

2006 Regulatory Updates: Packaging and Shipping Patient Specimens *and* Cultures

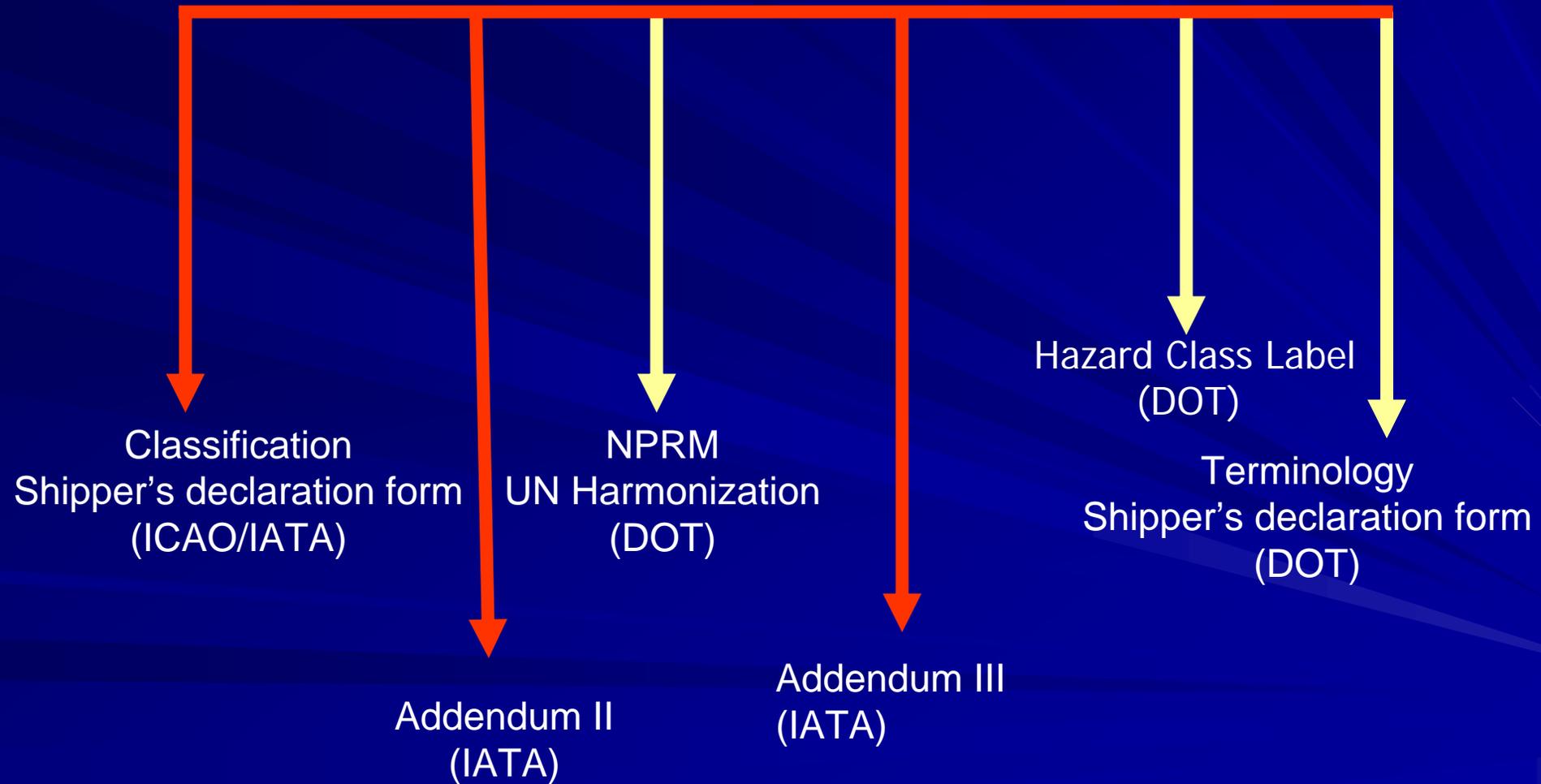
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Training & Curriculum Services Division
Office of Workforce and Career Development
Centers for Disease Control & Prevention

