EXPERTS IN INFECTION CONTROL AND HEALTHCARE COMPLIANCE SERVICES




Stericycle

# REGULATORY UPDATE
# NEW DOT CHANGES
# OCTOBER 1, 2006

# DOT CHANGES REGULATIONS FOR UN HARMONIZATION

- On June 2, 2006 DOT Pipeline and Hazardous Materials Safety Administration (PHMSA) published final rules for Infectious Substances and Regulated Medical Waste to adopt new regulations to ensure greater acceptable level of safety for transportation of infectious substances and to be more in line with United Nations (UN) Recommendations.

- Regulations will take effect October 1, 2006 with a compliance date for printed materials such as containers, corrugated boxes and shipping documents to be in compliance by October 1, 2007

- There are significant impacts and changes to the classification, packaging, documentation and shipping of Diagnostic Specimens or Biological Substances. Stericycle will not be covering this area of the regulations as they do not pertain to regulated medical waste, however we strongly recommend that customers become familiar with these regulations and contact their specimen currier to further identify the impacts on their operations.

- There is a section of the regulation covering exempted materials and exempt human or animal specimens, believed to cause negligible risk. These will not be covered in this presentation as they do not pertain to regulated medical waste.

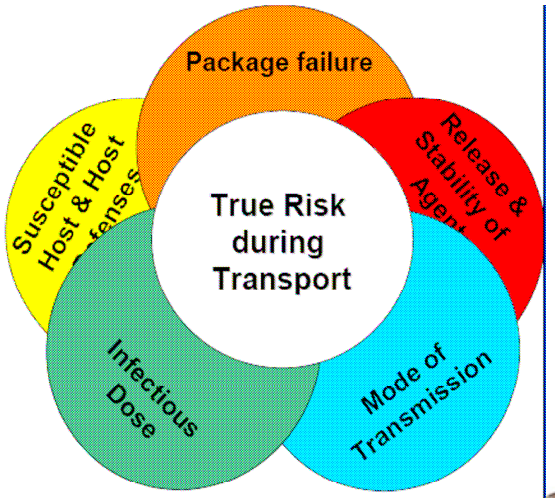
- This presentation covers the changes most significantly impacting Regulated Medical Waste services provided for Stericycle customers.



# Overview of DOT Changes Affecting Regulated Medical Waste

## Main DOT Regulated Medical Waste Issues Changed:

- Description change in packaging and shipping documents
- Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B
- Packaging and shipping document provisions for the new Categories
- Clarification of sharps container packaging



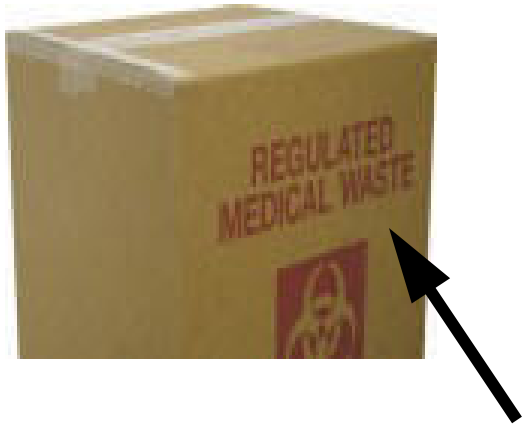
# Description change in packaging and shipping documents

- DOT made a change in the Hazardous Materials Table to be more in line with UN Hazardous Materials descriptions – 49 CFR 172.101

- Change impacts proper labeling of the containers and proper description (or name) on the shipping document or manifest

- Current requirement for proper description:
  - *Regulated Medical Waste*

- New requirement for proper description:
  - *Regulated Medical Waste, n.o.s.*
  - *n.o.s. – "not otherwise specified"*




**NEW:** ***Regulated Medical Waste, n.o.s.***

- The proper name must appear on at least one side of the container and must be in the description of the shipping document or manifest. For bulk and large packaging additional labeling requirements apply. Additional state regulations may apply, please see your local representative.

# Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B

- Current categorization of waste materials fall under Risk Groups based on pathogenicity, mode/ease of transmission and degree of risk to individuals/communities and effective preventative agents and treatment.
  - Risk Group 1(least dangerous) through 4 (most dangerous)
- Risk Groups were originally intended for classification of infectious substances in lab environments with significantly different environment, engineering controls and personal protective equipment than transportation
  - Risk Groups 2 and 3 were acceptable as Regulated Medical Waste
  - Risk Group 4 materials were not accepted as regulated medical waste. This waste is assigned under a different UN number and considered infectious under the definition
- New regulations change the classification to Categories A and B established by the UN which are intended to take into consideration transportation conditions for handling infectious substances.



# Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B

DOT mainly wanted to further define infectious substances under Class 6, Division 6.2
Infectious substance: a material known or reasonably expected to contain a pathogen.

DEFINITIONS FOR CATEGORY A AND B:

- *Category A – an infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category A cannot be classified, packaged or accepted as regulated medical waste.*

- *Category B – an infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. Category B waste is considered regulated medical waste.*

  - Category A waste materials should be treated in accordance with CDC guidelines in Guideline for Environmental Infection Control in Health-Care Facilities, 2003 - http://www.cdc.gov/ncidod/dhqp/gl_environinfection.html.
  - Treated Category A material is no longer considered Regulated Medical Waste by DOT but rather a solid waste, however, there may be additional state and local regulations which may apply for proper final disposition of treated waste materials.



# Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B

DEFINITION OF Category A and B substances are assigned UN identification numbers:

- UN 2814 – Category A infectious substances affecting humans and animals (previously Risk Group 4 and **cultures** of some materials previously Risk Group 2 or 3)
- UN 2900 – Category A infectious substances affecting animals only (previously Risk Group 4)
- UN 3373 – Biological substance, Category B
- **UN 3291 – Regulated Medical Waste (Discarded Category B infectious substances previously Risk Group 2 or 3)**

***DEFINITION OF CULTURE:*** *Infectious substance containing a pathogen that is intentionally propagated. Culture does not include a human or animal patient specimens.*

*For example growth of an infectious substance in a Petri dish for research*



# Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B

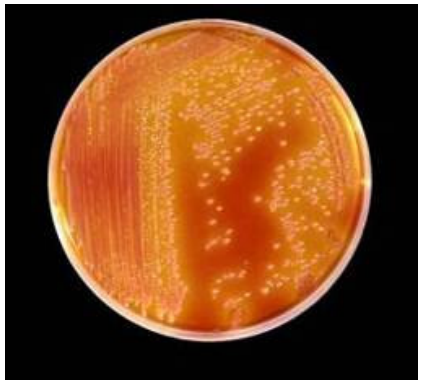
## Current substances identified as Risk Group 2 and 3 may now appear as a Category A material if it is a culture

**Example:** **Current identification of HIV is Risk Group 3:**

Materials included under HIV Risk Group 3 include PPE, blood products, sharps, and cultures

**New identification of HIV:**

- ✓ Cultures of HIV will now be considered Category A
- ✓ Materials such as PPE, blood products, sharps would be still considered Regulated Medical Waste

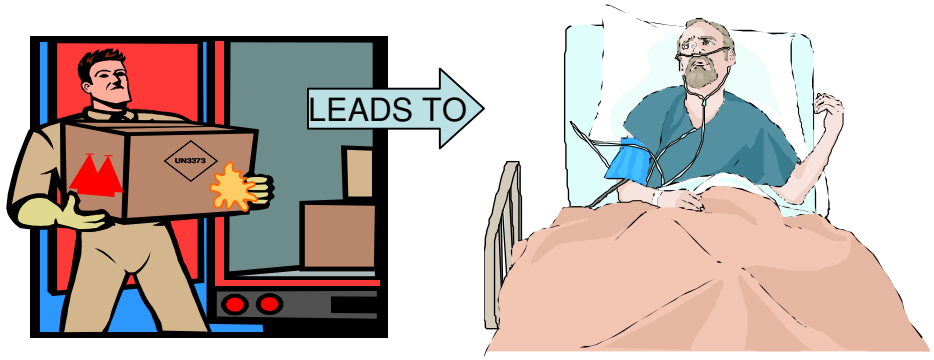


# Categorization of Wastes: Risk Groups 1-4 versus the new Categories A and B

## Indicative examples of Category A:

- **Cultures *or* patient specimens** and any other potentially contaminated materials 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

***EXPOSURE MAY LEAD TO FATALITY***




- New classification system and additional packaging requirements is intended to reduce incidents of more hazardous infectious substances during transport.
- As are reminder Category A materials may not be classified, packaged or accepted as Regulated Medical Waste

DOT has identified certain substances as Category A materials in the following Table. As stated in the regulations, this is not intended to be an all inclusive listing.

