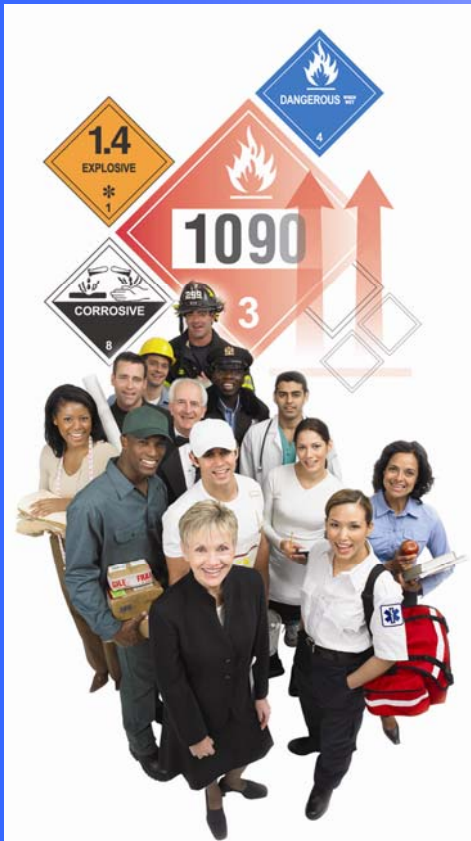




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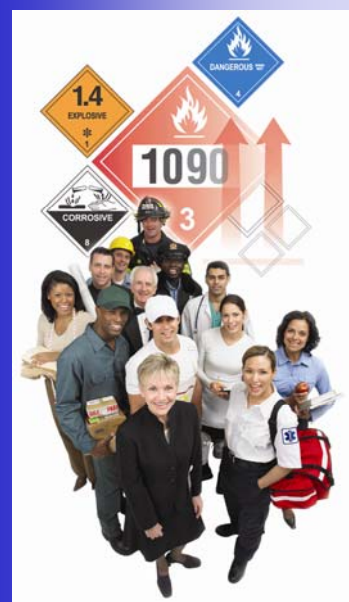


Transporting Infectious Substances Safely



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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

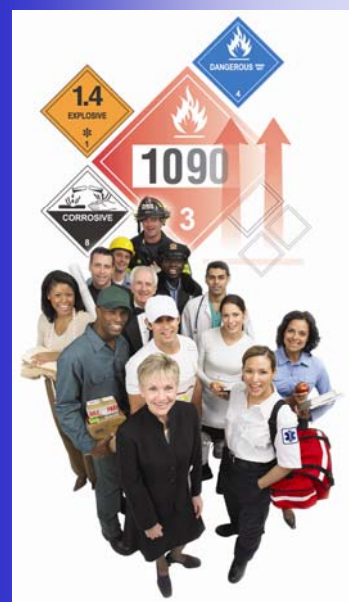


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Safety Administration



Transporting
Infectious
Substances
Safely

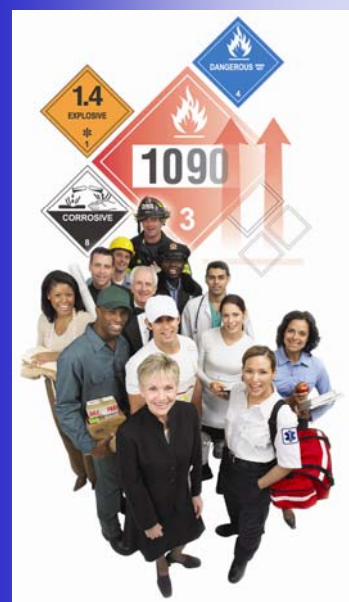
Objective

- **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**



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U.S. DOT Hazardous Materials Regulations (HMR)

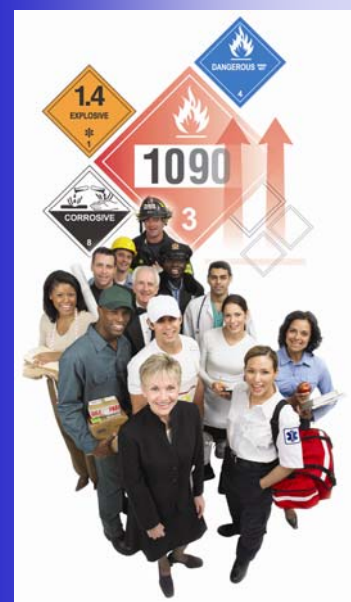
The HMR govern the packaging and safe transportation of hazardous materials by air, highway, rail, and water (except bulk transportation onboard vessel).





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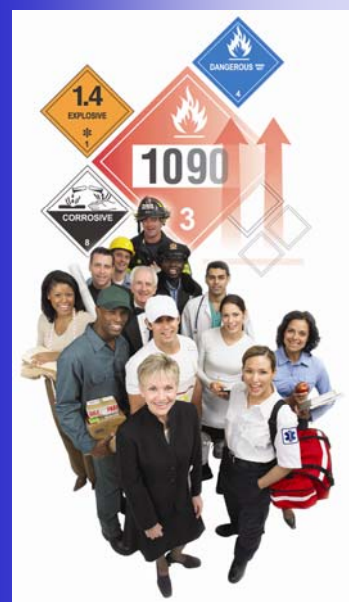
Other Federal Regulations Governing Safe Transport of Infectious Substances

- **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**



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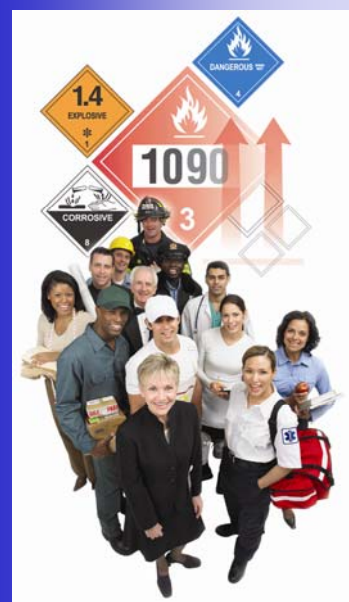
International Regulations

- **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 the HMR in harmonization with international documents



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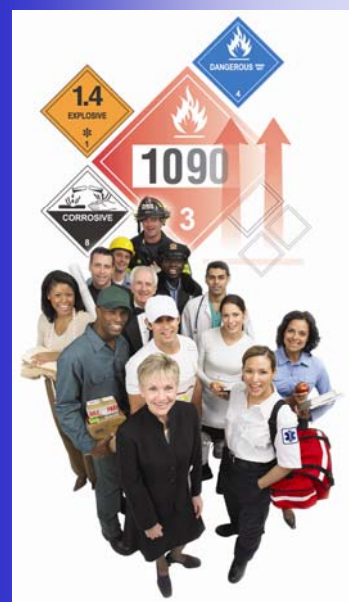
HM226A Final Rule