Harmonization



2005

2006



Infectious Substance Label



Label with "404" CDC number expired 10/1/05

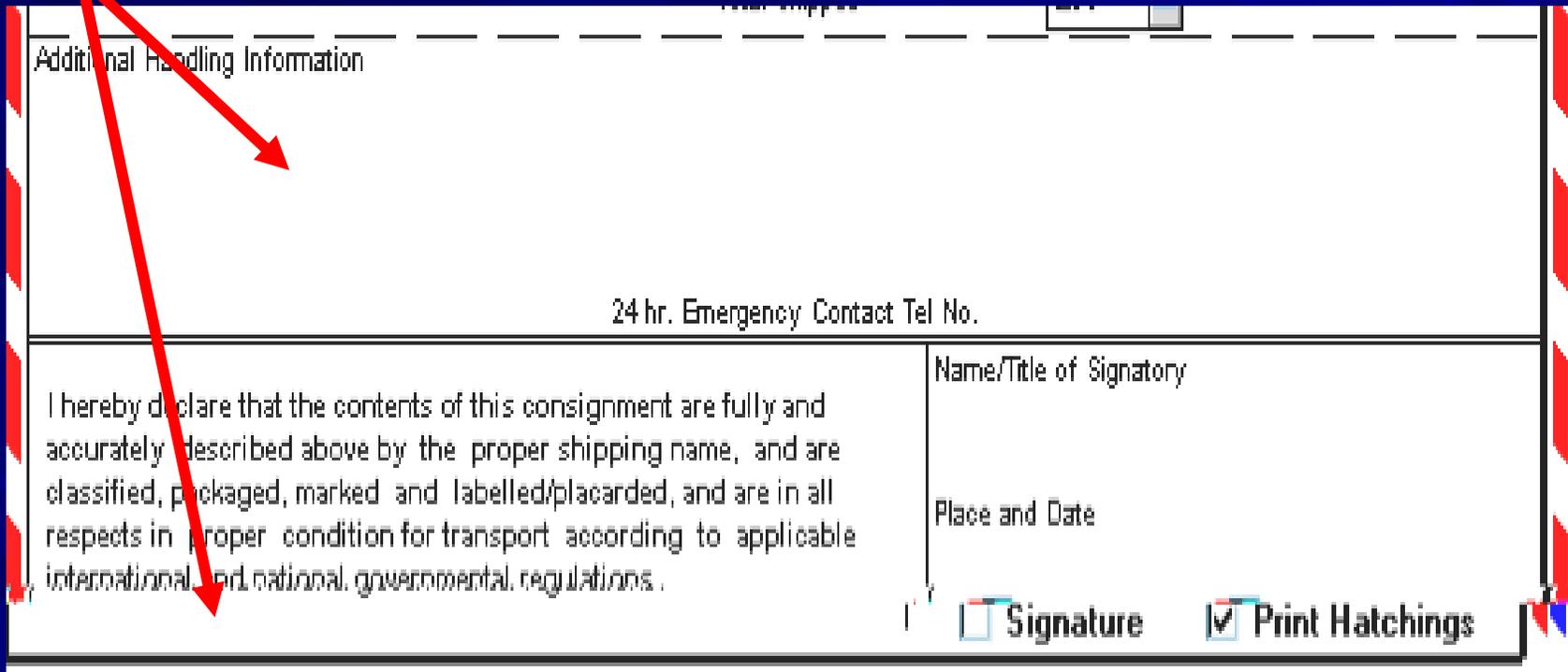
2005: DOT and IATA

- Format Change (effective Jan 1, 2007)
- Certification (2005)

NATURE AND QUANTITY OF DANGEROUS GOODS						
Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and Type of Packing	Packing Instructions	Authorization
Additional Handling Information						
Emergency Telephone Number						
I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to the applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.				Name/Title of Signatory		
				Place and Date		
				Signature <i>(see warning above)</i>		

Shipper's Certification

Add *"I declare that all of the applicable air transportation requirements have been met"* to older forms at one of two places



The diagram shows a shipping form with a red and white striped border. A red arrow points from the text above to the 'Additional Handling Information' section. The form is divided into several sections:

- Additional Handling Information:** A large empty box at the top.
- 24 hr. Emergency Contact Tel No.:** A section below the first one.
- Declaration:** A section containing the text: "I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international, and national, governmental regulations."
- Name/Title of Signatory:** A section to the right of the declaration.
- Place and Date:** A section below the signatory name.
- Signature:** A section with an unchecked checkbox.
- Print Hatchings:** A section with a checked checkbox.

2006: Shipper's Declaration

■ Retention (effective 1/09/06)

– Hazardous materials

■ Shipper

– Two years

■ Carrier

– One year

– Hazardous waste

■ Three years

– Shipper

– Carrier

Shipper's declarations: Book

DECLARATION FOR DANGEROUS GOODS
1. PAYE

2006: DOT Terminology

■ *Special permit*

- Replaces *exemption*
 - In most HMR appearances
- Notations and Markings
 - Packagings and shipping papers
 - Use DOT-SP (previously DOT-E)
- Valid for up to two years

IATA 3.6.2 Classification

- January 1, 2005 *Dangerous Goods Regulations*
 - Remove classification according to risk groups
 - Classify according to risk in transport
- March 22, 2005: Addendum II
 - New proper shipping name
 - Additional non-regulated materials
- July 5, 2005: Addendum III
 - Exemptions
 - Definitions

2005: IATA Addendum II

- Biological substance, category B
 - PSN for UN3373
- Advance notice
 - Will replace *diagnostic specimen & clinical specimen* (as of 1 January, 2007)



◇ Biological substance
Category B

◇ Clinical specimen

◇ Diagnostic specimen

2005: IATA Addendum III

■ Exemptions

- *Dried blood spots*
 - Absorbent material
- Fecal occult blood screening tests



2005: IATA Addendum III

■ Definitions

– Patient specimen (3.6.2.1.4)

- Those collected directly from humans or animals, including, but not limited to excreta, secreta, blood and its components....

