



U.S. Department  
of Transportation

**Research and  
Special Programs  
Administration**

400 Seventh Street, S.W.  
Washington, D.C. 20590

MAR 24 1999

Mr. Wayne S. Lester  
Manager, Safety Programs  
Allegheny Airlines, Inc.  
1000 Rosedale Avenue  
Middletown, PA 17057

Reference No. 99-0037

Dear Mr. Lester:

This is in response to your recent letter concerning differences in the text accompanying the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label in our DOT Chart 10 (1994) and DOT Chart 11 (1998), entitled "Hazardous Materials Marking, Labeling & Placarding Guides." You asked if placing this label on a package in transportation indicates the package contains a Division 6.2 (infectious substance) hazardous material.

The answer is yes. Under 49 CFR 173.134(a)(1) of the DOT Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180), a material meeting the definition of an etiologic agent in 42 CFR 72.3 of the Department of Health and Human Services, Centers for Disease Control and Prevention (CDC) regulations also meets the definition of an infectious substance under the HMR. The ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label, depicted in 42 CFR 72.3(d)(1), is required by CDC to be displayed on the outside of a package containing an etiologic agent. Such a package is also required to display the INFECTIOUS SUBSTANCE label depicted in 49 CFR 172.432, unless otherwise excepted. For example, under § 173.134(b), an etiologic agent that is a biological product or a diagnostic specimen is not subject to any of the requirements in the HMR.

You also stated that sometimes your company is offered packages of donor organs for transport that display the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label but do not display the INFECTIOUS SUBSTANCE label. You asked if these shipments are subject to the HMR. Shipment of a donor organ is not subject to the HMR unless the item as packaged contains a material that is otherwise subject to regulation, such as "Carbon dioxide, solid" (dry ice). For questions concerning the display of the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label on such packages, I suggest you contact Jonathan Y. Richmond, PhD., Director, Office of Health and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road, NE, Atlanta, GA 30333, (404) 639-2453.

# Allegheny

Airlines, Inc.

Wayne S. Lester  
Mgr. Safety Programs

Mr. Edward Mazzullo  
Director OHMS  
U.S. Department of Transportation  
400 7<sup>th</sup> Street, SW  
Washington, DC 20590

Re: DOT Chart 10 Confusion

Dear Mr. Mazzullo:

I am writing to ask for a written clarification on a placard, which appears in the DOT Chart 10. I am told that there is a new DOT Chart 11 available and I have ordered these charts, but in the meantime I need your assistance.

The DOT Chart 10 (dated February 1994) shows two labels under Class 6, Division 6.2. One is the Infectious Substance label and the other is a Biomedical Material label. The Biomedical Material label is the one giving our company trouble.

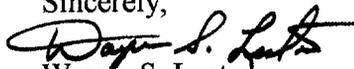
Our Flight Training Department instructs our pilots on the carriage of hazardous materials using the DOT Chart 10. Because the Biomedical Material label appears on the chart with the Infectious Substance label, our pilots believe this label to be a hazardous materials label. We have explained that this is an OSHA label and the mere appearance of the Biomedical Material label (or the Biohazard label) on a package does not indicate that the package is a hazardous material. This has not swayed the opinion of our flight crews and they continue to reject the shipment of donor organs simply because of the Biomedical Material label. We have reviewed 49 CFR 173.134, where the regulation talks about exceptions, however this does not satisfy our Flight Training Department concerning the appearance of the Biomedical Material label on the DOT Chart 10.

It would help us greatly if we could receive written confirmation from the DOT indicating that, although the Biomedical Material label does appear on the DOT Chart 10, this label appearing by itself on a package does not constitute a hazardous material.

Please reply to the attention of: Wayne Lester, Manager of Safety Programs, Allegheny Airlines, Inc., 1000 Rosedale Ave., Middletown, PA, 17057.

Your help in dealing with this matter is greatly appreciated.