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



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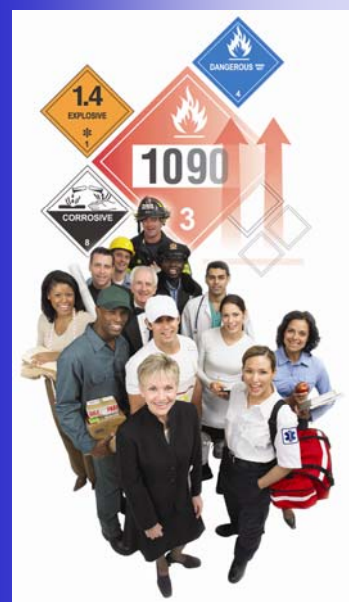
Significant Changes

- **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**



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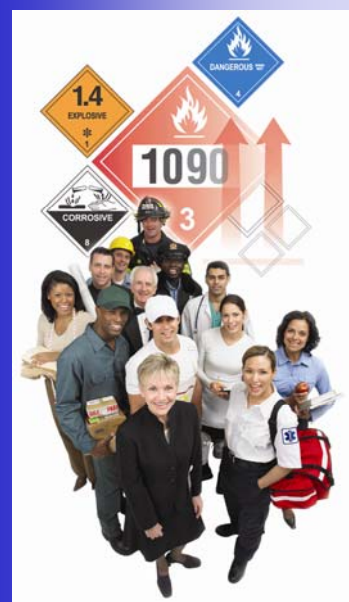
Significant Changes (cont'd)

- **Hazardous Materials Table Changes**
 - **Removed Diagnostic Specimen**
 - **Added Biological Substance Category B**
- **Security Plans**
- **Packing and Labeling**
- **Carriage by Aircraft**



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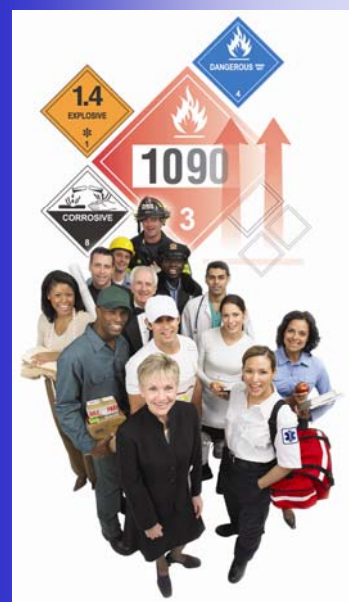
Division 6.2 Materials

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



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Infectious Substance Definition

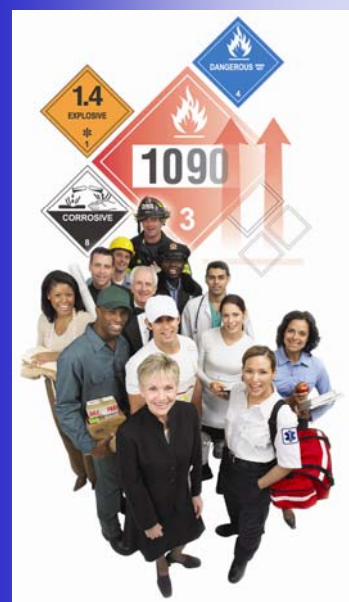
- **A material known or suspected to contain a pathogen:**
 - a microorganism (including bacteria, viruses, parasites, fungi) or other agent, that can cause disease in humans or animals.
- **Infectious substances must be assigned to one of four UN Identification numbers.**

§173.134(a)(1)



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Category A Infectious Substance

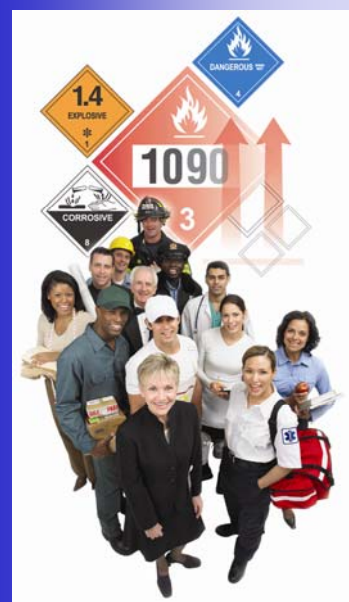
- **A form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed**
- **Classification based on:**
 - **known medical history or symptoms of source patient or animal**
 - **endemic local conditions or professional judgment**

§173.134(a)(1)(I)



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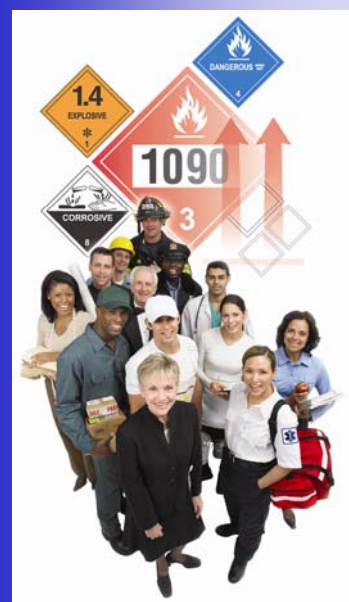
Category A Infectious Substance

- **Identified as:**
 - **Infectious substances, affecting animals *only*, UN2900; and**
 - **Infectious substances, affecting humans, UN2814**



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Category B Infectious Substance

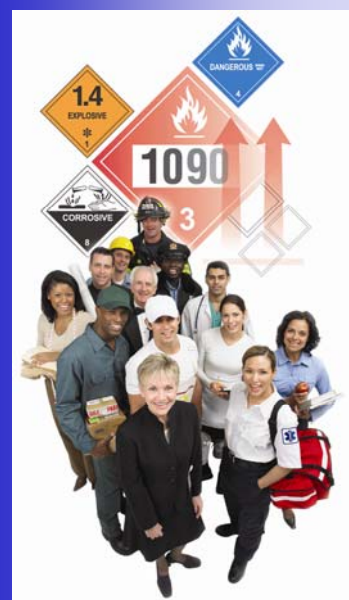
- **A form that is not generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposed.**
- **Identified as:**
 - **Biological substance,
Category B, UN3373**

§§173.134(a)(1)(ii); 172.101



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Biological Product Definition

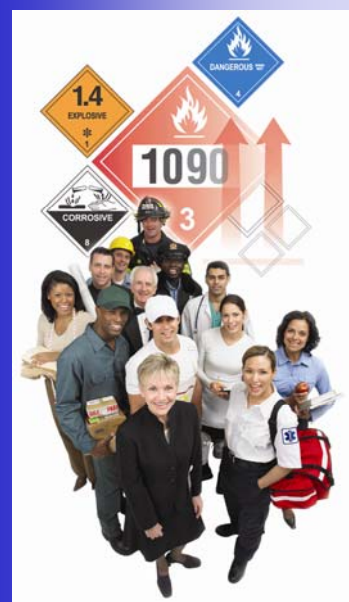
- **Virus, serum, toxin, antitoxin, vaccine, blood, blood component, allergenic product used in prevention, diagnosis, treatment of disease**
- **Includes materials manufactured in accordance with FDA, USDA regulations**
- **Excepted if subject to federal approval, permit or license requirements (FDA,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

§173.134(a)(2)