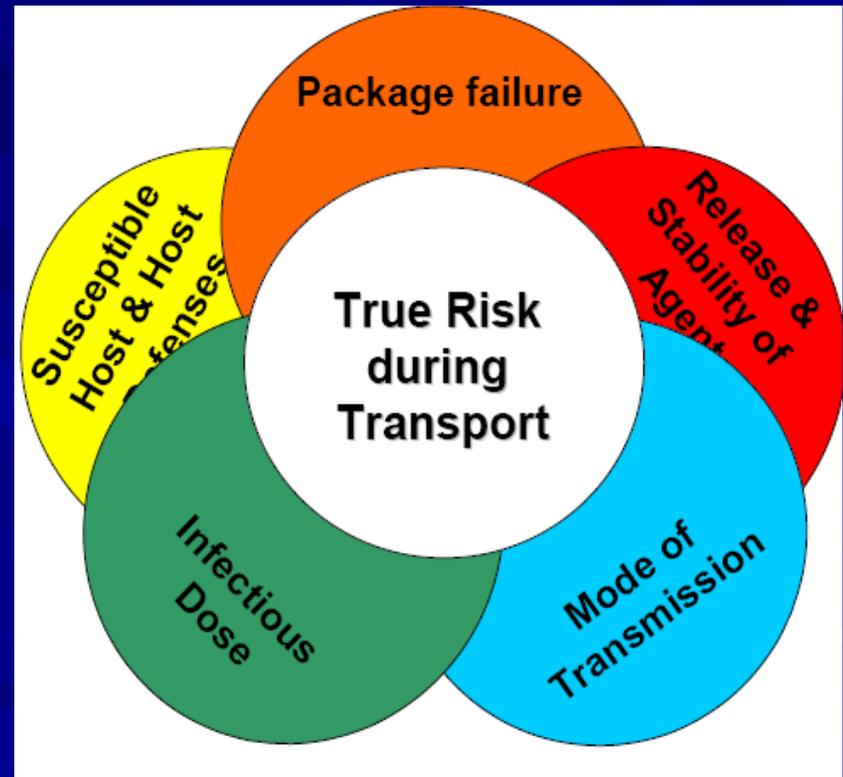
– Culture (3.6.2.1.3)

- Are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens

2005: Division 6.2

■ Clarify risks during *transport*

- Presence of infectious material
 - Intrinsic characteristics of agent
 - Effect of state of microorganism on risk
- Integrity of packaging
- Release of infectious material
- Exposure to infectious material
- Entry route



Division 6.2: Intrinsic Hazards

- Examine each agent
 - Pathogenicity
 - Route of infection
 - Infectious dose
 - 10 or 100,000

Disease or agent	Route	Dose
Q fever	inhalation	1-10
<u>Tuberculosis</u>	inhalation	<u>10</u>
Typhus	intradermal	3
<u>Anthrax</u>	inhalation	<u>1300</u>
Malaria	intravenous	10
Shigella flexneri	ingestion	180
Typhoid	ingestion	10 ⁵
Cholera	ingestion	10 ⁸
Measles	Intranasal spray	0.2
VEE	subcutaneous	1

Transportation Risks

- Exposure
 - Package failure
 - Contact with host
- Host susceptibility
 - Level of immunity
 - Vaccinations
 - Previous infections
 - Route of entry and host innate defenses
 - Tears and saliva
 - Mucus
 - Cilia
 - Stomach acids
 - Phagocytes

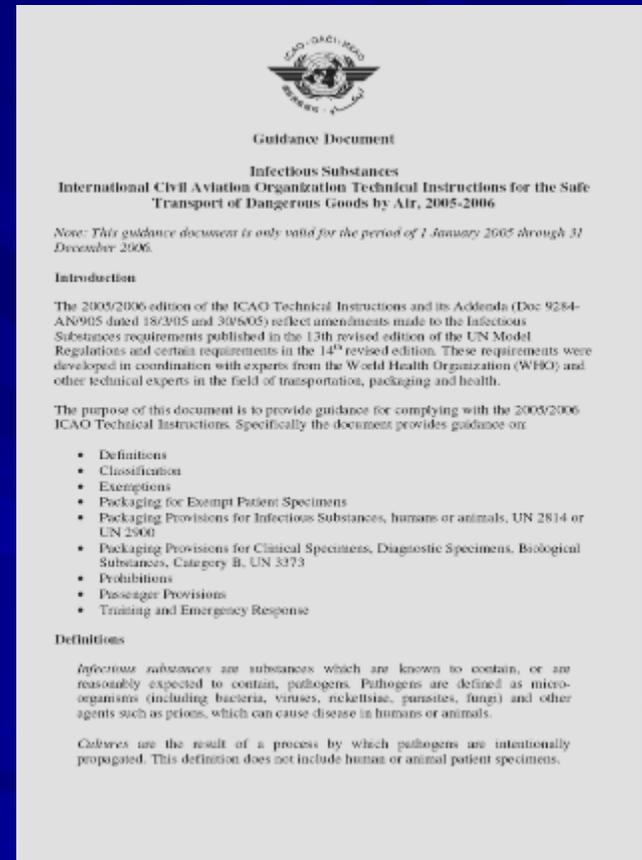


End Result

- Two general categories
 - Category A
 - Category B
- Exempted substances
 - Negligible risk

ICAO Guidance Document

- Valid through 12/31/06
 - Guidance for Division 6.2 materials, including
 - Definitions
 - Classification
 - Scenarios
 - Flowchart
 - Exemptions
 - Packaging
 - UN2814
 - UN2900
 - UN3373
 - Exempt human specimens



ICAO Classification (con't)

Patient specimen
or culture

Have any pathogens present been neutralized/inactivated?

