Transporting Infectious Substances Safely
Infectious Substances Guide

GUIDE TO CHANGES
EFFECTIVE OCTOBER 1, 2006

Transporting Infectious Substances Safely

FEDERAL REGISTER
Hazardous Materials: Infectious Substances; Harmonization With the United Nations Recommendations
Objective

• Provide a general overview of the regulatory requirements for transporting Division 6.2 materials:
  – Definitions and Package Selection
  – Marking and Labeling
  – Shipping Papers and Emergency Response Information
  – Security and Training

• Identify requirements for Regulated Medical Waste
U.S. DOT Hazardous Materials Regulations (HMR)

The HMR govern the packaging and safe transportation of hazardous materials by air, highway, rail, and water (except bulk transportation onboard vessel)
Other Federal Regulations Governing Safe Transport of Infectious Substances

- Department of Health and Human Services (HHS)
  42 CFR Parts 72 and 73 – Interstate Shipment of Etiologic Agents and Select Agents and Toxins

- Department of Labor/OSHA
  29 CFR, Section 1910.1030 – Bloodborne Pathogens
International Regulations

- The International Civil Aviation Organization (ICAO)
  - ICAO Technical Instructions for the safe Transport of Dangerous Goods
- The International Maritime Organization (IMO)
  - International Maritime Dangerous Goods Code (IMDG Code)
- The HM226A Final Rule on Infectious Substances
  - Brought HMR in harmonization with international documents
HM226A Final Rule

- Hazardous Materials: Infectious Substances; Harmonization With United Nations Recommendations
  - Published: Federal Register Vol. 71, No. 106, June 2, 2006
  - Effective: October 1, 2006
Significant Changes

• New Classification System
  – Category A and Category B
    • NO MORE RISK GROUPS

• New and Revised Definitions
  – Modified Division 6.2 material
  – Modified Biological Product
  – Modified Regulated Medical Waste
  – Modified Culture
  – New Patient Specimen
Significant Changes (cont’d)

• Hazardous Materials Table Changes
  – Removed Diagnostic Specimen
  – Added Biological Substance Category B
• Security Plans
• Packing and Labeling
• Carriage by Aircraft
Division 6.2 Materials

- Infectious Substance
- Biological Product
- Cultures and Stocks
- Regulated Medical Waste
Infectious Substance Definition

• A material known or suspected to contain a pathogen:
  – a microorganism (including bacteria, viruses, parasites, fungi) or other agent, that can cause disease in humans or animals.

• Infectious substances must be assigned to one of four UN Identification numbers.

49 CFR173.134(a)(1)
Category A Infectious Substance

- A form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed

- Classification based on:
  - known medical history or symptoms of source patient or animal
  - endemic local conditions or professional judgment
Category A Infectious Substance

• Identified as:
  – Infectious substances, affecting animals only, UN2900; and
  – Infectious substances, affecting humans, UN2814
Category B Infectious Substance

- A form that is not generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed

- Identified as:
  - Biological substance, Category B, UN3373

49 CFR 173.134(a)(1)(ii); 172.101
Biological Product Definition

• Virus, serum, toxin, antitoxin, vaccine, blood, blood component, allergenic product used in prevention, diagnosis, treatment of disease
• Includes materials manufactured in accordance with FDA, USDA regulations
• Excepted if subject to federal approval, permit or license requirements (FDA, USDA)

49 CFR 173.134(a)(2)
Biological Product Identification

• When known or expected to contain pathogens of Category A or Category B (unless excepted):

  • **Category A**
    – UN 2814
    – UN 2900

  • **Category B**
    – UN 3373

49 CFR 173.134(a)(2)
Culture Definition

• An infectious substance containing a pathogen that is intentionally propagated

• Does not include human or animal patient specimens

49 CFR 173.134(a)(3)
Patient Specimen Definition

• Human or animal material (excreta, secreta, blood, tissue, tissue swabs) transported for diagnostic or investigational purposes

• Transported as Category B infectious substances
  – not considered capable of causing permanent disability or life-threatening or fatal disease in healthy humans or animals if exposure occurs

49 CFR 173.134(a)(4)
Regulated Medical Waste Definition

• Waste or reusable material, *other than Category A*,
  – derived from medical treatment of humans or animals including diagnosis and immunization; or
  – from biomedical research
    • includes production and testing of biological products

49 CFR 173.134(a)(5)
Regulated Medical Waste Identification

• Contains or suspected to contain Category A substance
  – must be identified as a Category A infectious substance UN 2814 or UN 2900, as applicable.