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Biological Product Identification

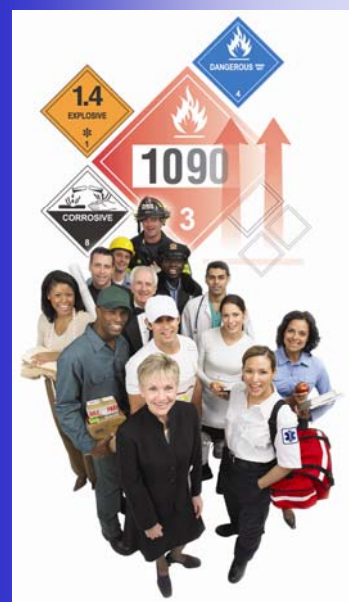
- **When known or expected to contain pathogens of Category A or Category B (unless excepted):**
- **Category A**
 - UN 2814
 - UN 2900
- **Category B**
 - UN 3373

§173.134(a)(2)



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Culture Definition

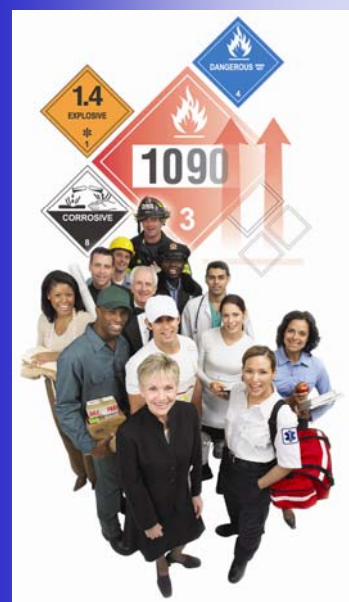
- **An infectious substance containing a pathogen that is intentionally propagated**
- **Does not include human or animal patient specimens**

§173.134(a)(3)



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Patient Specimen Definition

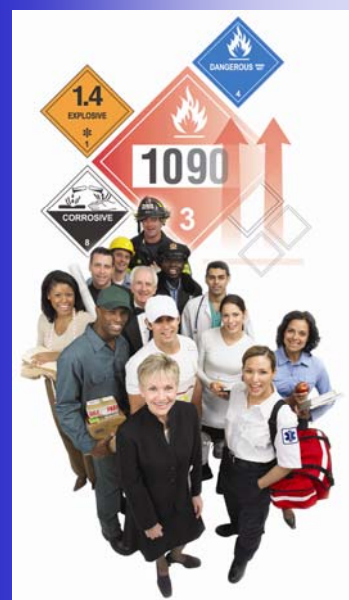
- **Human or animal material (excreta, secretions, blood, tissue, tissue swabs) transported for diagnostic or investigational purposes**
- **Transported as Category B infectious substances**
 - **not considered capable of causing permanent disability or life-threatening or fatal disease in healthy humans or animals if exposure occurs**

§173.134(a)(4)



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Regulated Medical Waste Definition

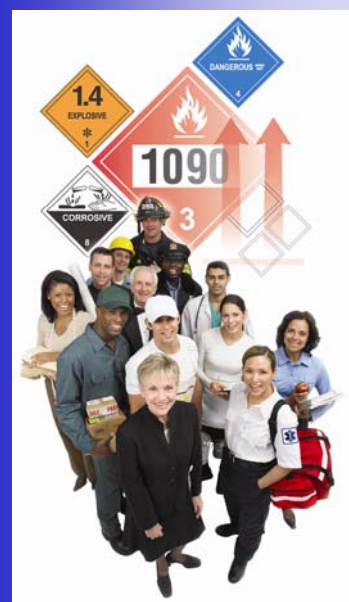
- **Waste or reusable material, *other than Category A*,**
 - derived from medical treatment of humans or animals including diagnosis and immunization; or
 - from biomedical research
 - includes production and testing of biological products

§173.134(a)(5)



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Regulated Medical Waste Identification

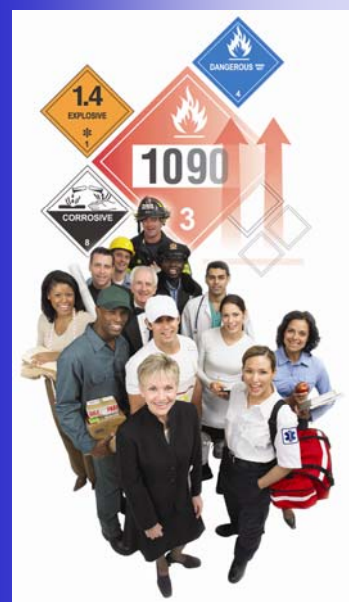
- **Contains or suspected to contain Category A substance**
 - must be identified as a **Category A infectious substance UN 2814 or UN 2900, as applicable.**
- **Contains Category B**
 - identified as **Regulated Medical Waste, UN 3291**

§173.134(a)(5)



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Exceptions

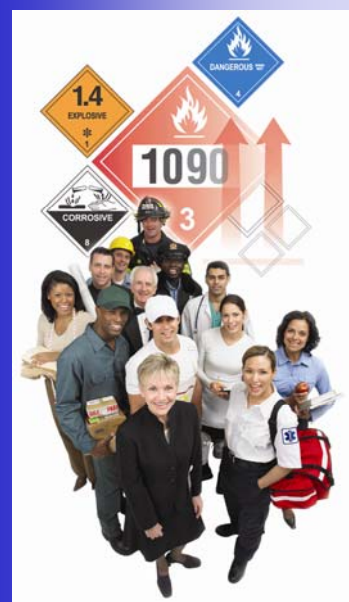
- **A material that is unlikely to cause disease in humans or animals**
- **Non-infectious biological materials from humans, animals, or plants**
- **A material containing neutralized or inactivated pathogens and no longer pose a health risk**
- **Blood collected for transfusion or preparation of blood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

§173.134(b)



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Exceptions (cont'd)

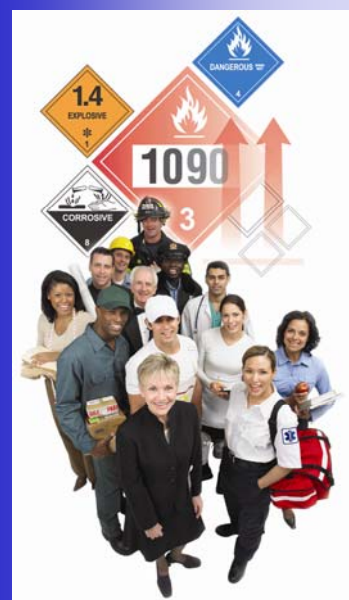
- **Laundry, medical equipment conforming to OSHA regs 29 CFR 1910.1030**
- **Any waste or recyclable material, other than RMW**
- **Corpses, remains, and anatomical parts intended for interment, cremation, or medical research**

§173.134(b)



