Transportation (US DOT) regulates shipping in the United States; the DOT regulations are found in the Code of Federal Regulations, 49 CFR 173.

The United States Postal Service (USPS) regulations are found in the Domestic Mail Manual (C023). Any materials shipped through the USPS must meet their regulations.
- IATA Regulations
  [www.iata.org/index.htm](http://www.iata.org/index.htm) select - shop
  Cost = $275.00 + shipping (for 2013)

- US DOT
  then select “Regulations and Federal Haz Mat Law”

- USPS
  [www.usps.gov](http://www.usps.gov) search for Domestic Mail Manual and follow the links
IATA and ICAO

- The IATA regulations are taken from the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. ICAO is an agency of the United Nations.
US DOT and the USPS harmonized their regulations with IATA

- IATA regulations only apply to air transport by IATA members. US DOT is the *governmental* regulatory authority in the United States for transport by air, water, or ground, except the U.S. mail.

- While IATA, US DOT and US Postal Service all use the same classification system for infectious substances, there are differences in their regulations.
## Who Enforces the Regulations?

<table>
<thead>
<tr>
<th>Regulations</th>
<th>Enforcement By</th>
</tr>
</thead>
<tbody>
<tr>
<td>IATA</td>
<td>Member airlines accept or reject dangerous goods based on the <em>Dangerous Goods Regulations</em> and any limitations as set by the particular carrier.</td>
</tr>
<tr>
<td>US DOT</td>
<td>US DOT Inspectors, For air shipment – FAA Inspectors</td>
</tr>
<tr>
<td>US Postal Service</td>
<td>US Postal Inspectors</td>
</tr>
</tbody>
</table>
Additionally.....

Each transporter may set additional requirements above those of the regulations.

Example: Federal Express requires that the “Shippers Declaration for Dangerous Goods” be typed in an approved program; a hand written document will not be accepted.
This training will cover IATA regulations and highlight some US DOT and SC State Courier Service differences.
The regulations apply to anyone who:

- handles the package of dangerous goods during transport,
- offers dangerous goods for transport,
- transports dangerous goods, or
- causes dangerous goods to be transported.
Employees Must Be Trained

Employees who **only** ship infectious substances, category B, must be trained on proper packaging and labeling for category B infectious substances.
Employees Must Be Trained

For employees who will package and ship infectious substances, category A, the training is more involved and must include:

- An overview of the regulatory requirements
- Function specific training on the activities the employee will be responsible for, such as classification of infectious substances, packaging, labeling the outside container and completing shipping documentation.
- Safety training to include understanding the hazards of the infectious agent, safe handling and emergency response procedures.
- Security awareness
Training

IATA - Training must be conducted every two years or whenever the regulations change. Effective Jan. 1, 2009, training records must be retained for 36 months.

DOT – Training must be conducted every three years or whenever the regulations change.
Shipper’s Responsibilities

- Classify - determine if materials meet the definitions of dangerous goods
- Identify - select the proper shipping name
- Packaging
- Marking and labeling
- Documentation
- Recordkeeping
Shipper’s Responsibilities

- Employees must have safety training which covers the hazards presented by the dangerous goods being shipped and emergency response procedures. This information will not be covered in this presentation. Laboratory employees should have already received this training though their bloodborne pathogen training and microbiology training.
Security Training for Employees

- Employees who ship Category A Infectious Substances must have security training.
- Security Training may be developed specifically for your site or a DOT developed module may be used, which includes a written test.

Training Records must include:

- the individual’s name
- the most recent training completion date
- a description, copy or reference to training materials used
- the name and address of the organization providing the training; and
- a copy of the certification issued when the individual was trained, which shows that a test has been completed satisfactorily.
Remember!

- IATA regulations apply to transport by air by IATA member airlines (passenger or cargo aircraft).

