Training Requirements

• Individuals wishing to ship dry ice and/or ‘exempt human/animal specimens’ (specimens) must undergo training to understand the hazards posed by these materials and the corresponding safety practices that must be used to reduce or eliminate those hazards.

• Following completion of this module, a short quiz must be satisfactorily completed in order to be authorized to prepare packages, sign shipping documents, or perform any other shipping function discussed in this module involving dry ice or specimens.

• Individuals viewing this presentation outside of RASCAL, if unable to complete the related quiz in RASCAL, must contact biosafety@columbia.edu to obtain a hard copy of the quiz.

• Please note – certification to ship other dangerous goods requires separate training not satisfied by this module. Please contact EH&S with specific questions.
Overview

• Introduction
  – Hazardous Materials in transit
  – Dry ice as a hazardous material
  – Exempt human/animal specimens-identification and hazards

• General HAZMAT Awareness
  – Introduction to HAZMAT shipping regulations
  – HAZMAT Table and ICAO/IATA Technical Instructions

• Function-specific dry ice shipping instructions
  – Packaging
  – Marking
  – Labeling
  – Paperwork

• Safety
• Security
• Additional recommendations
• Excepted Quantities of hazardous chemicals used as preservatives (e.g. ethanol, formalin)
Introduction – Hazardous Materials

• Many ordinary goods and materials are classified as “Hazardous Materials (HAZMATs*)” when offered for transport.

• The US Department of Transportation has identified “human error” as a contributing factor in most transportation incidents. Proper training is the best means of preventing hazardous materials transportation incidents.

• *Please note – The terms “HAZMATs” and “dangerous goods” are used interchangeably throughout this presentation.
Introduction – Dry Ice

- The US Department of Transportation (DOT) and the International Air Transport Association (IATA) both regulate shipments of packages containing dry ice as a “Dangerous Good.”

- Dangerous goods are those items that pose a potential hazard to human health or the environment during transit.
Introduction – Dry Ice

• May 25, 2001
  – Pilots nearly overcome by asphyxiation on runway by improperly loaded package of frozen shrimp packed on dry ice.

• This and similar incidents that have occurred due to improperly packaged or undeclared shipments of dry ice illustrate the need to ensure the safe handling of dry ice and other hazardous materials in transit.

• It is important to remember that the responsibility for the safe transport of packages containing dangerous goods lies with the shipper (you!) – Federal regulations provide for substantial civil and/or criminal penalties against violators.
Introduction – Exempt Specimens

Specimen – (material) collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and swabs, and body parts transported for research, diagnosis, investigational activities, disease treatment and prevention.

Exempt Specimen – specimen for which there is minimal likelihood that pathogens are present.

The ‘exempt’ designation allows for the shipment of low risk material with fewer restrictions/requirements than ‘infectious’ materials.

Examples: human or animal specimens from which, based on clinical or case history, the presence of pathogens is not suspected.

Material transported for testing related to the diagnosis of infectious disease may not be classified as exempt.
Introduction – Limitations of Training Module

• The requirements discussed in this module pertain to dry ice, exempt specimens, and excepted quantities specifically. Packages containing other hazardous materials, including certain chemical, biological or radiological substances with or without dry ice, are subject to additional requirements not covered in this module. For training regarding the shipment of Biological Substances Category B (BSCB) or Genetically Modified Microorganisms (GMMO), see RASCAL module “TC0507 – Shipping Biological (infectious and potentially infectious) Materials, Genetically Modified Microorganisms, and Exempt Specimens”

  – Non-exempt biological materials offered for shipment are classified as either Category A or B, depending on their risk of infection. Please see http://ehs.columbia.edu/ShippingHazMaterials.html for additional information on the shipment of biological materials.

• This module discusses the regulations specific to the shipment of dry ice and exempt specimens by air. Please contact EH&S regarding the applicability of these regulations for shipment by other modes, such as DHL or FedEx Ground.

• If you are unsure if any materials you are shipping are hazardous materials, please contact EH&S.
General HAZMAT Awareness

Regulatory Overview

– The federal regulations governing domestic air transport of dangerous goods are published at 49 CFR 100 - 185. These regulations have been harmonized with those published under the IATA Dangerous Goods Regulations, and must be followed for all air shipments.
General HAZMAT Awareness, cont.

