

Packaging and Shipping of UN 3373, Biological Substances

Satellite Conference and Live Webcast

Thursday, December 7, 2006

1:00 - 3:00 p.m. (Central Time)

Produced by the Alabama Department of Public Health
Video Communications and Distance Learning Division

Faculty

Patricia Payne, PhD, MT (ASCP)

Consultant, Alabama Public Health

Laboratory

Consultant, JBM Associates

Lexington, Kentucky

Program Objectives

- **Classify, mark and label UN 3373 Biological Substances properly for transport to the State Lab in the Alabama County Health Department courier system.**
- **Outline DOT training requirements for packaging and shipping UN 3373 Biological Substances.**

Program Objectives

- **Outline the responsibilities of the shipper and the shipper's employer regarding training, record keeping, and the handling of specimens.**

Regulatory Agencies

- **Department of Transportation (DOT)**
 - **49 CFR Part 171-178**
 - **Hazardous Materials Regulations (HMR)**



Other Agencies



Who is a HazMat Employee?

- Packages hazmat (e.g. labels/marks)
 - Division 6.2 materials
 - Dry ice (transported by air or vessel)
- Prepares materials or documentation.
 - Classifies
 - Documents package contents
 - Shipping declaration forms
 - Air waybills, etc.

Who is a HazMat Employee?

- Transports hazmat
 - Motor vehicle
 - Air carrier
 - Vessel

Training Requirements

- Category B infectious substances.
- Each person who offers or transports a Category B infectious substance must know about the requirements of this section (§173.199).
 - No formal training requirement.
 - No testing requirement.
 - No documentation requirement.

Training Requirements

- Precaution!
- Accrediting agencies
 - College of American Pathologists (CAP)
 - Joint Commission on Accreditation of Healthcare Organizations (JACHO)
- OSHA requirements
 - Safety training
 - Emergency response protocols

Shipper's Responsibilities

- Identify
- Classify
- Pack
- Mark
- Label
- Document

Identify

What is a hazardous material?

Hazardous Materials

- Class 1: Explosives
- Class 2: Gases
- Class 3: Flammable Liquids
- Class 4: Flammable Solids
- Class 5: Oxidizers/Organic Peroxides
- Class 6: Toxic and Infectious Substances

Hazardous Materials

- Class 7: Radioactive Material
- Class 8: Corrosives
- Class 9: Miscellaneous Hazardous Material
 - (includes Dry Ice)

Hazard Class 6

- Class 6: Toxic and Infectious Substances.
 - Division 6.1 – Poisonous Material
 - Division 6.2 – Infectious Substance

Division 6.2 Classification



Division 6.2

- Two general categories
 - Category A
 - Category B

Definition: Infectious Substances

- A material known or reasonably expected to contain a pathogen.... which cause disease in humans or animals.
 - Category A or Category B

Definition: Patient Specimen

- Human or animal materials collected directly from humans or animals and transported for diagnosis.
- Specimens in transport media
 - Transwabs
 - Culture media
 - Blood culture bottles

Definition: Cultures

- An infectious substance containing a pathogen that is intentionally propagated. This definition does not include human or animal patient specimens.

Not Regulated as Division 6.2, if

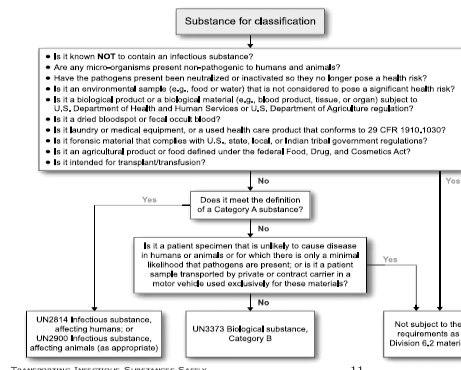
- Dried specimens
 - Blood spots
 - Feces (occult blood testing)



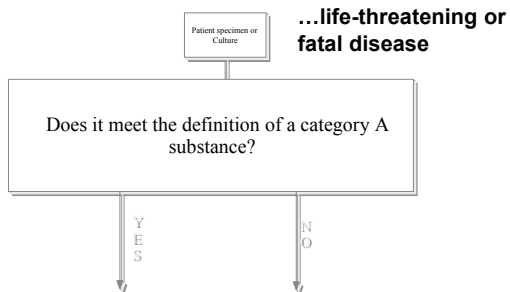
Non-regulated Blood or OPIM



DOT: Classification Reference



Category A Infectious Substance



Category A

- Indicative examples:
 - Patient specimens containing or suspected of containing pathogens that include:
 - Ebola virus
 - Hantaan virus
 - Monkeypox
 - Variola virus

Category A

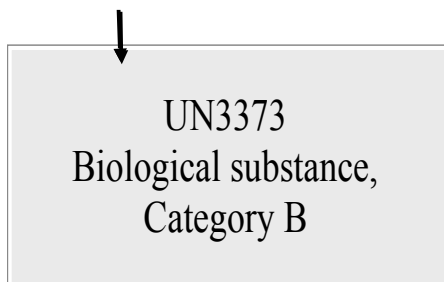
- Indicative examples:
 - Cultures known or suspected to be:
 - *M. tuberculosis*
 - *Francisella tularensis*
 - Verotoxigenic *E. coli*
 - *Bacillus anthracis*
 - *Brucella abortus*
 - *Brucella melitensis*
 - *Brucella suis*
 - *Yersinia pestis*

Not Category A

- Is it a patient specimen or a culture?