Is it known not to contain infectious substances?

Are **all** micro-organisms present non-pathogenic for humans/animals?

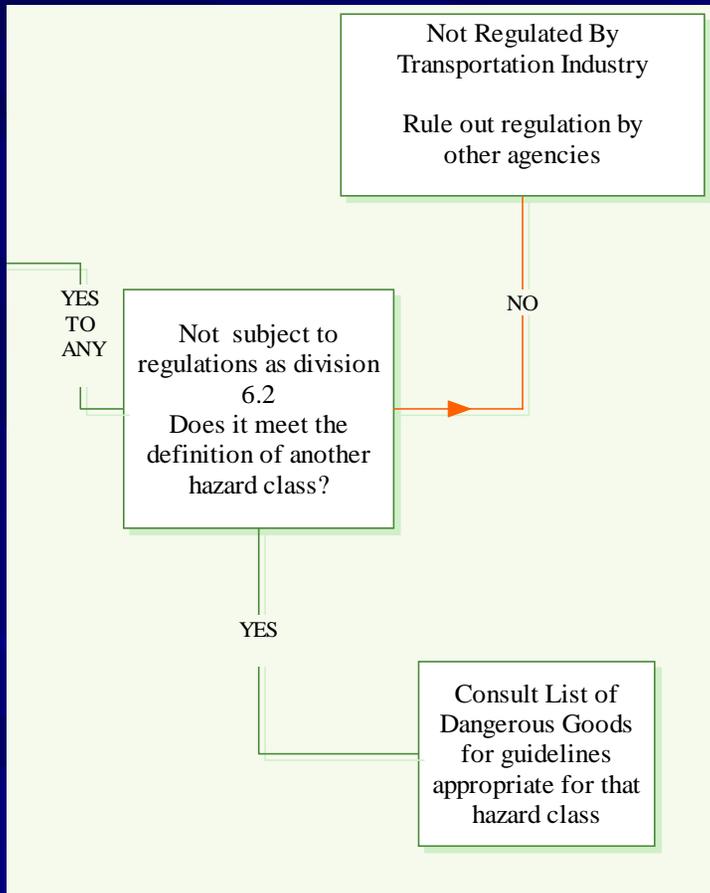
Is it dried bloodspot/faecal occult blood?

Is it an environmental sample e.g. food and water that is not considered to pose a significant health risk?

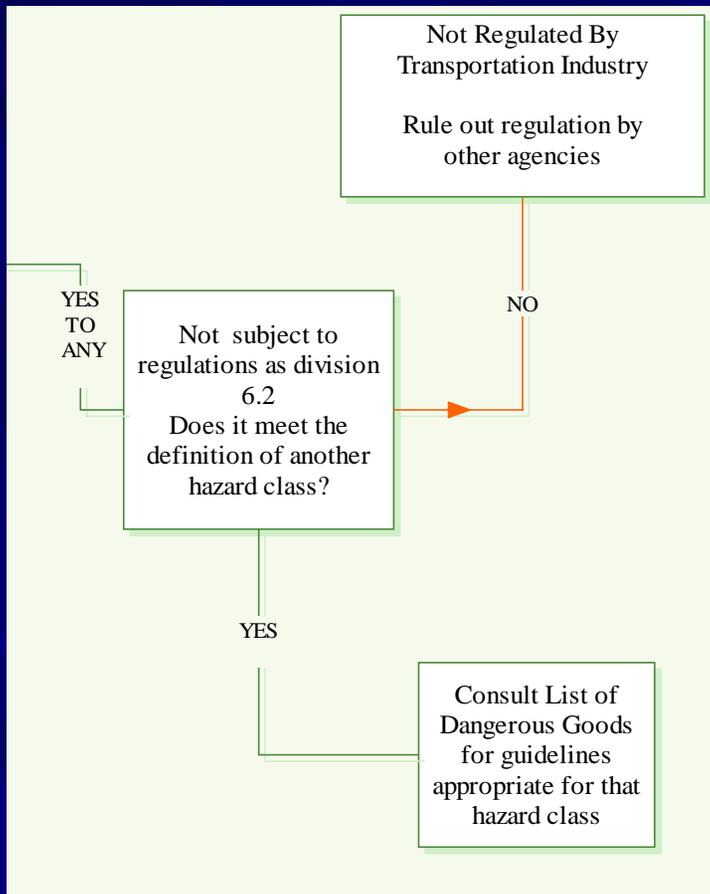
Is it for transplant/transfusion?



ICAO Classification (con't)



ICAO Classification (con't)



ICAO Classification (con't)

Have any pathogens present been neutralized/inactivated?

Is it known not to contain infectious substances?

Are **all** micro-organisms present non-pathogenic for humans/animals?

Is it dried bloodspot/faecal occult blood?

Is it an environmental sample e.g. food and water that is not considered to pose a significant health risk?

Is it for transplant/transfusion?

NO



Does it meet the definition of a Category A substance?

Regulated Materials

- Does it meet the definition of a Category A substance?