• Regulatory Overview
  – 49 CFR contains information pertaining to the following areas of HAZMAT shipment:
    • Definition of HAZMATs and Hazardous Materials Employees
    • Training requirements
    • Preparation of HAZMATs for shipment
    • Container manufacturing and testing requirements
    • Rejection of improperly prepared or incorrectly documented packages
    • Safety and security requirements during HAZMAT shipments
General HAZMAT Awareness, cont.

• Regulatory Overview
  – 49 CFR:
    • Definition of Hazardous Materials
      – Materials classified by the DOT as explosive or radioactive, compressed gases, flammable, infectious, oxidizing, reactive, toxic, or corrosive.
      – These materials are identifiable by various hazard communications means, including placards and labels, and Material Safety Data Sheets (MSDS).
      – DOT also regulates other materials that pose “miscellaneous” hazards, such as dry ice.
    • Definition of Hazardous Materials Employee
      – (1) A person who is: (i) Employed on a full-time, part time, or temporary basis… and who in the course of such full time, part time or temporary employment directly affects hazardous materials transportation safety;… (i) Loads, unloads, or handles hazardous materials; … (iii) Prepares hazardous materials for transportation; (iv) Is responsible for safety of transporting hazardous materials
General HAZMAT Awareness, cont…

• Regulatory Overview
  – 49 CFR
    • Training requirements
      – Initial training upon hire
      – Refresher training every 2 years
      – Satisfactory completion of test
      – Certification
Examples of HAZMAT Communication and Signage –
These placards may appear as placards on vehicles transporting HAZMATs and/or may appear as smaller labels on packages of HAZMATs, including dry ice.
General HAZMAT Awareness – Hazardous Materials Table and ICAO/IATA Technical Instructions

All of the operational requirements for properly preparing a shipment of a dangerous good are located in the Hazardous Materials Table. This table forms the basis for the HAZMAT regulations.

- The complete Hazardous Materials Table is located at 49 CFR 172.101
- Understanding the proper use of the table is critical to the proper performance of many HAZMAT shipping functions.
- For air transport of dangerous goods, this information is located in the ICAO/IATA technical instructions (TI). Please contact EH&S to review a copy of the ICAO/IATA TI.
- Following the instructions located in the ICAO TI will ensure compliance with the DOT HAZMAT regulations.
General HAZMAT Awareness, cont…

The DOT Hazardous Materials Table defines the materials regulated by DOT, and prescribes the proper packaging requirements for transit. These requirements are mirrored in the ICAO/IATA Technical Instructions.

The excerpt from the HAZMAT Table displays the entry for Dry Ice. The full table is arranged alphabetically by shipping name. There is no HAZMAT Table entry for exempt human or animal specimens.

Each column of the table provides critical information used in the preparation of dangerous goods packages.

<table>
<thead>
<tr>
<th>Symbols</th>
<th>Hazardous materials descriptions and proper shipping names</th>
<th>Hazard class or Division</th>
<th>Identification Numbers</th>
<th>PG</th>
<th>Label Codes</th>
<th>Special provisions (§172.102)</th>
<th>(8) Packaging (§173.xxx)</th>
<th>(9) Quantity limitations (see §§173.27 and 175.75)</th>
<th>(10) Vessel stowage</th>
</tr>
</thead>
<tbody>
<tr>
<td>AW</td>
<td>Carbon dioxide, solid or Dry ice</td>
<td>9 UN1845</td>
<td>III</td>
<td>None</td>
<td>217</td>
<td>217 240</td>
<td>200 kg 200 kg C 40</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- This excerpt from the HAZMAT Table displays the entry for Dry Ice. The full table is arranged alphabetically by shipping name. There is no HAZMAT Table entry for exempt human or animal specimens.

- Each column of the table provides critical information used in the preparation of dangerous goods packages.
The DOT Hazardous Materials Table

- Columns 2, 3, 4 and 5 contain the proper shipping name, hazard class, UN Identification Number and packing group, respectively. These pieces of information will appear on the outside of packages containing dry ice as well as on the air waybill for dry ice shipments.