- US DOT regulations apply to any transport IN COMMERCE in the United States. Therefore, the US DOT regulations do not apply to in-house couriers or transport by private vehicle. However, for everyone’s safety, infectious substances should always be properly packaged, labeled and marked.
For shipping purposes, Infectious substances are considered ‘dangerous goods’.

US DOT uses the term ‘hazardous materials’.
There are 9 classes of dangerous goods and many divisions.

Infectious substances are in class 6 (Toxic & Infectious Substances)
Dry Ice

If you ship with dry ice, be aware that dry ice is a dangerous good and is in Class 9 (Miscellaneous Dangerous Goods)
Definitions

- **INFECTIOUS SUBSTANCES** are substances which are known or are reasonably expected to contain pathogens. Pathogens are defined as microorganisms (including bacteria, viruses, rickettsiae, parasites, fungi) and other agents such as prions, which can cause disease in humans or animals.
Definitions

- **CULTURES**: Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined in 3.6.2.1.4. [Note – For example, a swab placed in a genprobe bottle would not meet this definition of a culture]

- **PATIENT SPECIMENS** are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.
Infectious substances are divided into 2 categories – A and B

**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. Indicative examples of substances that meet these criteria are given in Table 3.6.D. on slide # 31. The full Table 3.6.D. is in the “Read Me First File.”
Infectious substances are divided into 2 categories – A and B

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

- IATA regulations no longer require that all cultures which cause disease in humans be shipped as Infectious substances, Category A.

- **Most** cultures shipped to the Bureau of Laboratories from SC hospitals will now be classified as Infectious substances, Category B.
Cultures Classified as Infectious Substance, Category B

- Salmonella spp.,
- Listeria spp.,
- Shigella spp.,
- Most cultures of Biosafety Level 2 (BSL2) organisms
Cultures Classified as Infectious Substance, Category A

- **Known cultures of** *Bacillus anthracis*, *Brucella abortus*, and *Yersinia pestis*

- *Escherichia coli*, verotoxigenic (*BSL2 organism, but causes serious or life threatening illness*)

- *Neisseria meningitidis* (*BSL2 organism, but causes serious or life threatening illness*)

- See Table 3.6.D in the “Read Me First File” for more information
How Are Cultures for Rule in/Rule out of Select Agents classified for Shipment?

If transport is by the SC State courier to the Bureau of Laboratories:

- The culture may be classified as Category A or B since a UN certified shipper is used and the SC State courier does not require a “Shipper’s Declaration for Dangerous Goods” for Category A substances. However, it is very important that “Special Pathogens” is marked on the “To” label and prior notification is made.
How Are Cultures for Rule in/Rule out of Select Agents classified for Shipment?

If transport is by commercial carrier:

- The culture should be classified as Category A.
- On the “Shipper’s Declaration for Dangerous Goods” instead of the organism name, place the phrase “Suspected Category A, infectious substance” in parentheses under the shipping name.
A Portion of Table 3.6.D from IATA Dangerous Goods Regulations
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicted

Note: This table is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria must be assigned to category A.

<table>
<thead>
<tr>
<th>UN Number and Proper Shipping Name</th>
<th>Microorganism</th>
</tr>
</thead>
</table>
| UN 2814 Infectious substance, affecting humans | *Bacillus anthracis* (cultures only)  
*Brucella abortus* (cultures only)  
*Yersinia pestis* (cultures only)  
Eastern equine encephalitis virus (cultures only)  
Escherichia coli, verotoxigenic (cultures only)  
Ebola virus  
Hepatitis B virus (cultures only)  
.......... |
### Examples of Classifications of Infectious substances

<table>
<thead>
<tr>
<th>Material</th>
<th>Infectious Substance, category A</th>
<th>Infectious Substance, category B</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Known</strong> culture of <em>Bacillus anthracis</em></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Tube of blood from a patient infected with <em>Bacillus anthracis</em></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Tube of blood from a person infected with <em>Brucella abortus</em></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>
Remember

When determining the proper classification for an infectious substance, the shipper must consider the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses a higher degree of risk than Category B.
Proper shipping names and shipping requirements are found in the IATA “List of Dangerous Goods” table.