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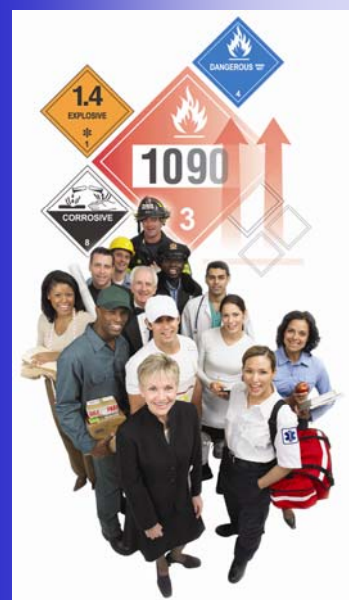
Packaging Requirements

173.24 173.24a 173.24a(c)	General Packaging Requirements for all HAZMAT Changes regarding Infectious Substances and mixed contents
173.134(b) 173.134(c)	Exceptions for: Division 6.2 Packaging Regulated Medical Waste
173.196	Category A Infectious Substance
173.197	Regulated Medical Waste
173.199	Category B Infectious Substance
178.609	6.2 Packaging Tests



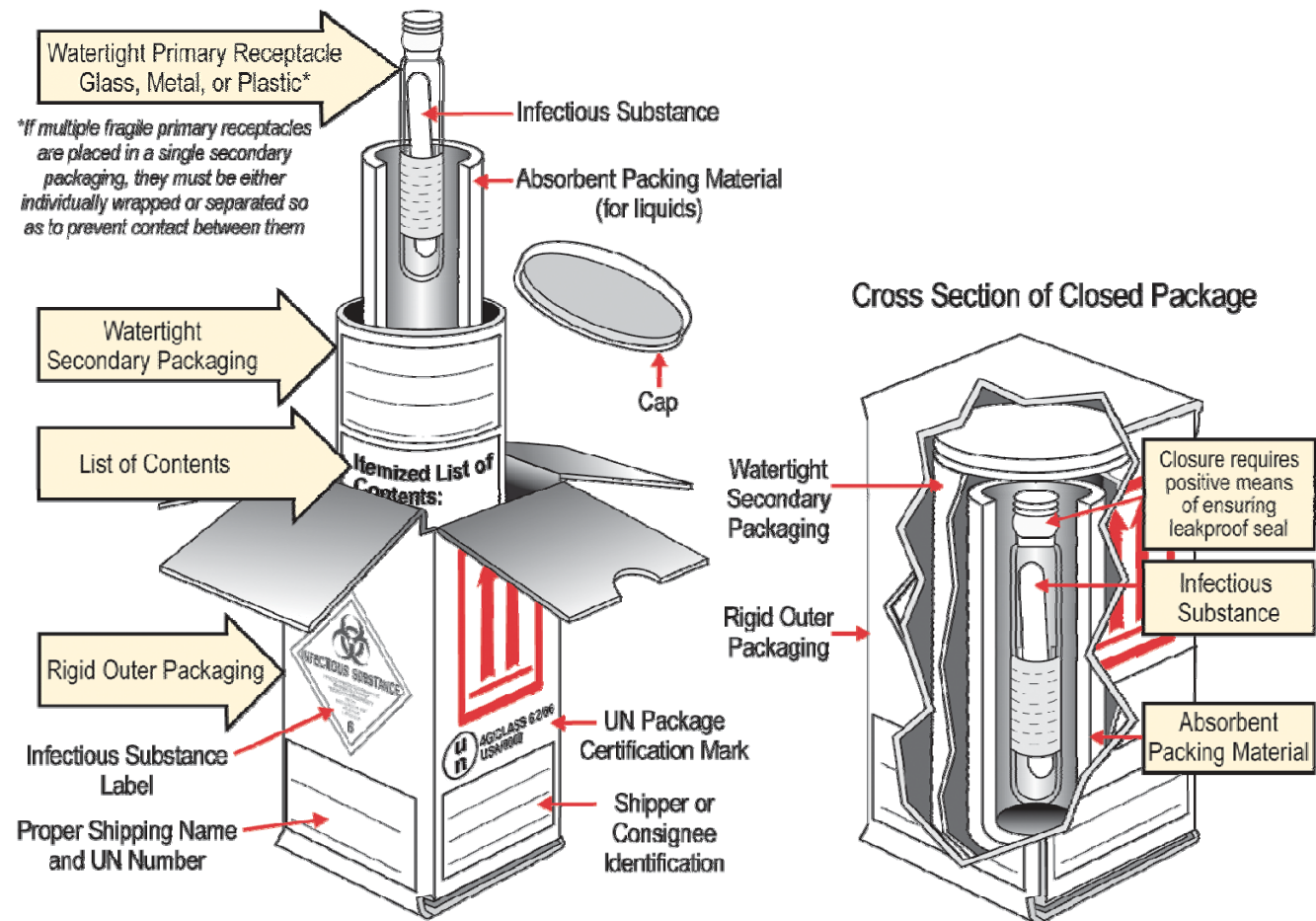
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Category A Packaging