Exposure

May Lead To



Permanent disability, life-threatening or fatal disease

Category A

- Indicative examples:
 - Cultures or patient specimens containing or suspected of containing pathogens that include:
 - Ebola virus
 - Variola virus
 - Monkeypox
 - Cultures *only* of some microorganisms, including:
 - *Francisella tularensis*
 - *Coccidioides immitis*
 - *Mycobacterium tuberculosis*
 - Rabies
 - West Nile Virus

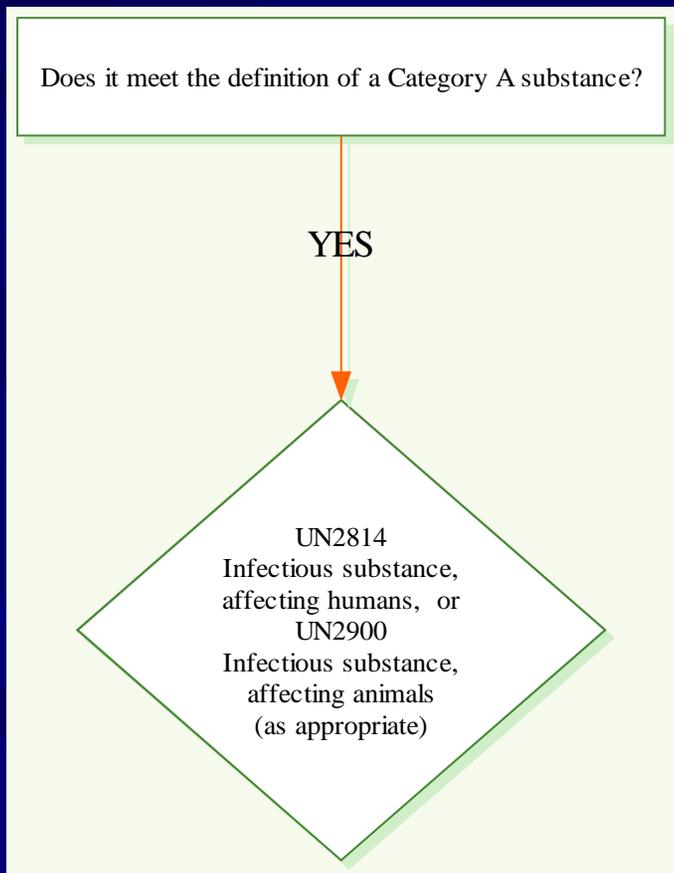


Category A

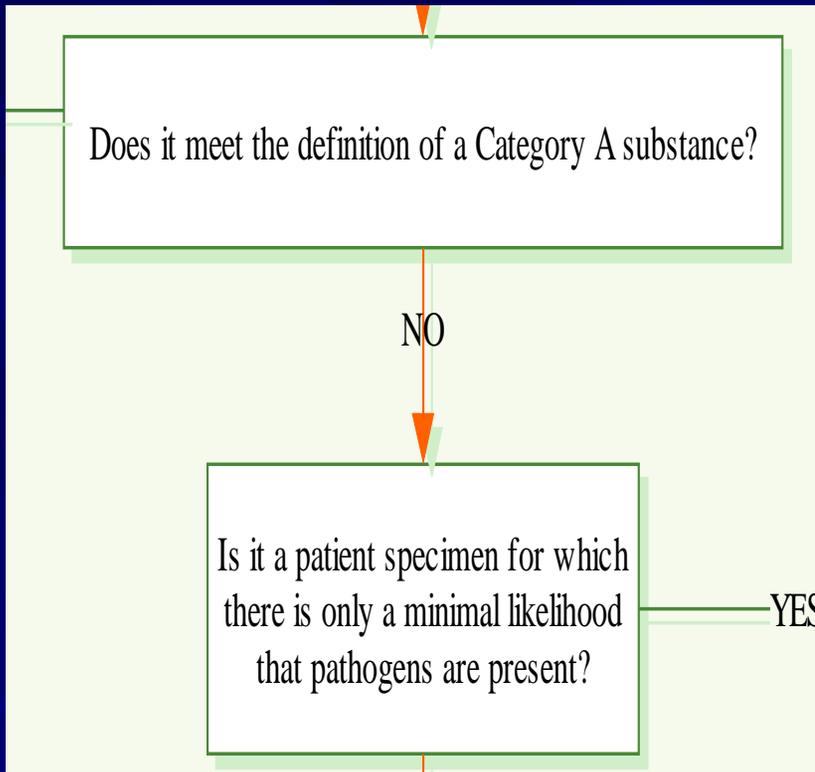
- Considerations
 - New or emerging pathogens meeting Category A criteria
 - Professional doubt about pathogenic criteria



ICAO Classification (con't)



Not Category A



- Use professional judgment
 - Known medical history
 - Symptoms
 - Individual circumstances of the source
 - Endemic local conditions
- Consult list of examples
 - ICAO Guidance Document
 - IATA 3.6.2.2.3.6

Exempt Specimens

- *Exempt human or animal specimens include*
 - Samples transported for the purpose of:
 - Testing for non-infectious substances
 - Therapeutic drug monitoring
 - Samples sent for tests conducted for insurance or employment purposes *and* are intended to determine the presence of drugs or alcohol
 - Pregnancy tests
 - Biopsies to detect cancer

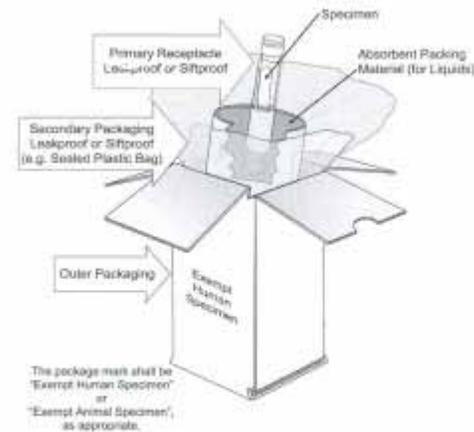


Exempt human specimens

Is it a patient specimen for which there is only a minimal likelihood that pathogens are present?