Sincerely,

  
Wayne S. Lester

Mack  
1240 NJ  
99-0037

# Interpretation Letters

**Requester** Wayne S. Lester  
**Company** Allegheny Airlines, Inc.  
**Phone** 717-948-5411

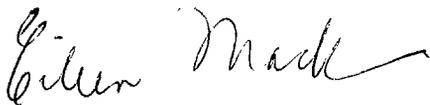
**Date Received:** 2/9/99  
**Tracking Number:** 99-0037  
**Revision Date:** 2/9/99

|                      |                          |                          |                          |
|----------------------|--------------------------|--------------------------|--------------------------|
| <b>Date Assigned</b> | 2/9/99                   | <b>Date of Letter</b>    | 2/9/99                   |
| <b>Staff</b>         | Mack                     | <b>First Draft Due:</b>  | 3/2/99                   |
| <b>Section</b>       | 1240NI                   | <b>First Draft Date:</b> |                          |
| <b>Subject</b>       | Labeling                 |                          |                          |
| <b>Concurrence</b>   |                          |                          |                          |
| <b>Status</b>        |                          | <b>Status Date</b>       |                          |
| <b>Sign Date</b>     |                          | <b>Signor</b>            |                          |
| <b>HBP</b>           | <input type="checkbox"/> | <b>Copy to Docket</b>    | <input type="checkbox"/> |
|                      |                          | <b>Copy to DHM-60</b>    | <input type="checkbox"/> |
| <b>Comment</b>       |                          |                          |                          |

2/18 Allegheny doesn't carry hazard  
Pilots confused.  
175.10 - ~~Company~~ <sup>Company mail (discussions  
abt what  
constitute  
company  
mail)</sup> items  
- Donor organs (blood  
products - not  
infectious  
If it comes from lab it will  
have OSHA mark

14 121 65

## TELEPHONIC CONVERSATION RECORD

| <i>Specialist Placing Call:</i> Eileen Mack   | ROUTING |     |
|---|---------|-----|
| <i>Date of Call:</i> 2/23/99, 9:45 a.m.   | SYMBOL  | INT |
| <i>Person(s) Contacted:</i> (1) <b>Jerry Davis</b> , Consumer Safety Officer; (2) <b>Mary Ganikos</b> , PhD., Chief, Public and Professional Education Branch,  |         |     |
| <i>Their Organization:</i> (1) Office of Compliance, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 400 South, Rockville, MD, 20852, (301) 827-6220, (2) Division of Transplantation, Health Resources and Services Administration (HRSA), 5600 Fishers Lane, Rockville, MD, 20857, (301) 443-7577  |         |     |
| <i>Date of Incoming Letter:</i> Re: Letter from Wayne Lester, Allegheny Airlines, Inc., 100 Rosedale, Ave., Middletown, PA 17057, (717) 948-5411, No date (Received 2/9/99)   |         |     |
| <i>Specific Subject (including section #'s and key words):</i> Are donor organs biological products? Does any agency within the Department of Health and Human Services regulate the transport of donor organs?   |         |     |
|   |         |     |
| <i>Summary:</i> While preparing the response to Mr. Lester's letter on whether donor organs with the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label are regulated by DOT in transportation, the question came up as to whether donor organs were excepted from regulation as a biological product. Mr. Davis said the answer is no and that the FDA does not regulate donor organs. He referred me the HRSA. I spoke to Dr. Ganikos, who explained her agency was concerned with organ procurement and information outreach but had no regulations regarding how they are to be transported. On 2/22/98, I placed a call to Dr. Jonathan Richmond, Centers for Disease Control and Prevention, to learn if CDC has any regulations regarding donor organs. I am awaiting his response. |         |     |
| <i>Comments for Further Action:</i> Revise the draft to refer Mr. Lester to Jonathan Richmond and Jerry Davis. Include the recent phone report. Forward the draft for concurrence and signature.  |         |     |
| <i>Specialist Signature:</i>    |         |     |
| <i>Date:</i> 2/23/99  |         |     |