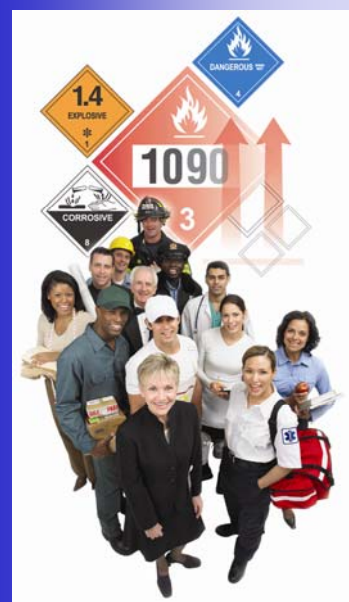


§173.196



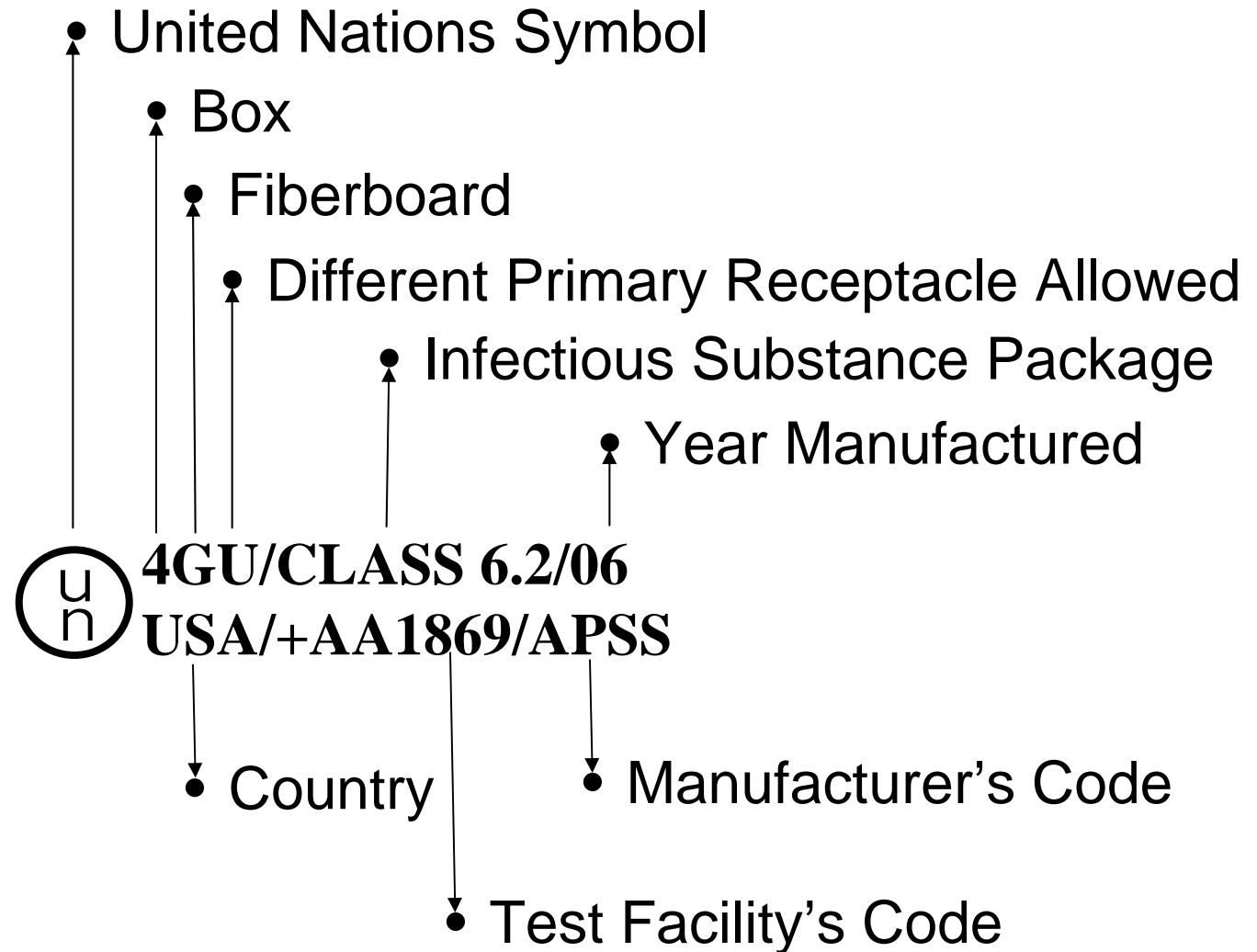
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UN Packaging – Division 6.2 Category A

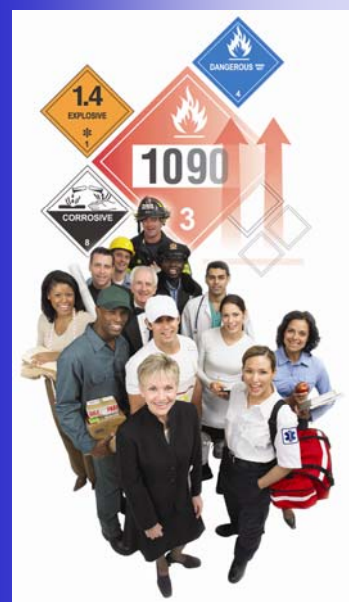


§ 178.503(f)



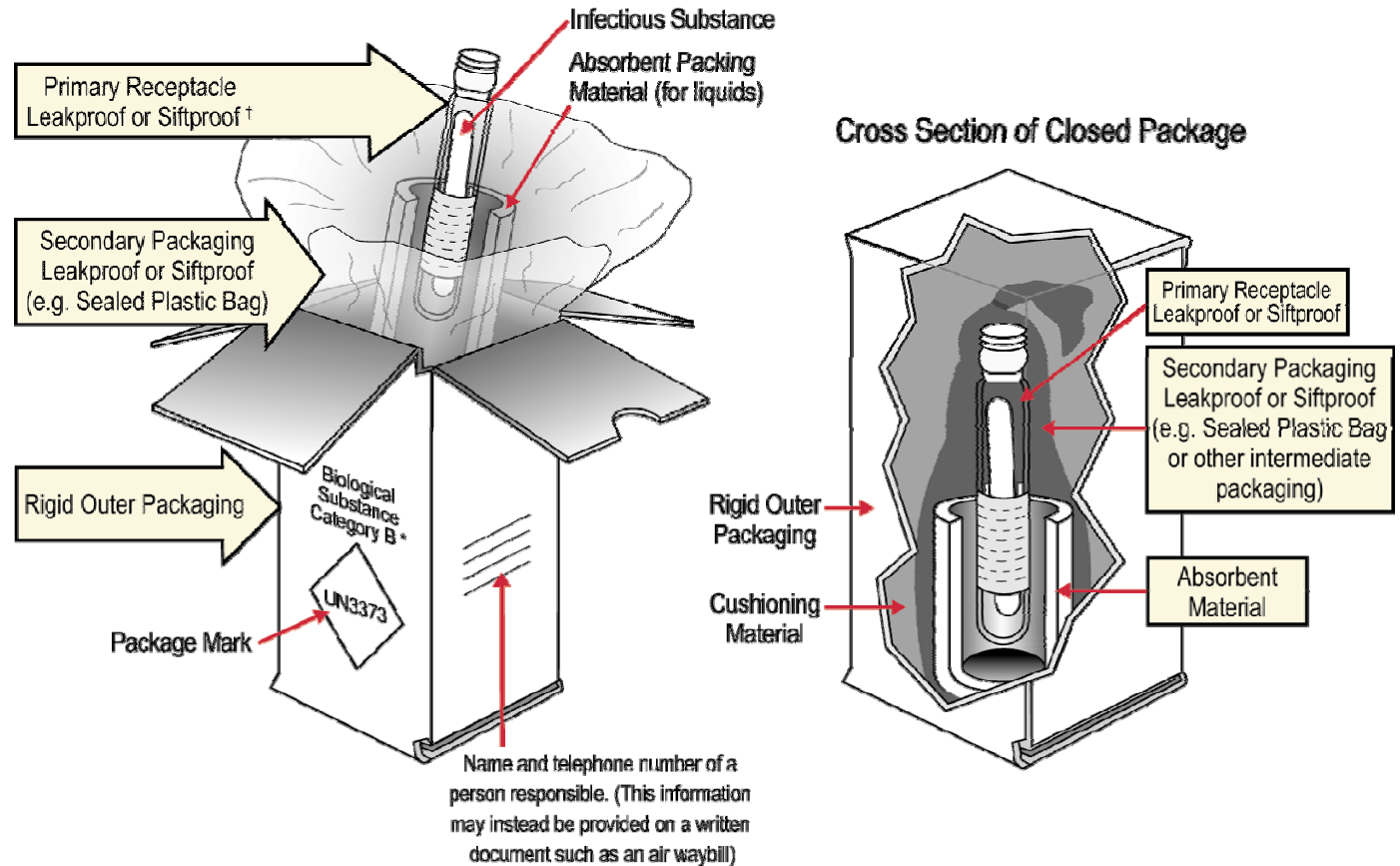
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Category B Packaging