• Contains Category B
  – identified as Regulated Medical Waste, UN 3291

49 CFR 173.134(a)(5)
Exceptions

• A material that is unlikely to cause disease in humans or animals
• Non-infectious biological materials from humans, animals, or plants
• A material containing neutralized or inactivated pathogens and no longer pose a health risk
• Blood collected for transfusion or preparation of blood products sent for testing (unless believed to contain an infectious substance)

49 CFR 173.134(b)
Exceptions (cont’d)

• Laundry, medical equipment conforming to OSHA regs 29 CFR 1910.1030
• Any waste or recyclable material, other than RMW
• Corpses, remains, and anatomical parts intended for interment, cremation, or medical research

49 CFR 173.134(b)
## Packaging Requirements

<table>
<thead>
<tr>
<th>Regulation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>173.24</td>
<td>General Packaging</td>
</tr>
<tr>
<td>173.24a</td>
<td>Requirements for all HAZMAT</td>
</tr>
<tr>
<td>173.24a(c)</td>
<td>Changes regarding Infectious Substances and mixed contents</td>
</tr>
<tr>
<td>173.134(b)</td>
<td>Exceptions for:</td>
</tr>
<tr>
<td>173.134(c)</td>
<td>Division 6.2 Packaging Regulated Medical Waste</td>
</tr>
<tr>
<td>173.196</td>
<td>Category A Infectious Substance</td>
</tr>
<tr>
<td>173.197</td>
<td>Regulated Medical Waste</td>
</tr>
<tr>
<td>173.199</td>
<td>Category B Infectious Substance</td>
</tr>
<tr>
<td>178.609</td>
<td>6.2 Packaging Tests</td>
</tr>
</tbody>
</table>
Category A Packaging

- Watertight Primary Receptacle
  - Glass, Metal, or Plastic*
  - *If multiple fragile primary receptacles are placed in a single secondary packaging, they must be either individually wrapped or separated so as to prevent contact between them

- Watertight Secondary Packaging

- List of Contents

- Rigid Outer Packaging
  - Infectious Substance Label
  - Proper Shipping Name and UN Number

- Infectious Substance
- Absorbent Packing Material (for liquids)
- Cap

Cross Section of Closed Package

Closure requires positive means of ensuring leakproof seal

Infectious Substance
Absorbent Packing Material

49 CFR 173.196
UN Packaging – Division 6.2 Category A

- United Nations Symbol
- Box
- Fiberboard
- Different Primary Receptacle Allowed
- Infectious Substance Package
- Year Manufactured

4GU/CLASS 6.2/06
USA/+AA1869/APSS

- Country
- Manufacturer’s Code
- Test Facility’s Code

49 CFR 178.503(f)
Used Health Care Products

- Products not conforming to CFR1910.1030 returned to manufacturer
- Triple non-spec package
- BIOHAZARD mark on primary and secondary packaging
- Itemized list
- No shipping paper, label, or emergency response information

49 CFR 173.134(b)(12)(ii)
Regulated Medical Waste (RMW) Packaging

- Rigid
- Leak resistant
- Impervious to moisture
- Burst, tear, and break resistant
- Puncture resistant for sharps
- Sealed to prevent leaks
- Meets UN PG II specs of Part 178

49 CFR 173.197
Regulated Medical Waste

- **Bulk packaging**
  - Large packaging (UN spec)
  - BOP (non-spec)
  - Biohazard Mark
  - CART – requires drop test at PG II level

- **Inner packaging**
  - Solids: plastic film bag (ASTM performance tests)
  - Liquids: rigid, general packaging requirements in Part 173
  - Sharps: puncture-resistant, PG II performance level if over 20 gallons; closure procedures

49 CFR 173.197
Regulated Medical Waste Exceptions

• Non-bulk RMW transported by private or contract carrier
  – No label if OSHA BIOHAZARD mark
  – Non-spec packaging and OSHA packaging
    (other than waste concentrated stock culture of an infectious substance)

• Cultures/stocks in OSHA packaging and vehicle used exclusively to transport RMW
  (Category B infectious substance)

49 CFR 173.134(c)
From Regulated to Non-Regulated

Once sterilized, regulated medical waste is no longer considered a Division 6.2 material
Marking Requirements