- Column 6 indicates the label(s) that must appear on the package. As indicated by the word “None” in column 6, if a package contains no dangerous goods other than dry ice, the only label that is required is “9 – Miscellaneous.” Labels are available through EH&S or for purchase through the vendors listed at the end of this module.
General HAZMAT Awareness, cont…

The DOT Hazardous Materials Table

- Column 7 contains information on special provisions or requirements based on state regulations or other rules.

- Column 8A, 8B, and 8C indicates the packaging instructions for dry ice. These instructions can be found at 49CFR 173.217 for non-bulk packages.

- Columns 9A and 9B provide instructions on the maximum allowable quantity of dry ice allowed in a package depending on the mode of transportation.
General HAZMAT Awareness, cont…

• Columns 8A and 8B – **49 CFR173.217**

• Requires packaging capable of safely venting carbon dioxide gas

• Requires the following to appear on the air waybill –
  – Proper shipping name (“Dry Ice” or “Carbon Dioxide, solid”); This must appear in exact order with no shorthand or abbreviations.
  – Class 9;
  – UN 1845;
  – The number of packages; and
  – The net weight of dry ice in each package.

• The net weight of the carbon dioxide, solid (dry ice) must be marked on the outside of the package.
General HAZMAT Awareness, cont…

- Columns 8A and 8B – 49 CFR173.217
  - Recall – The requirements of the DOT HAZMAT Table are mirrored in the IATA/ICAO technical instructions for packages of dry ice.

- The ICAO/IATA version is found in IATA Packing Instruction 954.

- To review IATA Packing Instruction 954 in detail, please contact EH&S.
General HAZMAT Awareness, cont...

Packaging
Packaging Requirements

Ventilation

• Packages must permit for the release of carbon dioxide gas during transit. To prevent dangerous pressure build-up, dry ice must never be placed inside an airtight, unvented container.

• Always use insulated gloves when handling dry ice.

Package Integrity

• Shipments containing dry ice must be packaged to withstand the normal rigors encountered in transit, including vibration, rough handling or dropping during loading and unloading, and any changes in temperature, humidity and altitude.
Packaging Requirements, cont.

Packaging Materials

– Dry ice must be shipped in containers that are able to withstand its extremely low temperature. Accordingly, plastics that can become brittle or permeable at these temperatures should not be used.

– Check manufacturers’ recommendations to ensure your packing materials are compatible with dry ice.
Packaging Requirements, cont.

Exempt Human or Animal Specimens

• Leak-proof primary and secondary containers
• Outer packaging of adequate strength for its capacity, mass and intended use and with at least one surface having minimum dimensions of 100 mm x 100 mm
• For liquids, sufficient absorbent between primary and secondary containers so that no release will reach the outer packaging
• Multiple fragile primary containers must be wrapped or separated to prevent contact between them
General HAZMAT Awareness, cont.

- Packaging
- Marking
- Labeling

exempt human specimen
Packaging Requirements, cont.

Labeling and Marking

Dry ice is regulated as a Class 9, “miscellaneous” hazard class by DOT and IATA.

Proper packaging and labeling of dry ice will minimize risk to personnel during all stages of transportation.

“Exempt human (or animal) specimen” is the only package marking required for these materials.
Packaging Requirements, cont.

Labeling and Marking

• The outermost container must display the Hazard Class 9 DOT diamond, “UN 1845, Dry Ice, 9” and the net weight of dry ice, in kilograms. This label must be affixed to a vertical side of the box, not the top or bottom, and must appear in a vertical position, as shown, not on its side.

Reminder – This module covers the requirements for packages containing Dry Ice, Exempt Specimens, or Excepted Quantities with NO OTHER HAZMATs. Please contact EH&S for information on shipping other chemical, biological, or radiological HAZMATs.
General HAZMAT Awareness, cont.

- Packaging
- Markings
- Labeling
- **Shipping papers**
Packaging Requirements, cont.

Paperwork

• The airbill used for packages containing dry ice must display the words:
  “UN 1845, Dry Ice, 9,, number of packages X net weight of dry ice in kilograms”

• Many transporters’ paperwork (such as FedEx) contain check-boxes to meet this requirement. Proper notation must be made if a check-box is not available.