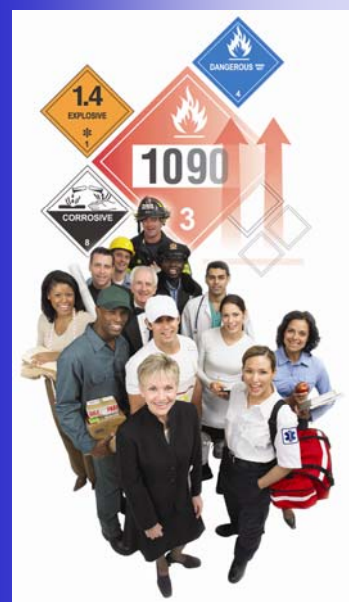


§173.199



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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**

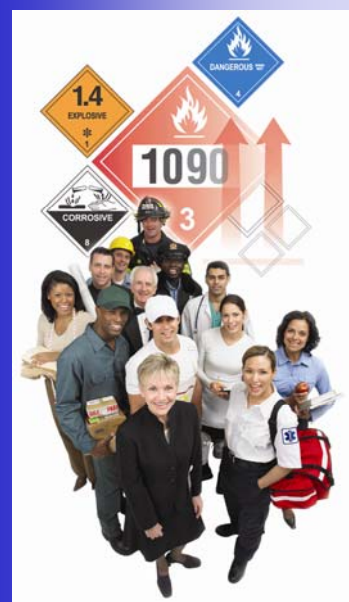


§173.134(b)(12)(ii)



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Regulated Medical Waste (RMW) Packaging

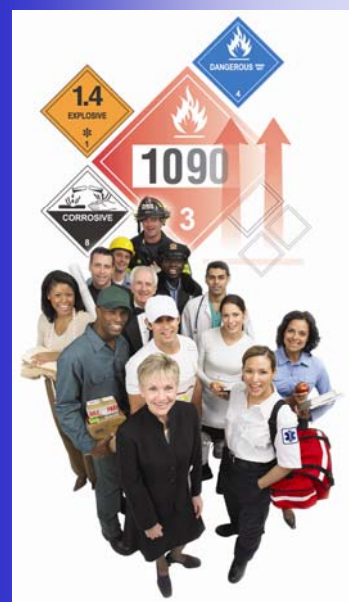
- **Rigid**
- **Leak resistant**
- **Impervious to moisture**
- **Burst, tear, and break resistant**
- **Puncture resistant for sharps**
- **Sealed to prevent leaks**
- **Meets UN PG II specs of Part 178**

§173.197



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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

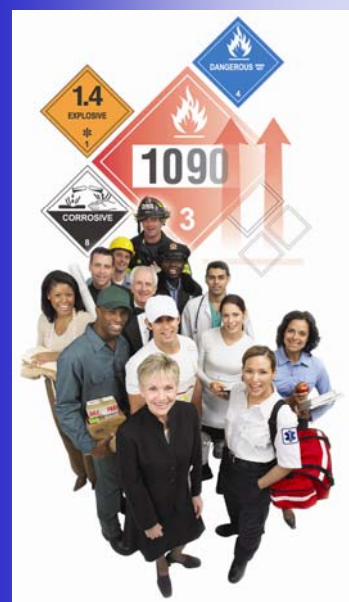


§173.197



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Regulated Medical Waste Exceptions

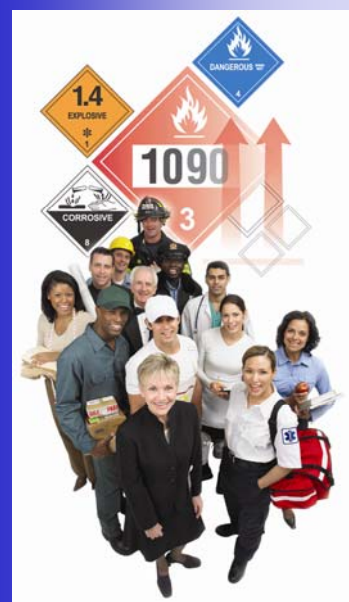
- **Non-bulk RMW transported by private or contract carrier**
 - No label if OSHA BIOHAZARD mark
 - Non-spec packaging and OSHA packaging (other than waste concentrated stock culture of an infectious substance)
- **Cultures/stocks in OSHA packaging and *vehicle used exclusively to transport RMW* (Category B infectious substance)**

§173.134(c)



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From Regulated to Non-Regulated

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

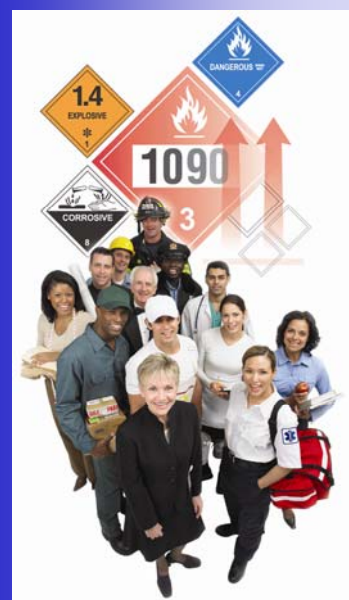


RMW entering autoclave unit



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Marking Requirements

Marking requirements for packages include:

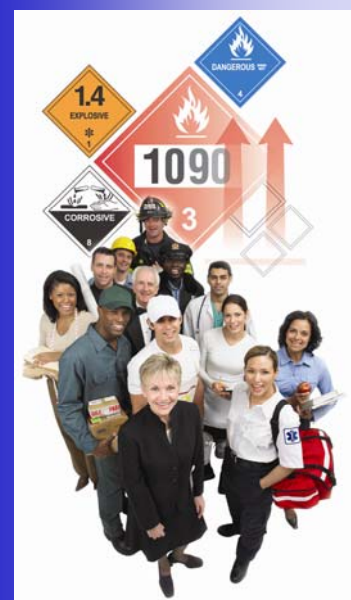
- Proper shipping name and technical name when applicable**
- Identification number**
- Consignee or consignor name and address**
- DOT Special Permit (if applicable)**
- Orientation arrows (if applicable)**
- Net quantity of dry ice (if applicable)**

Part 172, Subpart D



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Proper Shipping Names and Identification Numbers

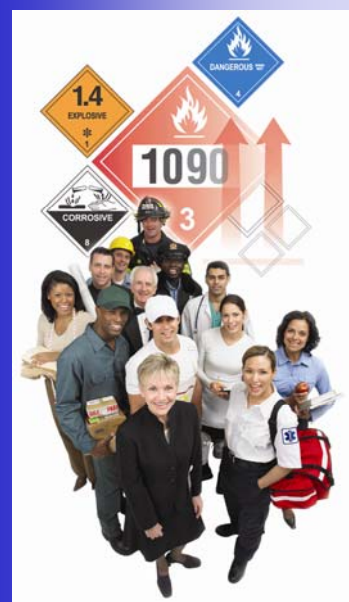
- **Biological substance, Category B, UN3373**
- **Category A infectious substance:**
 - **Infectious substances, affecting animals, *only*, UN2900**
 - **Infectious substances, affecting humans, UN2814**
- **Regulated medical waste, n.o.s., UN3291**