The next slide shows the proper shipping name and UN numbers needed to ship Infectious substances, Category A and B.
## Proper Shipping Names

(from IATA Dangerous Goods Regulations, effective 1 January – 31 December 2014, List of Dangerous Goods)

<table>
<thead>
<tr>
<th>Classification</th>
<th>Proper shipping name</th>
<th>UN number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Infectious substance, Category A (infects humans &amp; may infect animals)</td>
<td>Infectious substance, affecting humans</td>
<td>UN 2814</td>
</tr>
<tr>
<td>Infectious substance, Category A (only infects animals)</td>
<td>Infectious substance, affecting animals</td>
<td>UN 2900</td>
</tr>
<tr>
<td>Infectious substance, category B</td>
<td>Biological substance, category B</td>
<td>UN 3373</td>
</tr>
</tbody>
</table>
Packaging Infectious Substances

All packaging is based on a “triple” receptacle shipper.

- Infectious substances, category A, must be packaged to meet packing instruction 620.

- Infectious substances, category B (most patient specimens) must be packaged to meet packing instruction 650.
A primary receptacle is the container (e.g., tube vial, bottle) that holds the specimen.

- Must be securely sealed and leak proof (screw top tubes must have a piece of waterproof tape around the top to prevent the top from coming loose in transit)

- Must be surrounded by absorbent material capable of taking up the entire liquid contents.

- Must be packed in the secondary receptacle in such a way that it will not break
**Secondary packaging** is the receptacle into which a primary receptacle and the absorbent and cushioning material are placed.

- Must be leak proof and securely sealed

- Biohazard label is placed on the outside of the secondary container for OSHA compliance

- Must be placed in the outer packaging so that it does not move

- *Never* place cold packs or dry ice inside the secondary packaging! Dry ice will cause a pressure build up and the secondary container may explode!!!
Outer packaging is the receptacle into which the secondary packaging with cushioning material are placed.

- The outer packaging must be rigid.
- The outer packaging bears the addressing information along with all required markings and labels.
- One side of the outside packaging must be 4 inches by 4 inches.
Cylinder shaped outside packaging will not be accepted by IATA member airlines.

However, the SC State courier will continue to accept cylinder shaped shippers for Biological substance, Category B.
Therefore, to ship the round TB sputum shipper by the USPS, the shipper must be placed in a cardboard box with all of the appropriate labels and markings on the outside packaging for a Biological substance, Category B.
An itemized list of contents is required.

The itemized list is placed OUTSIDE the secondary container. The laboratory requisition form should also be placed OUTSIDE the secondary container.

DO NOT place documents inside the secondary container.
Itemized List used by the Bureau of Laboratories

Shipped from: SC DHEC Bureau of Laboratories  
8231 Parklane Road  
Columbia, SC 29223  
Emergency Contacts: Connie Gray or Dr. Arthur Wozniak  
Emergency Telephone: (803) 896-0800

Shipped to: ________________________________

______________________________

Shipping Temperature

_____ ambient
_____ cold packs
_____ dry ice

Next day delivery required

_____ No
_____ Yes

<table>
<thead>
<tr>
<th>Specimen or Culture</th>
<th>Number of tubes or plates</th>
<th>Volume in each tube or plate</th>
<th>Total volume</th>
<th>Proper shipping classification (circle only one)</th>
</tr>
</thead>
<tbody>
<tr>
<td><em>Mycobacterium tuberculosis</em></td>
<td></td>
<td></td>
<td></td>
<td>Infectious substance, category A or Infectious substance, category B</td>
</tr>
</tbody>
</table>


Example of proper triple packaging

Cross Section of Proper Packing

Packing and Labeling of Infectious Substances
Packaging Requirements for Infectious substances, category B

- Category B specimens and cultures must be packed in good quality packaging, which must be strong enough to withstand the shocks and loadings normally encountered during transport.