• There are no specific paperwork requirements for exempt specimens.
“Dangerous Goods” check-box – Check “Yes – Shipper’s Declaration Not Required” for packages containing only dry ice, exempt specimens, or excepted quantities with no other HAZMATs.

“Dry Ice” check box – Place an “X” in this box and indicate the net weight of dry ice, in Kg, in the package.

Checkbox requirements refer to dry ice, not exempt specimens.
General HAZMAT Awareness, cont.

- Packaging
- Markings
- Labeling
- Shipping papers
- Segregation
- Incident reporting
- Security
Safety - Hazards of Dry Ice

• Explosion
  – Dry ice releases large volumes of carbon dioxide gas as it sublimates. If enclosed in a sealed container, this release of gas can cause a dangerous build-up of pressure, and ultimately, an explosion.

• Suffocation
  – The presence of a large volume of carbon dioxide in a confined or poorly-ventilated space can pose an asphyxiation hazard due to a lack of available oxygen.

• Temperature
  – Carbon dioxide exists as a solid at approximately -110° F. This extremely low temperature can rapidly cause severe frostbite in contact with exposed skin.
Safety - Hazards of Exempt Specimens

By definition, ‘minimal likelihood’ exists that exempt specimens contain materials capable of causing infectious disease.

Remember, the operative term is ‘likelihood’; it would be impossible to guarantee sterility and an individual’s health status may negatively impact resistance to infection.

Because these specimens arise from animals or humans, Universal Precautions (barrier precautions) should be observed when handling exempt specimens. Always wear a lab coat, single use nitrile or vinyl gloves and eye protection when splash potential exists.
Safety –
Dry Ice Leaks and Spills

• In the event of a release of dry ice during package handling or preparation:

  – **Do not** handle dry ice with bare hands as this may result in rapid frostbite or injury
  – Ventilate the area where the dry ice has spilled/leaked, and be aware of potentially hazardous concentrations of CO₂ gas
    • CO₂ is heavier than ambient air and will remain in low areas without adequate forced ventilation
  – Use heavy gloves and tongs or other means to remove pellets to an insulated container, or to a well ventilated area to sublime
  – Never store or use dry ice in a cold room. The re-circulated atmosphere can concentrate CO₂ to dangerous levels.
Safety – Exempt Specimen Leaks and Spills

In the event of a release of exempt specimen materials, treat the situation as a biological spill of low risk microbiological material.

- Wear a lab coat, single use nitrile gloves and eye protection.
- Cover spilled materials with paper towels or other absorbent material.
- Apply a 1:10 dilution of household bleach in a volume approximating the quantity released.
- Dispose of clean-up material in regulated medical waste bags.
Safety –
HAZMAT Shipment Security

• The DOT regulations specify that all Hazardous Materials Employees receive a minimum level of security awareness training.
• For example, shippers of dry ice must limit access to their packages to trained personnel only, and should ensure their package remains in their possession until it is transferred to the carrier.
• **Shippers must not leave packages containing dry ice at drop boxes.**
Safety –
HAZMAT Shipment Security

Several areas of potential security vulnerability are important to consider when offering HAZMATs for shipment.

• Access
  o Allow only trained personnel to handle your package prior to pick-up; **do not leave at a drop box location.**
  o Immediately report any suspicious persons or activity in your laboratory or in any area where hazardous materials may be present.

• Personnel
  o Only trustworthy individuals should be trained to perform HAZMAT functions.
  o If you are unsure if a person has been trained, ask to see their certificate
Safety –
HAZMAT Shipment Security

Improperly handled HAZMATs have the potential to cause harm to human health and the environment in transit. The following are examples of areas where HAZMATs in transit could pose safety and security threats:

- Critical Transportation Infrastructure
  Incidents involving HAZMATs in transit can affect the integrity of roads, bridges, tunnels, transportation routes and other vulnerable facilities.

- Personal Safety
  HAZMATs are often loaded onto passenger aircraft for transportation. Improperly prepared packages can endanger passengers and vehicles.
Packaging Requirements, cont.