§172.101



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Marking and Label Requirements

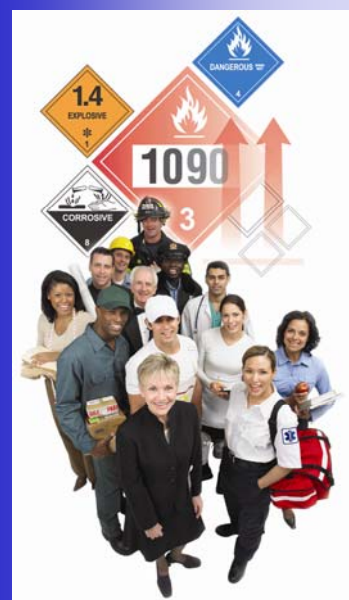
- **Category A**
 - Proper shipping name, UN 2814 or UN 2900 (as applicable)
 - Shipper or Consignee identification
 - Infectious Substance Label
 - Orientation arrows (as applicable)
- **Category B**
 - Proper shipping name
 - UN 3373 marking
 - Name and telephone number of responsible person (may be placed on separate document such as air waybill)
 - Orientation arrows (as applicable)

§172, Subparts D and E



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Marking and Label Requirements (cont'd)

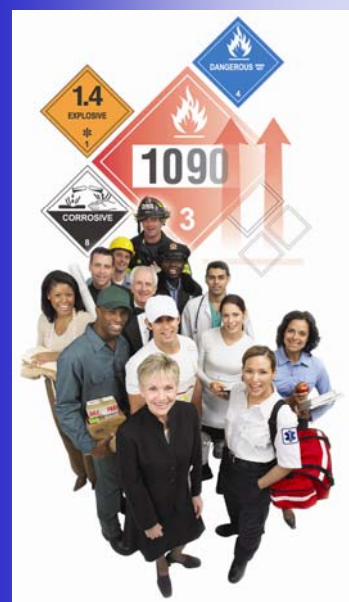
- **Regulated medical waste**
 - Proper shipping name
 - UN 3291
 - Consignor or Consignee name and address
 - Infectious substance label
 - Orientation arrows (as applicable)

§172, Subparts D and E



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Biological Substance, Category B Marking

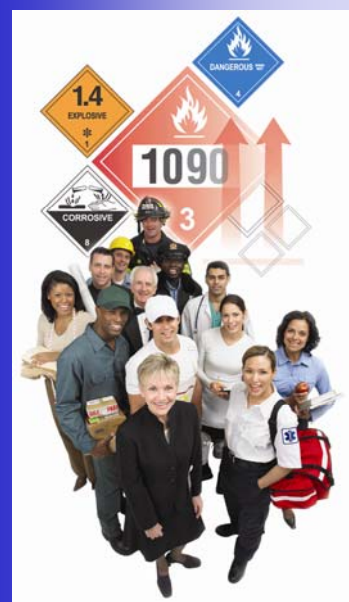
UN3373

§173.199(a)(5)



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Division 6.2 Label

- **Required label for:**
 - **Category A Infectious Substance**
 - **Regulated Medical Waste (unless excepted)**

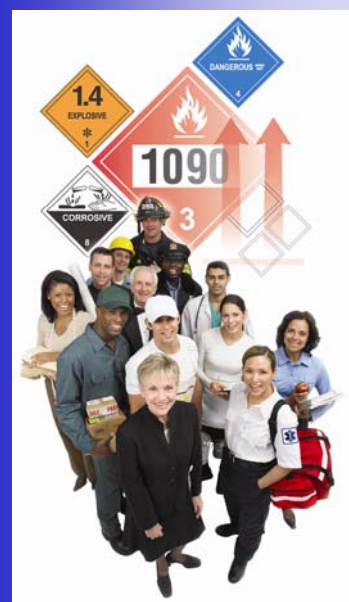


§172.432



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Shipping Papers

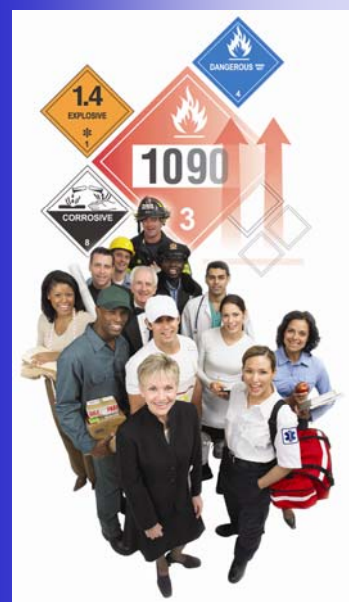
- **Category A**
 - **Identification Number**
 - **Proper Shipping Name**
 - "suspected Category A infectious substance"
(technical name as applicable)
 - **Hazard Class/Division**
 - **Packing Group**
 - **Total Quantity**
 - **Shipper's Certification**
 - **Emergency Response Telephone Number**
- **Category B (unless excepted)**
 - **No shipping papers required**

Part 172, Subpart C



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Shipping Papers – Regulated Medical Waste

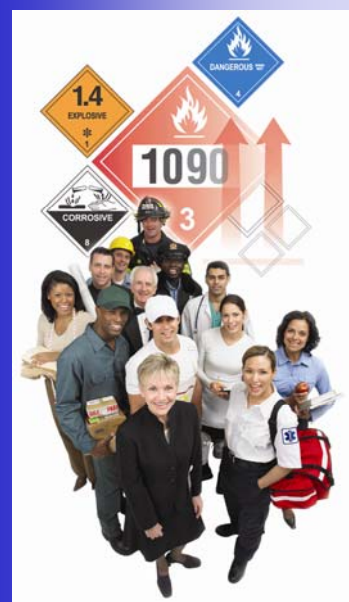
- **Shipping description:**
 - **Proper Shipping Name**
 - **Hazard Class/Division**
 - **Identification Number**
 - **Packing Group**
 - **Total Quantity**
 - **Shipper's Certification**
 - **Emergency Response Telephone Number**

§173.134.(c)



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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**

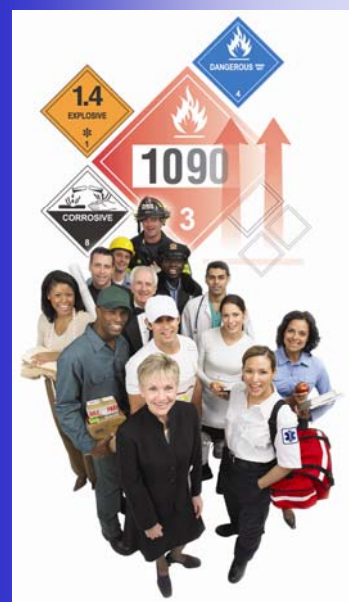


Photo: Lawrence Berkeley National Lab



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Pipeline and
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Safety Administration



Transporting
Infectious
Substances
Safely

Division 6.2 Materials of Trade (MOTS)

