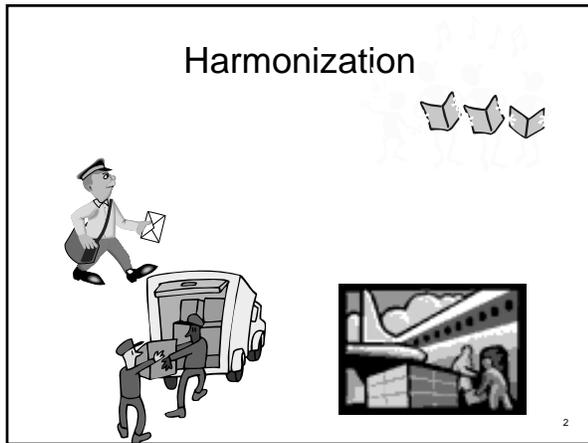


2006 Regulatory Updates: Packaging and Shipping Patient Specimens and Cultures

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

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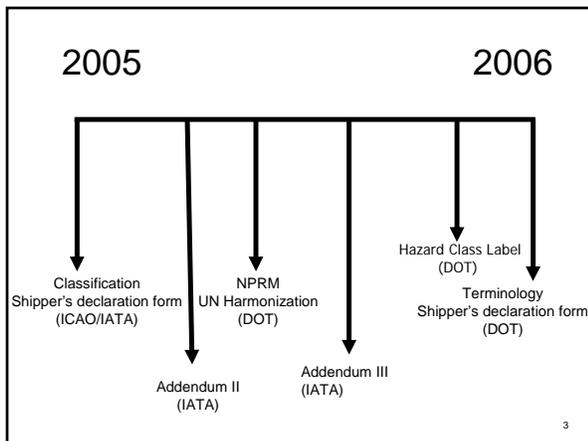
Harmonization



2

2005

2006



3

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 (Division 6.1)	Packing Group	Quantity and Type of Packaging	Packing Instruction	Authentication

Additional Handling Information

Emergency Telephone Numbers

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 labeled/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 (or stamp)

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

Additional Handling Information

24 hr. Emergency Contact Tel No. 800/451-8346

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 labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

Name/Title of Signatory
Place and Date
 Signature Print Hatchings

2006: Shipper's Declaration

■ Retention (effective 1/09/06)

– Hazardous materials

- Shipper
 - Two years
- Carrier
 - One year

– Hazardous waste

- Three years
 - Shipper
 - Carrier



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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

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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

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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

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2005: IATA Addendum III

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



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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, secret, 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

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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



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Division 6.2: Intrinsic Hazards

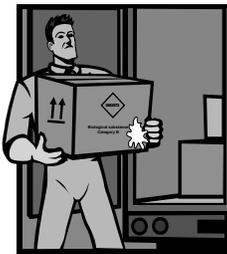
- Examine each agent
 - Pathogenicity
 - Route of infection
 - Infectious dose
 - 10 or 100,000

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

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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



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End Result

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

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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



http://www.icao.int/icao/net/dcs/9284/guidance_doc_infectious_substances.pdf

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ICAO Classification (con't)

Print 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?

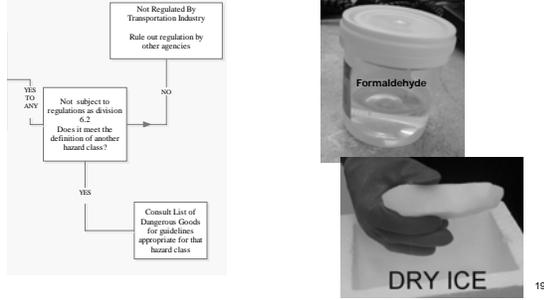
Is it an environmental sample e.g. food and water that is not considered to pose a significant health risk?

Is it for transplant/transfusion?

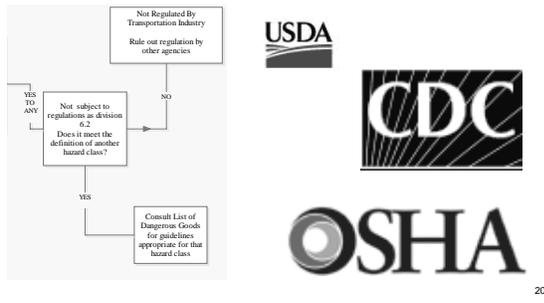


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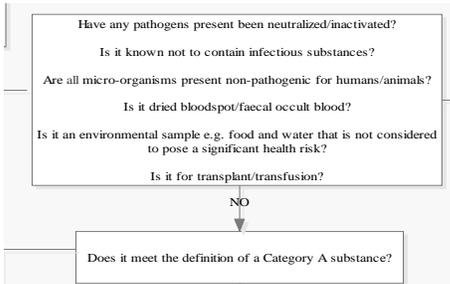
ICAO Classification (con't)