# Category A Infectious Substance Table

- **Category A infectious substances UN No. and proper shipping name - UN 2814**
- **Bacillus anthracis (cultures only)**
- **Brucella abortus (cultures only)**
- **Brucella melitensis (cultures only)**
- **Brucella suis (cultures only)**
- **Burkholderia mallei-- Pseudomonas mallei-- Glanders (cultures only)**
- **Burkholderia pseudomallei-- Pseudomonas pseudomallei (cultures only)**
- **Chlamydia psittaci--avian strains (cultures only)**
- **Clostridium botulinum (cultures only)**
- **Coccidioides immitis (cultures**
- **Coxiella burnetti (cultures only)**
- Crimean-Congo hemorrhagic fever virus
- **Dengue virus (cultures only)**
- **Eastern equine encephalitis virus (cultures only)**
- **Escherichia coli, verotoxigenic (cultures only)**
- Ebola virus
- Flexal virus
- **Francisella tularensis (cultures only)**
- Guanarito virus
- Hantaan virus
- Hantaviruses causing hemorrhagic fever with renal syndrome
- Hendra virus
- **Herpes B virus (cultures only)**
- **Human immunodeficiency virus (cultures only)**
- **Highly pathogenic avian influenza virus (cultures only)**
- **Japanese Encephalitis virus (cultures only)**
- Junin virus
- Kyasanur forest disease virus
- Lassa virus
- Machupo virus
- Marburg virus
- Monkeypox virus
- **Mycobacterium tuberculosis (cultures only)**
- Nipah virus
- Omsk hemorrhagic fever virus
- **Poliovirus (cultures only)**
- **Rabies and other lyssa viruses (cultures only)**



# Category A Infectious Substance Table

- **Rickettsia prowazekii (cultures only)**
- **Rickettsia rickettsia (cultures only)**
- **Rift Valley fever virus (cultures only)**
- **Russian spring-summer encephalitis virus (cultures only)**
- Sabia virus
- **Shigella dysenteriae type I (cultures only)**
- **Tick-borne encephalitis virus (cultures only)**
- Variola virus
- **Venezuelan equine encephalitis virus (cultures only)**
- **Vesicular stomatitis virus (cultures only)**
- **West Nile virus (cultures only)**
- **Yellow fever virus (cultures only)**
- **Yersinia pestis (cultures only)**
- **UN 2900--Infectious substances affecting animals only.**
- **African swine fever virus (cultures only)**
- **Avian paramyxovirus Type 1-- Velogenic Newcastle disease virus (cultures only)**
- **Classical swine fever virus (cultures only)**
- **Foot and mouth disease virus (cultures only).**
- **Lumpy skin disease virus (cultures only)**
- **Mycoplasma mycoides--Contagious bovine pleuropneumonia (cultures only)**
- **Peste des petits ruminants virus (cultures only)**
- **Rinderpest virus (cultures only)**
- **Sheep-pox virus (cultures only)**
- **Goatpox virus (cultures only)**
- **Swine vesicular disease virus (cultures only)**

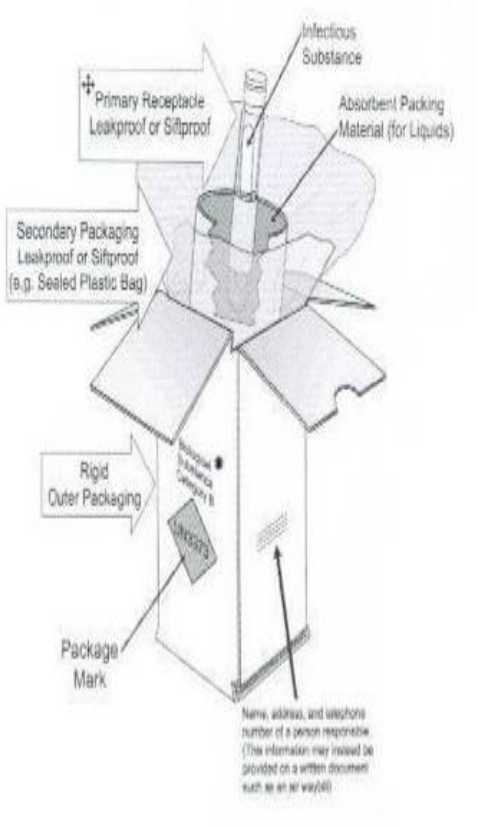
 ***Not a complete list per DOT.***

# Packaging and Shipping Document Provisions

- Category A (UN 2814 and UN 2900)– new regulations require additional triple packaging including new marking and testing certification in addition to changes to shipping documents;  details under 49 CFR 173.196