- The packaging must be capable of passing a 1.2 meter (3.9 feet) drop test.

- If the transport is by air, the primary or secondary packaging must pass a pressure test.
Packaging Requirements for Infectious substances, category B

- For air transport, at least one surface of the outer packaging must have a minimum dimension of 4 inches x 4 inches.

Note: A ziplock biohazard bag may serve as the secondary receptacle for a category B specimen if transport is by ground in the state courier system.
Markings and Labels Required on the outside container for Infectious substances, category B

- For transport, an UN 3373 marking must be on the outside receptacle. The words “Biological substance, Category B” must be marked on the outer package adjacent to the diamond-shaped UN 3373 marking.

Note - Do not place biohazard stickers on the outside container. The biohazard marking should be on the secondary receptacle and may be on the primary receptacle.
Documentation Required for Infectious substances, category B

- A “Declaration of Dangerous Goods” is **not** required.
Quantity Limits for Infectious substances, category B

IATA regulations allow 1 liter in a primary receptacle for category B specimens. The outer packaging must not contain more than 4 liters.

**NOTE:** Most DHEC shippers are designed for a **maximum of 50 ml** of liquid patient specimens. Remember, there must always be adequate absorbent materials to absorb the amount of liquid in a primary receptacle.
Shipping Temperatures

Check the test section in the Bureau of Laboratories Services Guide, if unsure of temperature requirements for the infectious substance being shipped.

- If the specimen must be shipped cold, but not frozen, use cold packs. Ice will melt and leak during shipping.

  [NOTE: All patient specimens shipped for PCR testing should be shipped cold.]

- If the specimen must be shipped frozen, additional labeling is required for dry ice.
The Bureau of Laboratories provides the shipper shown below for shipping specimens, which must be shipped cold or frozen. The shipper shown is labeled for shipping in the SC State Courier system; the UN 3373 marking would need to be added for a commercial transporter. If the shipper contains dry ice, the markings and label shown on the next slide would need to be added.
Labeling required for Dry Ice

- Class 9 DOT label
- DRY ICE UN 1845
- The amount of dry ice in the package in kilograms must be shown. One pound equals 2.2 kg.
- Dry ice must also be listed on the “Shippers Declaration For Dangerous Goods”
Overpack Example

Must have all the markings and labels as the outside container, plus a label stating “Overpack” and the total amount of contents in grams or milliliters.
Packaging, Marking and Labeling requirements are much more rigid for Infectious substances, category A
Additional Requirements for Infectious Substance, Category A Packaging

- Packaging must be UN certified (this means the packaging unit has passed drop, impact and pressure tests)

- The UN Certification number must be marked on the outside container
UN Certified Packaging

UN Certified Packaging must be used as a complete shipping package as received from the manufacturer. Substitution of parts of the packaging with other manufacturer’s shipping materials is not allowed.
Additional Requirements for Infectious Substance, Category A packaging

- Maximum quantity per shipper is 50 ml or 50 grams on passenger aircraft and 4 liters on cargo aircraft.
Effective November 1, 2006, the USPS no longer accepts Infectious substance, Category A, shipments.

Infectious substances, Category A must be sent with private transporters, such as FedEx.
Prior Arrangements

Do you need to make prior arrangements for receipt? Will someone be there to receive your shipment if you ship on Friday?

Note: This is not necessary for most cultures being sent to the Bureau of Laboratories through the state courier system. Procedures are in place to receive state courier shipments on Saturdays and holidays.
Bioterrorism Specimens and Cultures

Prior notification is requested for specimens and/or cultures being sent for “rule out/rule in” testing for bioterrorism agents.

Please notify:

Amanda Moore - 803-896-0777 or Megan Davis – 803-896-0870, before shipping these patient specimens or cultures.