• Carriers are obligated to reject improperly prepared packages.
• Failure to meet ANY of the previously reviewed requirements when shipping a package containing dry ice can result in serious delays in delivery, fines, and/or criminal penalties.
Recommendations

• Patient specimens for which there is a minimal likelihood that pathogens are present are not subject to DOT or IATA shipping regulations, provided that the specimens are packaged in a way that will prevent leakage during transport. Packages of this type must display the words “Exempt Human Specimen.”

• For all other shipments, the terms “specimens” or “diagnostic specimens” are no longer acceptable terminology, and must not appear on the package. Please contact EH&S for further guidance on shipping potentially infectious materials.

• Reusing a dry ice box is a good use of resources. If you choose to reuse a box, completely obliterate all unnecessary marking such as hazard labels, addresses, FedEx (or other courier) labels and barcodes. Use caution if reusing a box that has been used to ship infectious material or diagnostic specimens. Only reuse a box if you can personally verify it is not contaminated and its integrity is intact. A box should not be reused if it is torn, cut, stained, or if the insulation is cracked or broken.
Recommendations, cont.

• Secure your samples in such a way that when the dry ice sublimates, they will not move freely inside of the insulated box. This can be accomplished by wedging your samples in place with cardboard or styrofoam. Fragile containers such as glass tubes or vials should be wrapped with cushioning material and placed in a secondary container.

• Minimize the volume of air to which the dry ice is exposed in order to slow the rate of sublimation. If there is any air space after you fill your package with dry ice, fill it with packing peanuts or other material to reduce the volume of air space.
Recommendations, cont...

• Carriers generally recommend that shipments contain 5-10 pounds (2.27-4.54 kg) of dry ice per 24 hours in transit. Refer to your package manufacturer’s recommendations. Make arrangements with your consignee to make sure your package will be received on its intended delivery date. Take into account local holidays or closings that might delay package receipt.

• Dry ice shipments can be made with FedEx and DHL. UPS and the U.S. Postal Service have extremely restrictive policies concerning shipments of HAZMATs; therefore, do not ship dry ice with UPS or the U.S. Postal Service.
Excepted Quantities - Specimens in Preservative

Specimen shipments may require inclusion of an appropriate preservative.

• This section addresses the shipment of specimens using small quantities of ethanol or formalin.
• This section is also applicable to the off-site shipment of pre-filled vials containing these materials for subsequent specimen collection and return.
Excepted Quantities - Specimens in Preservative

• In large quantities, ethanol and formalin are fully regulated when offered for transport. However, when shipping the quantities typically used for preserving specimens, ‘small quantity exceptions’ apply, allowing for a more streamlined shipping process.

• Table 2.6.A below, taken from the ICAO/IATA handbook, defines quantity limits for these preservatives.

• For formalin and for the most commonly available packaging used to send samples in ethanol, code E2 applies, limiting inner packages to a volume of 30 mL and outer packages to an aggregate volume of 500 mL.

<table>
<thead>
<tr>
<th>Code</th>
<th>Maximum net quantity per inner packaging</th>
<th>Maximum net quantity per outer packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td>30 g/30 mL</td>
<td>1 kg/1 L</td>
</tr>
<tr>
<td>E2</td>
<td>30 g/30 mL</td>
<td>500 g/500 mL</td>
</tr>
</tbody>
</table>
Excepted Quantities - Specimens in Preservative

TRAINING

‘Excepted Quantities’ are still Dangerous Goods when offered for transport. As such, all training requirements, including the need for biennial refresher training through RASCAL, remain in effect.
Excepted Quantities - Specimens in Preservative

SCOPE

- At effective preservative concentrations, ethanol is subject to shipping regulations, including when it is used in small volumes.
- 10% formalin (4% formaldehyde) is exempt from shipping regulations*.
- However, due to the potential for a release of even dilute solutions to disrupt shipping, the University requires adherence to specific packaging requirements.

* only shipments of 10% or more of formaldehyde (~25% formalin) are subject to DOT and IATA regulations.
Exptected Quantities - Specimens in Preservative

• Because of its status as a Dangerous Good when offered for transport (even in excepted quantities), the requirements for shipping ethanol will be presented first.