Category B

Cultures



Not Category A

- Patient specimens
 - Minimal likelihood to contain pathogens?
 - Use professional judgment
 - Access to patient information
 - HIPPA

Not Category A

- Patient specimens
 - Transported in “exclusive use” vehicle

Is it a patient specimen that is unlikely to cause disease in humans or animals or for which there is only a minimal likelihood that pathogens are present; or is it a patient sample transported by private or contract carrier in a motor vehicle used exclusively for these materials?

UN3373
Biological substance,
Category B

Non-regulated Precaution!

- Provides relief from transportation regulations
 - Not necessarily from any other regulations



Pack, Mark, Label

Category B Infectious Substances

Category B Infectious Substances

- Triple packaging
 - Category B



Primary Receptacle

- Leakproof or siftproof
- Absorbent (liquid)
- Cushioning
 - Multiple receptacles
 - Fragile receptacles

Secondary Packaging

- Contains
 - Primary receptacle
 - Cushioning
 - Absorbent
- Leakproof or siftproof

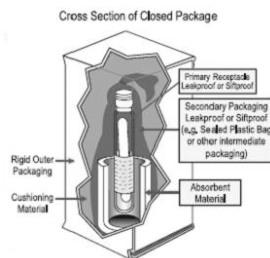
OSHA Labeling Requirement

- Blood and OPIM
 - Either
 - Primary receptacle
 - Or secondary packaging

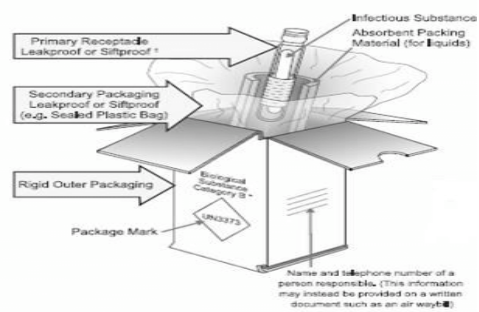


Outer Packaging

- Rigid
- Adequate size
 - 3.9 in x 3.9 in.
- Capable of drop test
 - 4 feet



Category B



§ 173.199 Category B Miscellaneous Information

- Follow package instructions
- Providers
 - Maintain copies
 - 1 year (minimum)

Packaging Reuse

- Reuse if no leakage during previous transport
- Disinfect following leakage
 - Secondary
 - Outer packaging

General Labeling Requirements

- Remove irrelevant labels and markings.
- Place labels and marking on one surface.
- Place proper shipping name adjacent to UN3373 marking.

Transport by Motor Vehicle

Exceptions: Infectious Substance

- Apply only to patients specimens.
- Apply only to category B infectious substances.

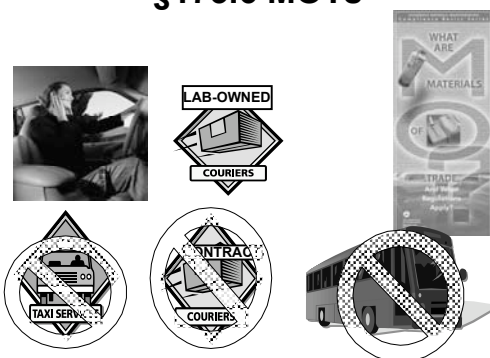
DOT: Category B Exception

- Patient specimens
 - Transported in “exclusive use” vehicle

Alabama Department of Public Health

- Regulated patient specimens
 - Not category A infectious substance
 - Package / mark / label as Category B

\$173.6 MOTs



§173.6 MOTs

- Apply only to patients specimens.
- Apply only to Category B infectious substances.

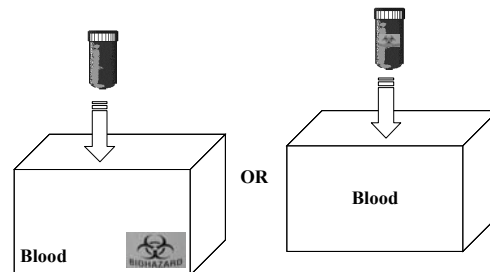
§173.6 MOTs

- Combination packaging
 - Inner packaging
 - Leakproof (liquids)
 - Strong, tight outer packaging
 - Absorbent (liquids)
 - Securely closed
 - Secured against movement

§173.6 MOTs

- Quantity Limits
 - Per package
 - Per motor vehicle
 - ≤ 200 kg (440 lb)

MOTs : Package Markings



§173.134 vs. MOTs

- Consider
 - Employer guidelines
 - Recipient lab policy
- ADPH employees
 - Must package as Category B

§173.134 vs. MOTs

- Consider
 - Frequency of use
 - Routine transport
 - Emergency situations
 - Public health threats
 - Public perception

Summary

- **ADPH employees**
 - **Category B infectious substances (patient specimens)**
 - **Package and mark as Category B**
 - **Follow OSHA labeling requirements for transport**

Summary

- **Non-ADPH shippers and couriers**
 - **Category B infectious substances (patient specimens and cultures)**
 - **Package and mark as Category B**
 - **Utilize DOT exception**
 - **Consider end recipient**

Precaution!

- **Compliance based on**
 - **Regulations**
 - **Not training materials**
- **Regulations are subject to change**
 - **Check periodically**
 - **Incorporate changes into protocols**

Upcoming Programs

**The Chronic Disease
Self-Management Program:
Why You Should Adopt This Program
Tuesday, January 9, 2006
12:00 - 2:30 p.m. (Central Time)**

**For complete list of upcoming
programs visit: www.adph.org/alphtn**