• Marking requirements for packages include:
  – Proper shipping name and technical name when applicable
  – Identification number
  – Consignee or consignor name and address
  – DOT Special Permit (if applicable)
  – Orientation arrows (if applicable)
  – Net quantity of dry ice (if applicable)
Proper Shipping Names and Identification Numbers

• Biological substance, Category B, UN3373
• Category A infectious substance:
  – Infectious substances, affecting animals, only, UN2900
  – Infectious substances, affecting humans, UN2814
• Regulated medical waste, n.o.s., UN3291
Marking Requirements

- § 173.4a(g)
- § 173.199(a)(4) Category B infectious substance
- § 172.323(c) & § 173.134(c)(1)(i)
- § 172.432 Label with "404" CDC number expired 10/1/05
- § 172.302 Bulk Marking (can also be on plain white placard)

INFECTIONOUS SUBSTANCE

®

UN3373

3291
Marking and Label Requirements

• Category A
  – Proper shipping name, UN 2814 or UN 2900 (as applicable)
  – Shipper or Consignee identification
  – Infectious Substance Label
  – Orientation arrows (as applicable)

• Category B
  – Proper shipping name
  – UN 3373 marking
  – Name and telephone number of responsible person
    (may be placed on separate document such as air waybill)
  – Orientation arrows (as applicable)
Marking and Label Requirements (cont’d)

• Regulated medical waste
  – Proper shipping name
  – UN 3291
  – Consignor or Consignee name and address
  – Infectious substance label
  – Orientation arrows (as applicable)

49 CFR Part 172, Subparts D and E
Biological Substance, Category B Marking

UN3373

49 CFR 173.199(a)(5)
Division 6.2 Label

• Required label for:
  – Category A Infectious Substance
  – Regulated Medical Waste (unless excepted)

49 CFR 172.432
Shipping Papers

• **Category A**
  – Identification Number
  – Proper Shipping Name
    • "suspected Category A infectious substance” (technical name as applicable)
  – Hazard Class/Division
  – Packing Group
  – Total Quantity
  – Shipper’s Certification
  – Emergency Response Telephone Number

• **Category B** (unless excepted)
  – No shipping papers required

49 CFR Part 172, Subpart C
Shipping Papers – Regulated Medical Waste

• Shipping description:
  – Proper Shipping Name
  – Hazard Class/Division
  – Identification Number
  – Packing Group
  – Total Quantity
  – Shipper’s Certification
  – Emergency Response Telephone Number
Emergency Response Information

- Requirements for providing and maintaining emergency response information identified in Part 172, Subpart G
- May be on shipping paper or other document
- Exception: not required if a shipping paper is not required
Division 6.2 Materials of Trade (MOTS)

• Definition
  – Hazmat on private motor carrier in direct support of principal business that is other than transportation

• Examples:
  – Home health care products, biological product or regulated medical waste

49 CFR 171.8; 173.6(a)(4)
MOTS Exception

- A Division 6.2 other than Category A contained in human or animal samples transported as:
  - Research, diagnosis, investigation activities; or disease treatment or prevention, i.e.
    - Blood and its components
    - Tissue and tissue fluids
    - Body parts; or
  - Biological product
  - Regulated medical waste (RMW)
MOTS Exception (cont.)

• Non-spec combination packagings with quantity limits
• Aggregate gross weight of all MOTS on motor vehicle may not exceed 200 kg (440 lbs)

49 CFR 173.6(a)(4) and (d)
Other Requirements – Security Plan

• A security plan is required for:
  – Select agent or toxin regulated by CDC under 42 CFR part 73
  – By April 1, 2007 for select agent or toxin regulated by USDA under 9 CFR part 121

• The plan must include:
  – Assessment of security risks
  – Address personnel security, unauthorized access, and en route security

49 CFR 172.800(b)(6)
Other Requirements – Training

- Federal hazardous materials transportation law 49 CFR, Part 172, Subpart H, requires training of all hazmat employees. Training must include:
  - General Awareness / Familiarization
  - Safety
  - Function Specific
  - Security Awareness
  - In-depth Security (when applicable)

- Anyone shipping infectious substances must have “knowledge and training”

49 CFR 172.704(a); 173.134(b); 173.199(e)
Questions?
Where to Find More Information...

http://hazmat.dot.gov
Hazardous Material Info-Center

1-800-HMR-4922
(1-800-467-4922)

E-mail: infocntr@dot.gov

Hours of Operation: 9 am – 5 pm ET

- Obtain answers to HMR questions
- Request copies of Federal Register, special permits or training materials
- Report HMR violations
- Fax on Demand