• At the end of this section there will be an explanation of which of the ethanol requirements also apply to formalin shipments.
Excepted Quantities - Specimens in Preservative (Ethanol)

• Ethanol is regulated as a dangerous good because of its inherent flammability.

• This section applies to ethanol shipments only when:
  – Inner/primary containers contain ≤ 30ml,
  – the total volume of ethanol in all containers in the package is ≤ 500ml,
  – no other hazardous material is present,
  – the specimen did not contain any infectious materials; or
  – it can be reasonably concluded that the ethanol rendered any infectious materials that may have been present noninfectious.
Excepted Quantities - Specimens in Preservative (Ethanol)

Packaging-securing the shipment

The following practices must be observed when preparing shipments of ethanol-preserved samples:

– The primary container (tube, specimen vial) must not be more than 90% full.
– Cap(s) must be positively secured with tape or wire.
– Primary containers must be cushioned to avoid breakage.
– Secondary packaging must be leak proof (zip-lock bag) and able to contain entire contents of primary container(s).
Excepted Quantities - Specimens in Preservative (Ethanol)

Packaging, (cont’d)

• Place sufficient absorbent such as spill pads between primary and secondary containers to absorb the entire contents of the primary containers.

• Materials must be chosen to avoid dangerous reactions between the packaging materials and items being shipped.

• Outer packaging must be wood, fiber board or other equally strong material.
Excepted Quantities - Specimens in Preservative (Ethanol)

Labeling - identifying the package: Attach the ‘Excepted Quantity’ Package Mark to the outer package.

* Insert: DOT Hazard Class for ethanol, “3”.

** Name and address of consignee or shipper, if not elsewhere on the package.

Minimum dimensions of marking: 4” x 4”. Must be black or red.
Excepted Quantities - Specimens in Preservative (Ethanol)

Documentation - information accompanying package

No specific shipping paper is required for ground transport. But if transported by air, the Air Waybill must include the statement, “Dangerous Goods in Excepted Quantities”.

If using FedEx, in section 6 (domestic) or section 8 (international), “Special Handling and Delivery…”, check the box that states, “Yes, Shipper’s Declaration not required”.

![Image of FedEx special handling form]
Excepted Quantities - Specimens in Preservative (Ethanol)

Package Tests

A representative complete package must be able to withstand, without loss of contents, drops from 1.8 meters on its base, top, longest and shortest sides, and a corner. It must also be able to withstand a 24 hour test applying a force equivalent to the weight of identical packages stacked to a height of 3 meters.

See end of this module for companies selling certified packaging. Or labs may perform and document such tests themselves.
Excepted Quantities - Specimens in Preservative (Formalin)

The 10% formalin solutions most commonly used for tissue preservation are not regulated by DOT or IATA. However, the corrosivity and irritation potential from a formalin release indicate the need for special shipping practices.
Excepted Quantities - Specimens in Preservative (Formalin)

To ship small amounts of formalin follow all of the previously described requirements for ethanol except:

• DO NOT use Excepted Quantity Package Mark.
• DO NOT use the “Dangerous Goods in Excepted Quantities” statement on any shipping documents.
• If using FedEx, DO NOT make any statements indicating the presence of Dangerous Goods.
• DO package material as described to ensure that contents arrive at their destination intact.
SUPPLIES

The following companies market packaging materials for the safe and legal transport of diagnostic specimens. This list is strictly informational; inclusion does not constitute an endorsement or recommendation by Columbia University.

SAF-T-PAK*  
800-814-7484  
http://www.saftpak.com

Therapak Corp.  
888-505-7377  
http://therapak.com

HazMatPak  
800-347-7879  
http://www.hazmatpac.com

Inmark  
800-646-6275  
http://www.inmarkinc.com

EXAKT Technol.  
800-923-9123  
http://exaktpak.com

Polyfoam Packers Corp.  
888-765-9362  
http://www.polyfoam.com

Source Packaging of New England  
800-200-0366  
http://sourcepak.com

Air Sea Atlanta  
404-351-8600  
http://airseaatlanta.com

All-Pak Inc.  
800-245-2283  
http://all-pak.com

*This vendor has been a particularly reliable contact for CU EH&S and others