## TELEPHONIC CONVERSATION RECORD

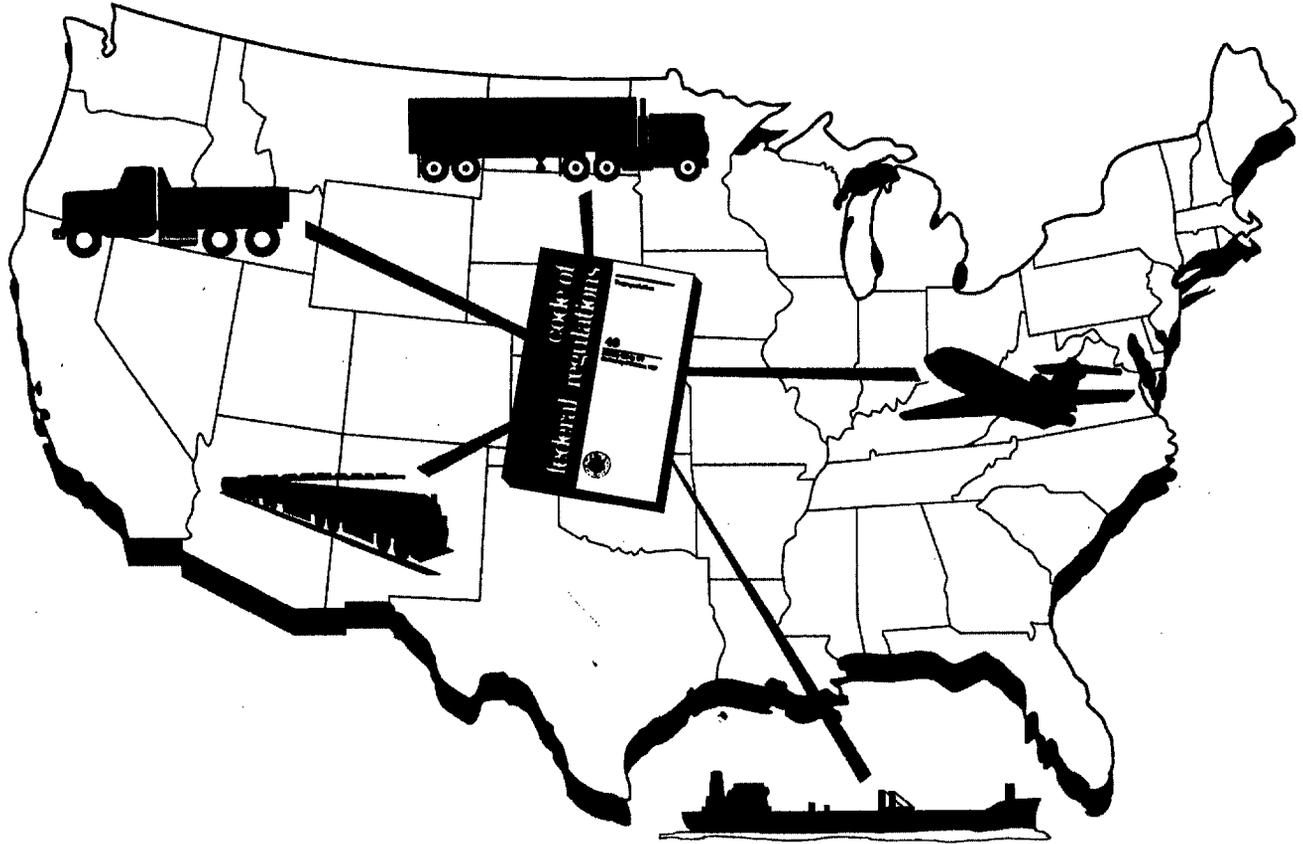
|  |                |            |
|--|----------------|------------|
| <i>Specialist Placing Call:</i> Eileen Mack  | <b>ROUTING</b> |            |
| <i>Date of Call:</i> 2/18/99, 3:45 p.m.  | <b>SYMBOL</b>  | <b>INT</b> |
| <i>Person(s) Contacted:</i> Wayne Lester, Manager, Safety Programs   |                |            |
| <i>Their Organization:</i> Allegheny Airlines, Inc., 1000 Rosedale Ave., Middletown, PA 17057, (717) 948-1910  |                |            |
| <i>Date of Incoming Letter:</i> No date (Received 2/9/99)  |                |            |
| <i>Specific Subject (including section #'s and key words):</i> Is placing the ETIOLOGIC AGENTS-BIOMEDICAL MATERIAL label on a package an indication that this package contains a Division 6.2 (infectious substance) material?   |                |            |
| <p><i>Summary:</i> Mr. Lester says Allegheny does not carry hazardous materials. They move company mail and donor organs. Occasionally, donor organs come in with the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label and the pilots refuse to carry them. When they consult the DOT Charts 10 and 11, shippers and carriers are confused as to whether the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label belongs to OSHA or CDC and if the item is infectious or not. DOT Chart 10 says the label is from CDC's regulations. DOT Chart 11 says the label is from OSHA's. I informed Mr. Lester that if the ETIOLOGIC AGENTS--BIOMEDICAL MATERIAL label is used, the item is infectious. I also explained that the reference in DOT Chart 11 to OSHA regulations is incorrect. I explained that OSHA's symbol is a trefoil with the words BIOHAZARD written underneath it. I also explained that it is used to express OSHA's universal precautions regulations, which provide relief for materials containing human blood only when it is known they do not contain a blood borne pathogen.</p> |                |            |
| <p><i>Comments for Further Action:</i> Forward the draft for concurrence and signature. The incoming letter is not dated, do not include a letter date in response.</p>  |                |            |
| <p><i>Specialist Signature:</i> </p>   |                |            |
| <p><i>Date:</i> 2/18/99</p>  |                |            |