YES

Subject to "exempt human (or animal) specimen" provisions

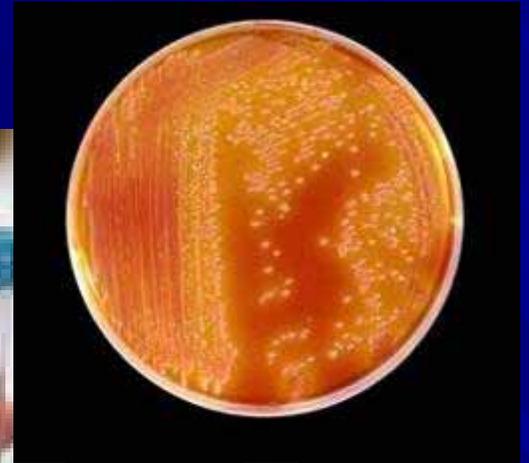


Category B

Is it a patient specimen for which there is only a minimal likelihood that pathogens are present?

NO

UN3373
Biological
substance,
category B

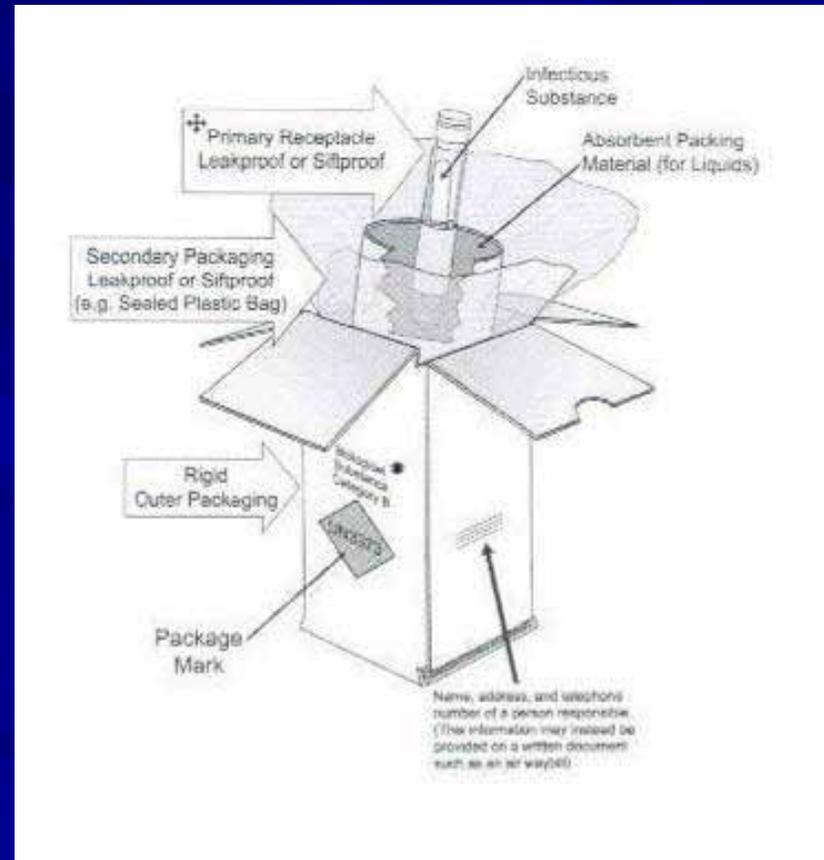


Category B

Is it a patient specimen for which there is only a minimal likelihood that pathogens are present?