Alternate: Brian Goootee 803-896-0956
When do you declare an Infectious Substance is a Select Agent?

- When the identification has been confirmed by the state public health laboratory and/or CDC
Shipping **Known** Select Agents and Toxins

- Select Agent Program must approve transfer
- APHIS/CDC Form 2 must be used
  Hospitals DO NOT use this form for “suspect” infectious substances.
- Currently takes 6 to 7 weeks for approval
- Recipient in transfer must be registered with the Select Agent Program for that agent.
Effective 1-1-2005, the name of the organism is no longer required on the outer packaging. Please, for security purposes, do not place the name on the outside packaging. However, the name of the organism is still required on the “Shipper’s Declaration For Dangerous Goods”.
The regulations no longer require that all cultures be shipped as Infectious substance, category A, which would include using UN certified shippers. However, the Bureau of Laboratories provides UN certified shippers for shipping infectious substances. We ask that a **UN certified shipper be used for all cultures** shipped to the Bureau of Laboratories. The shipper may be labeled for category A or B infectious substances.
Important Points to Remember

- Proper packaging, marking and labeling is the shipper’s responsibility.

- Make sure that the correct marking and labeling information is on the outside packaging.

- Do not put laboratory forms, cold packs, or dry ice inside the secondary container with the specimen.
Important Points to Remember

- The outside packaging should have the name and telephone number of a person who is knowledgeable about the contents of the shipment. This is important emergency information in the event an exposure occurs during shipping.
Important Points to Remember

Do NOT put biohazard labels on the outside packaging.

The biohazard label should be on the secondary receptacle.
Important Points to Remember

*Do not* use excessive tape to close the outside container.

One piece of *clear* packaging tape should be adequate.
Important Points to Remember

Do **NOT** cover or deface any label or marking.

A commercial transporter will not accept the package.
Important Points to Remember

Seal the package with clear shipping tape.

Cut the tape to open the package. Pulling the tape off often defaces the markings and labels on the outside packaging.
Documentation for Infectious Substance, Category A packages

Keep this documentation for a minimum of 2 years (select agents – 3 years) on each shipment with a commercial transporter:

- One copy of the “Shipper’s Declaration for Dangerous Goods”

- Documentation the material was received (email, tracking number showing receipt, etc.)
Additional Requirements for Infectious Substance, Category A Shipments

A “Shipper’s Declaration For Dangerous Goods” must be completed if the package will be transported by a commercial carrier.

Note – The state courier does not require a “Shipper’s Declaration for Dangerous Goods”. This is one very good reason to use the state courier system.
Shipper’s Declaration For Dangerous Goods

- Must be attached to the outside (usually the top) of the package in a ziplock bag

- Must be completed in triplicate, each as an original, with the red stripe down each side of the paper. Two copies are given to the transporter and one copy is kept for your files.
The “Shipper’s Declaration For Dangerous Goods” is a legal document. If it is not 100% correct, it is WRONG and your package will be refused for shipment and returned.
NOTE - Federal Express does not accept hand written Shipper’s Declarations. Beginning January 10, 2011, FedEx Express will require all Shipper’s Declarations originating in the U.S., excluding all 023 air waybill shipments, to be prepared using only the following methods:

a) FedEx approved vendor software application;

b) Preapproved shipper proprietary software; or

c) FedEx Express Automated Shipping Solutions that have dangerous goods error checks.

Note – A list of approved DG Shipping application vendors can be reviewed at www.fedex.com/us; dangerous goods (keyword). Shipper declaration “templates” from FedEx Express will no longer be accepted.
References

Information for this powerpoint was taken from the sources listed below.

- US DOT powerpoint “Transporting Infectious Substances Safely”
- USPS, Domestic Mail Manual
- Code of Federal Regulations, 42 CFR Part 73, (Select Agent Regulations)
Any Questions ??

Contact:
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