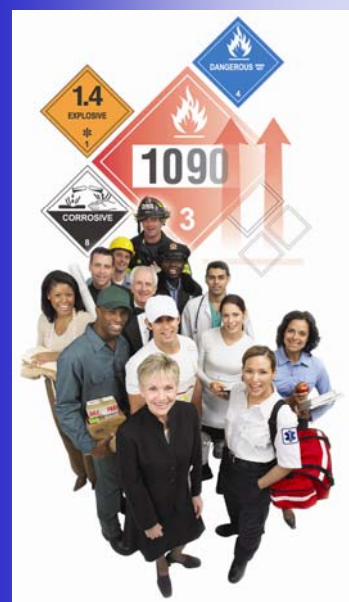
- **Definition**
 - Hazmat on private motor carrier in direct support of principal business that is other than transportation
- **Examples:**
 - Home health care products, biological product or regulated medical waste

§§171.8; 173.6(a)(4)



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MOTS Exception

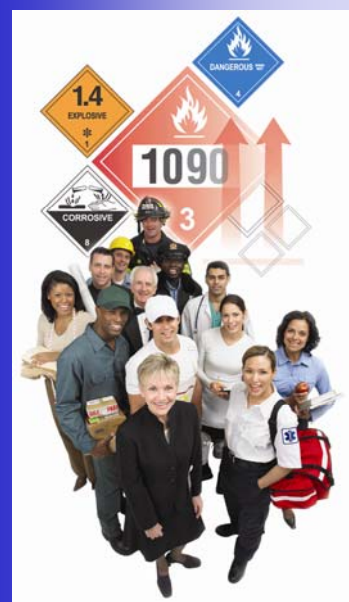
- **A Division 6.2 other than Category A contained in human or animal samples transported as:**
 - Research, diagnosis, investigation activities; or disease treatment or prevention, i.e.
 - Blood and its components
 - Tissue and tissue fluids
 - Body parts; or
 - Biological product
 - Regulated medical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

§173.6(a)(4)



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MOTS Exception (cont.)

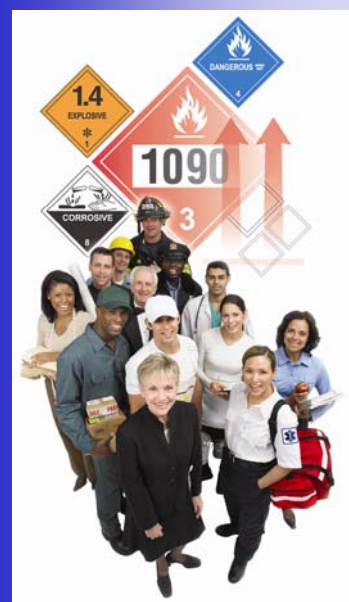
- **Non-spec combination packagings with quantity limits**
- **Aggregate gross weight of all MOTS on motor vehicle may not exceed 200 kg (440 lbs)**

§173.6(a)(4) and (d)



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Other Requirements – Security Plan

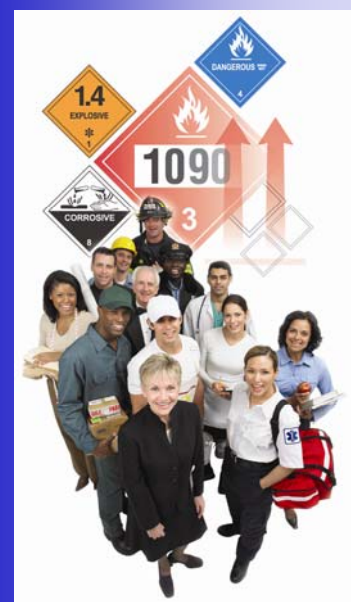
- **A security plan is required for:**
 - **Select agent or toxin regulated by CDC under 42 CFR part 73**
 - **By April 1, 2007 for select agent or toxin regulated by USDA under 9 CFR part 121**
- **The plan must include:**
 - **Assessment of security risks**
 - **Address personnel security, unauthorized access, and en route security**

§172.800(b) (6)



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Other Requirements – Training

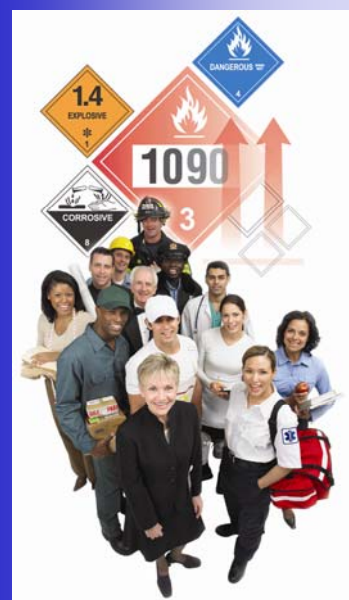
- **Federal hazardous materials transportation law requires training of *all* hazmat employees. These requirements are found in 49 CFR, Part 172, Subpart H**
- **Hazmat employee training must include:**
 - **General Awareness / Familiarization**
 - **Safety**
 - **Function Specific**
 - **Security Awareness**
 - **In-depth Security (when applicable)**
- **Anyone shipping infectious substances must have “knowledge and training”**

§ §172.704(a); 173.134(b); 173.199(e)



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*Where to Find More
Information . . .*

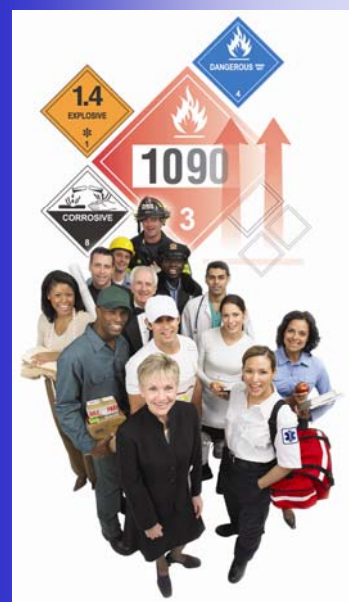


<http://hazmat.dot.gov>



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How Can You Reach Us?

Hazardous Materials

INFO-LINE

1-800-HMR49-22

(1-800-467-4922)

Hours of Operation: 9 am – 5 pm ET



DOT/PHMSA Photo

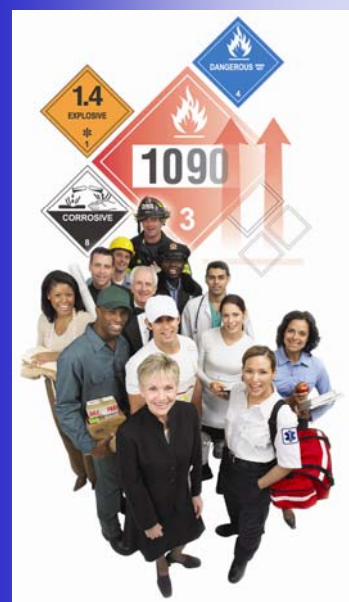
- Obtain answers to HMR questions
- Request copies of Federal Register, special permits or training materials
- Report HMR violations
- Fax on Demand

E-mail: infocntr@dot.gov



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Got A
Question?