NO

UN3373
Biological
substance,
category B



Classification Scenarios

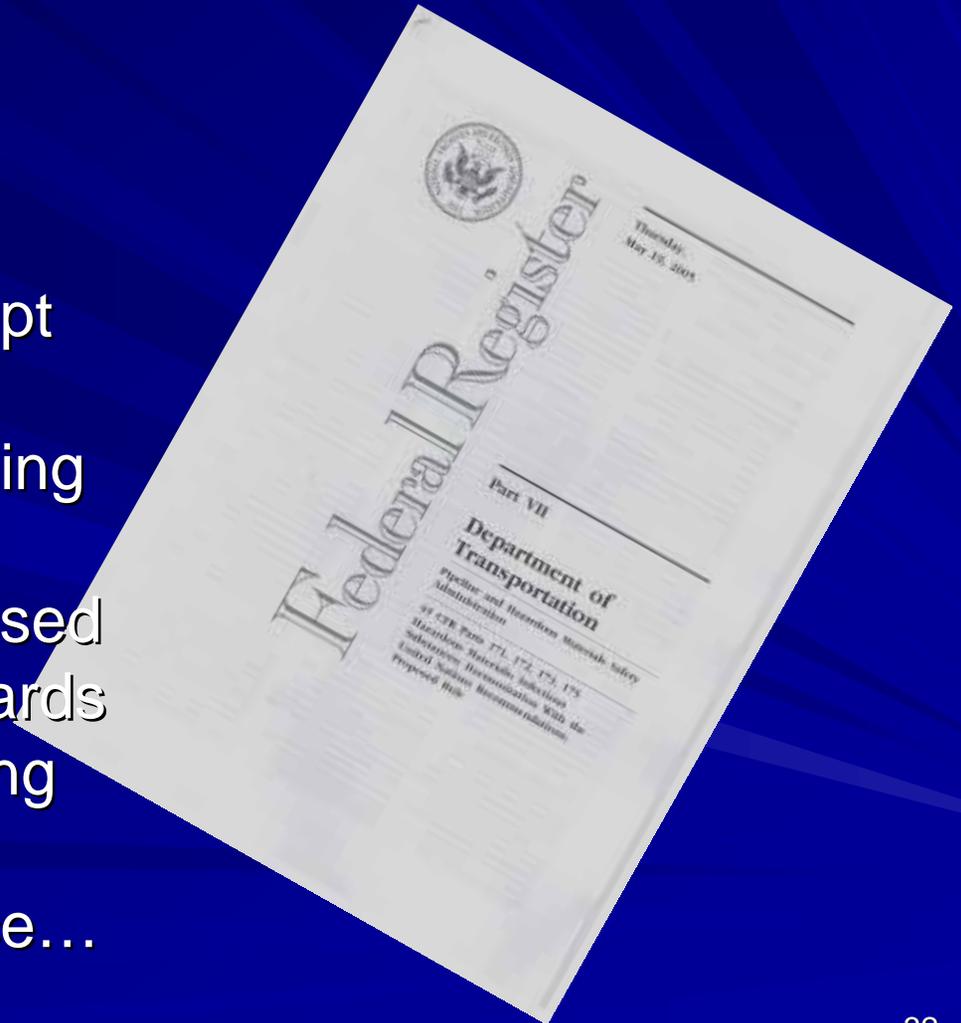
- Blood known or reasonably expected to contain:
 - Ebola virus
 - Hepatitis B
 - HIV
- Culture
 - *Mycobacterium tuberculosis*
 - *Mycobacterium bovis* (Bovine tuberculosis)
 - Influenza virus
 - Foot and mouth disease virus

DOT Classification

■ NPRM (5/19/05)

– SUMMARY:

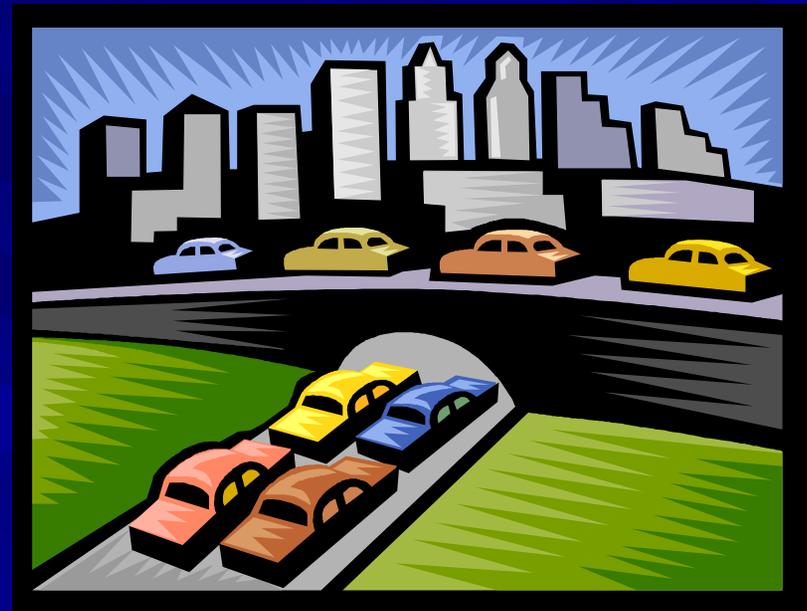
...proposing to adopt new classification criteria and packaging requirements consistent with revised international standards and to clarify existing requirements to promote compliance...



DOT Proposed Rulemaking

■ NPRM HM-226 A

- Category A and Category B classification
- Patient specimens likely to contain non-Category A pathogens
 - MOTs
 - § 173.134 exceptions
- *Patient specimens* unlikely to have pathogens
 - Not regulated



Other Expected Changes: 2006



UNITED STATES
POSTAL SERVICE

Hazardous, Restricted, and Perishable Mail
Publication 52

July 1999
Transmittal Letter

- A. **Filing Instructions.** This issue of Publication 52 replaces the April 1980 edition, which must be recycled.
- B. **Explanation.** This publication is revised in accordance with current standards in Domestic Mail Manual (DMM) 2000-2004. It is designed for use by postal employees as a resource for entry, label, and marking and also involved in providing mailing information to postal customers regarding hazardous materials, restricted matter, and perishable matter.
- C. **Distribution.** Order copies from the national distribution center (MDC) using PS Form 7390, MDC Supply Registration.
- D. **Comments and Questions.** Direct comments or questions concerning the content of Publication 52 to:
MANAGER
SHIPPING MAIL ACCEPTANCE
SIC POSTAL SERVICE
475 E. DENTON ST. SW. WASHINGTON
WASHINGTON, DC 20009-6904
- E. **Effective Date.** This edition of Publication 52 is effective July 1999.