- Category B (UN 3373)– new regulations require triple packaging however does not require actual certification but rather must be capable of successfully passing the tests in the regulations.  There are additional new marking requirements including color and size. There is a change in shipping documentation as well, does not require proper hazardous materials shipping documents or a manned 24/7 emergency phone number; details under 49 CFR 173.199

- Regulated Medical Waste (UN 3291)– no major changes to the packaging requirements except for the marking requirements to add n.o.s. to packages and shipping documents



# Clarification of sharps container packaging

- DOT experienced problems with compliance of sharps containers, especially larger containers, to meet the leak proof regulations
- Forces generators to properly select their sharps container systems
  Intended to help protect employees from sharps during transport
- Requires sharps containers to be either leakproof or packaged in such a manner as to be leakproof and puncture resistant.
- NOTICE:Additional local regulations may apply for transport

NOTICE TO BIOSYSTEMS CUSTOMERS: As a reminder per the, Special Permit 13556 you have been provided, Biosystems containers fall under the special permit requirements.  Biosystems containers may not have any liquids per the special permit.

# Clarification of sharps container packaging

| Container Type | Container Handling Requirement | Secondary Packaging Requirement |
|---|---|---|
| Sharps container without gasket | Sharps containers must be over packed with secondary packaging to ensure they are leak proof | Place sharps container in bag and place in reusable container.<br>Place sharps container in bag and place in corrugated box. |
| Sharps container with gasket and vent | Sharps container must be properly closed per the manufacturer requirements and vent properly closed | No additional packaging required as long as the vent is properly closed and lid is properly sealed |
| Sharps containers with gasket | Sharps container must be properly closed per the manufacturer requirements | No additional packaging required as long as lid is properly sealed |

***NOTICE: ADDITIONAL STATE REQUIREMENTS MAY APPLY***



# Overview of Changes to HM Regulations

| Regulation | Current | New | Comments |
|---|---|---|---|
| 49 CFR 172.101 | Regulated Medical Waste | Regulated Medical Waste, n.o.s. | Change in description. Will require changes to the shipping document and packaging to add ",n.o.s." |
| 49 CFR 173.134 | Defines Risk Groups 1-4; Regulated Medical Waste; Culture and Stocks; Identifies specification packaging for different infectious materials. No specifics for sharps. | Defines Category A and B infectious Substances; Regulated Medical Waste; Cultures; New specification for packaging of materials; clarifies specifically sharps containers (173.134 (c) (2). | •Replaced Risk Groups with the UN standards for Category A and B to better identify infectious substances for transportation purposes<br>•Changed definition of regulated medical waste allowing only Category B materials; Category A substances can not be packaged as Regulated Medical Waste; New Table to identify which substances fall under Category A<br>•Changed the definition of Cultures to be more encompassing<br>•Description of sharps containers and requirements for proper handling of these materials during transport were clarified |
| 49 CFR 173.197 | General provisions and information for defining and packaging infectious substances under each Risk Group; No sharps information | Provides general provisions and information for defining and packaging Category A and B ; Further defines sharps containers must be securely closed to prevent leaks or punctures in conformance with packaging instructions provided by the packaging manufacturer in accordance with 178.2 (c) | •Further outlines the specific packaging requirements for regulated medical waste transported by general transporter.<br>•Exception for exclusive carriers still apply; Cannot transport Category A materials as Regulated Medical Waste UN 3291<br>•Clarifies proper packaging requirements for sharps containers to be leak proof in transport either by themselves or in an over pack. |
| 49 CFR 173.199 | Diagnostic Specimens | Biological Substance Category B | Entire section changed to reflect the UN specifications |

**NOTICE: ADDITIONAL STATE REQUIREMENTS MAY APPLY**



# Overview of Changes to HM Regulations

- Additional resources:
  - DOT Hazmat main Home Page - www.hazmat.dot.gov
  - June 2, 2006 Federal Register with the new regulatory changes: http://hazmat.dot.gov/regs/rules/final/71fr/docs/71fr-32243.pdf .
  - Guideline for Environmental Infection Control in Health-Care Facilities, 2003 - http://www.cdc.gov/ncidod/dhqp/gl_environinfection.html
  - Centers for Disease Control and Prevention Clinician Outreach and Communication Activity Clinician Briefing (August 23, 2005) - http://www.bt.cdc.gov/coca/summaries/medicalwastemanagement_082305.asp
  - IATA Guidence Document on Infectious Substances - http://www.iata.org/whatwedo/dangerous_goods/infectious_substances.htm



# *QUESTIONS????*