ICAO Classification (con't)



ICAO Classification (con't)



Regulated Materials

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



Exposure

May Lead To



Permanent disability, life-threatening or fatal disease

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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



IATA Table 3.6 D (DGR, 47th Edition)

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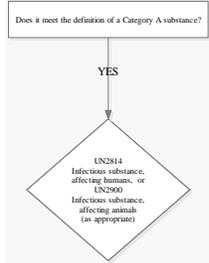
Category A

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



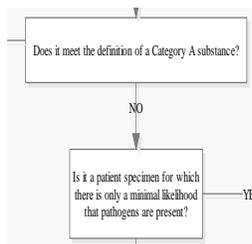
24

ICAO Classification (con't)



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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

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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



IATA 3.6.2.2.3.6

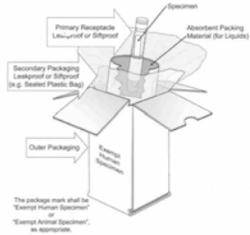
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Exempt human specimens

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



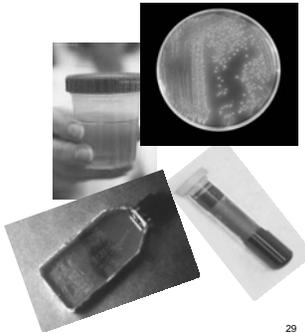
ICAO Guidance Document
Annex 3

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



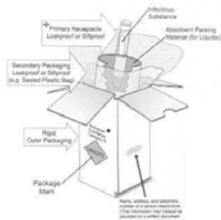
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Category B

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

NO

UN3373
Biological substance,
category B



ICAO Guidance Document
Annex 5

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Classification Scenarios

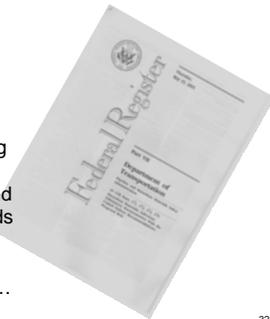
- Blood known or reasonably expected to contain:
 - Ebola virus
 - Hepatitis B
 - HIV
- Culture
 - *Mycobacterium tuberculosis*
 - *Mycobacterium bovis* (Bovine tuberculosis)
 - Influenza virus
 - Foot and mouth disease virus

2005-2006 ICAO Classification
Document Annex 1

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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...



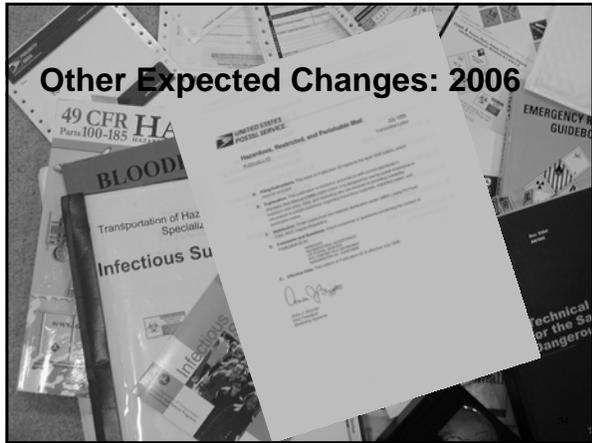
32

DOT Proposed Rulemaking

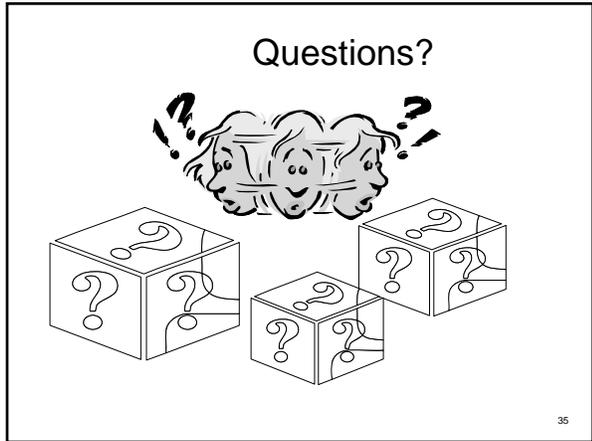
- NPRM HM-226 A
 - Category A and Category B classification
 - Patient specimens likely to contain non-Category A pathogens
 - MOTs
 - § 173.134 exceptions
 - *Patient specimens* unlikely to have pathogens
 - Not regulated



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Other Expected Changes: 2006



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.