Aida J. Escobedo
Vice President
Marketing Systems

49 CFR HAZARDOUS MATERIALS
Parts 100-185

BLOOD

Transportation of Hazardous Materials
Specialized

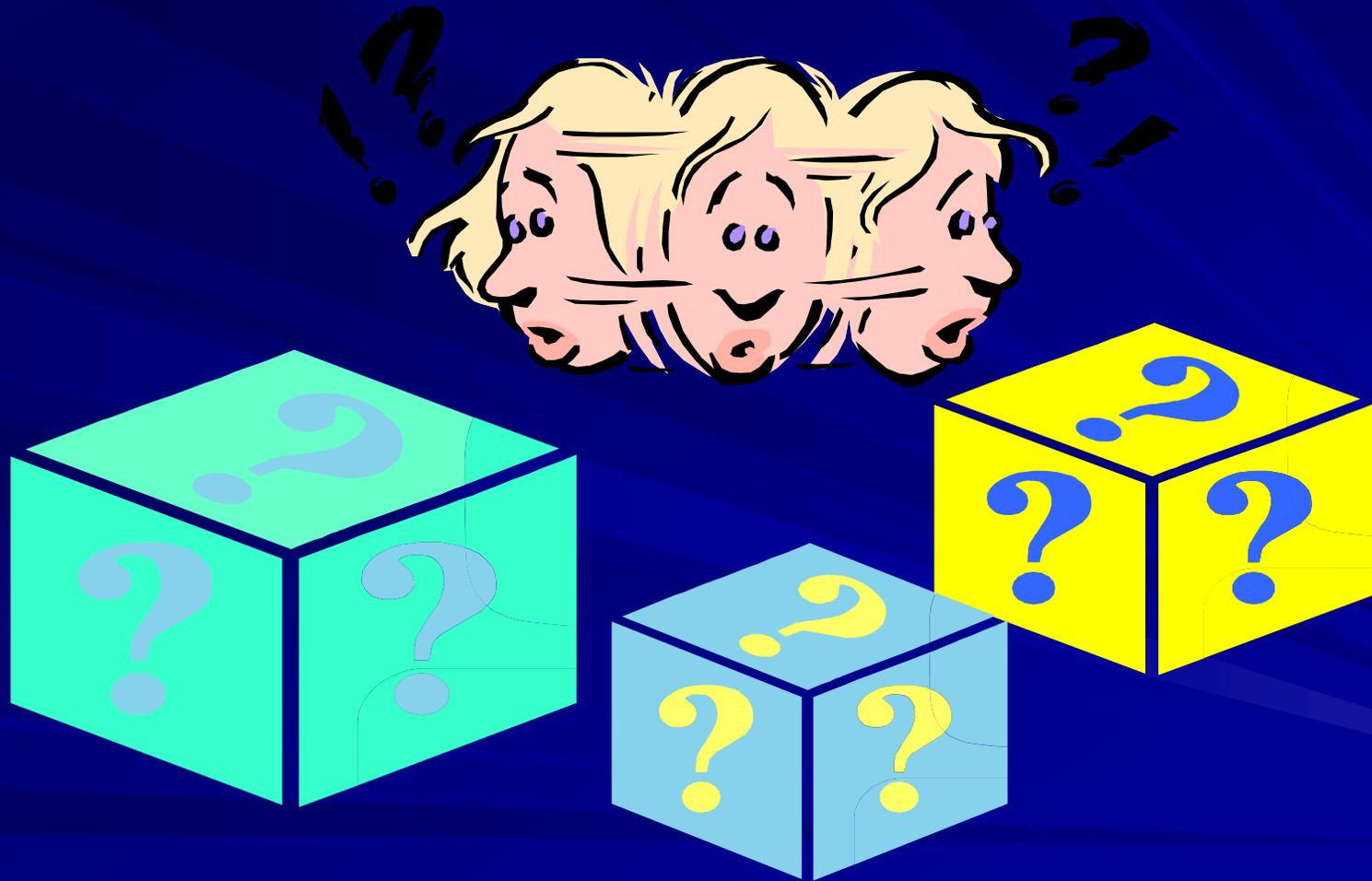
Infectious Substances

EMERGENCY RESPONSE
GUIDEBOOK

Doc 9284
AM/905

Technical Manual
for the Safe Handling of
Dangerous Materials

Questions?



2006 Regulatory Update
Packaging and Shipping
Patient Specimens and Cultures

For Individual Registration, Evaluation Form
and CEU Certificate

go to: www.cdc.gov/phtnonline

Course verification code = **PACKAGE**

Complete Process by: **March 23, 2006**

Request CA and FL CEU's on the evaluation. A FI licensure number is required. CA certificates will be sent in six- eight weeks after program. FI CEU credits will be submitted to CE Broker.