

# New 2005 Dangerous Goods Shipping Regulations

Focusing on the changes pertaining to  
biological materials  
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# Regulatory Bodies

## United States Department of Transportation (US DOT)

- 49 CFR Parts 100 to 185

## International Civil Aviation Organization (ICAO)

- Publishes a yearly set of Dangerous Goods Regulations for shipments transported by air
  - International Air Transport Association (IATA)

- UN Sub-Committee of Experts

# New Classification System for 2005

- Old classification system used WHO risk groups to classify biological material as infectious or diagnostic
  - Risk Groups 1-4, with 4 being the highest risk
- New system breaks biological materials into two categories
  - Category A , Infectious Substances
  - Category B , Infectious Substances

# Category A, Infectious Substances

- Category A Infectious Substances are defined but a list of serious human or animal substances that cause disease in humans or animals, and this list is assigned to UN 2814. A separate list of agents that cause serious disease in animals only is assigned to UN 2900
- Category A, 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

# Packaging Requirements for Category A, Infectious Substances

- Packing Instruction 602 (ICAO/IATA)
- 49 CFR §173.196 (US DOT)

# Packaging Requirements for Infectious Substances, Category A

- Tertiary system (3 components)
  - Primary receptacle
  - Secondary packaging
  - Rigid outer packaging
- Additional requirements for liquid Infectious Substances, Category A
  - Absorbent material between primary receptacle and secondary packaging
  - Internal pressure differential requirements (95 kPa / 14 psi) for liquid Infectious Substances, Category A

# Packaging Requirements for Category A, Infectious Substances

- Drop tests
  - 30 ft. / 9 m & Penetration test (15 lb. steel rod)
- Quantity Limitations (Air)
  - Liquid Infectious Substances, Category A
    - 50 mL per outer packaging – Passenger & Cargo Aircraft
    - 4 L per outer packaging – Cargo Aircraft Only
  - Solid Infectious Substances, Category A
    - 50 g per outer packaging – Passenger & Cargo Aircraft
    - 4 Kg per outer packaging – Cargo Aircraft Only

# Marking Requirements for Category A, Infectious Substances

- UN 2814 or UN 2900





# Category B, Infectious Substances

- This is the category previously known as Diagnostic Specimens
- Any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being shipped for diagnostic or investigational purposes, but excluding live infected humans or animals
- Includes cultures, such as swabs, that are collected for diagnosis
- Infectious Substances which do not meet the criteria for inclusion in Category A

# Category B, Infectious Substances

- Assigned to UN 3373
- Proper Shipping Name
  - Diagnostic Specimens
  - Clinical Specimens
  - Biological Substance, Category B
    - Note – the use of the proper shipping names Diagnostic Specimens and Clinical Specimens will no longer be permitted as of January 2007

# Packaging Requirements for Category B, Infectious Substances

- Packing Instruction 650 (ICAO/IATA)
- 49 CFR §173.199 (US DOT)

# Packaging Requirements for Category B, Infectious Substances

- Tertiary system (3 components)
  - Primary receptacle
  - Secondary packaging
  - Rigid outer packaging
- Additional requirements for liquid Category B, Infectious Substances
  - Absorbent material between primary receptacle and secondary packaging
  - Internal pressure differential requirements (95 kPa / 14 psi) for liquid Infectious Substances, Category B

# Packaging Requirements for Category B, Infectious Substances

- Drop test
  - 4 ft. / 1.2 m
- Quantity Limitations
  - Liquid Category B, Infectious Substances
    - 500 mL per primary receptacle / 4 L per outer packaging
  - Solid Category B, Infectious Substances
    - 400 g per primary receptacle / 4 Kg per outer packaging

# Marking Requirements for Category B, Infectious Substances

- New for 2005
- UN 3373 label – set on point
- Minimum dimension is 50mm x 50mm



# Key Changes Looming for 2007

- As previously mentioned – the proper shipping name for UN 3373 will be revised to read “ Biological Substance, Category B
- Exception from the infectious substance provisions for “ Patient Specimens” as long as they are transported in packaging “that will prevent leakage” and is marked “Exempt human specimen” or “Exempt animal specimen”

# Key Changes Looming for 2007

A **patient specimen** is defined as

human or animal materials, 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, and disease treatment and prevention



# Key Changes Looming for 2007

The proposal to have an “exception” for “patient specimens” is not listed as a definite in the ICAO Addendum. This may be due to the fact that numerous organizations have opposed this change to the regulation. One organization that has submitted comments against the “exception” is the World Health Organization (WHO)

# Key Changes Looming for 2007

The WHO disagrees based on the premise that healthy individuals may still harbor infectious diseases since it is not uncommon for individuals to be unknowingly infected with many viruses ( HIV, HEP B, HEP C ...)

Leading to:

- No packaging requirements
- No hazard communication
- No reporting of damaged packages

The WHO “feels the lack of such standards will increase the likelihood of improper packaging which is likely to result in increase damaged packages and potential exposure to transport workers. WHO is also concerned that the increased exposures will have a cascade effect and reduce the number of carriers that will transport infectious substances.”

# Key Changes Looming for 2007

- Material of Trade exceptions
- Sharps
- Exceptions for “Blood Spots” & “ Faecal occult blood screening”

Thank you