U.S. Department of  
Transportation  
**Research and  
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Administration**

# **DOT CHART 10**

## **Hazardous Materials Marking, Labeling & Placarding Guide**



Refer to 49 CFR, Part 172:

Marking - Subpart D

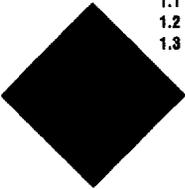
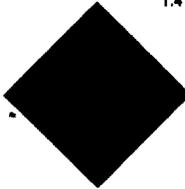
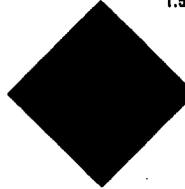
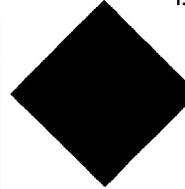
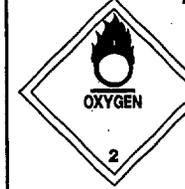
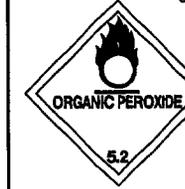
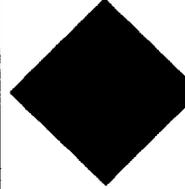
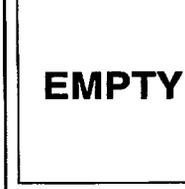
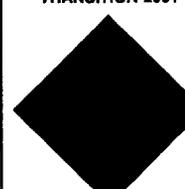
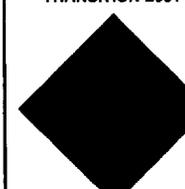
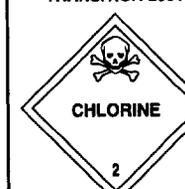
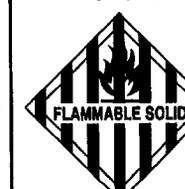
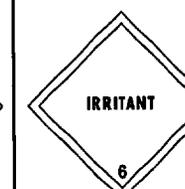
Labeling - Subpart E

Placarding - Subpart F

Emergency Response - Subpart G

**NOTE:** This document is for general guidance only and must not be used to determine compliance with 49 CFR, Parts 100-199.

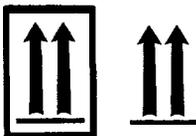
# Hazardous Materials Warning Labels

|  |   |   |   |   |  |  |
|--|---|---|---|---|--|--|
| <p><b>CLASS 1</b> Explosive<br/>1.1<br/>1.2<br/>1.3</p>  <p>*Include appropriate division number and compatibility group letter.</p> | <p><b>CLASS 1</b> Explosive<br/>1.4</p>  <p>*Include appropriate compatibility group letter.</p> | <p><b>CLASS 1</b> Explosive<br/>1.5</p>  <p>*Include appropriate compatibility group letter.</p>   | <p><b>CLASS 1</b> Explosive<br/>1.6</p>  <p>*Include appropriate compatibility group letter.</p> | <p><b>CLASS 2</b> Division<br/>2.1</p>  <p>Flammable gas</p>      | <p><b>CLASS 2</b> Division<br/>2.2</p>  <p>Non-flammable gas</p>  | <p><b>CLASS 2</b> Division<br/>2.2</p>  <p>Oxygen</p>           |
| <p><b>CLASS 2</b> Division<br/>2.3</p>  <p>Poison gas</p>  | <p><b>CLASS 3</b></p>  <p>Flammable liquid</p>   | <p><b>CLASS 4</b> Division<br/>4.1</p>  <p>Flammable solid</p>   | <p><b>CLASS 4</b> Division<br/>4.2</p>  <p>Spontaneously Combustible</p>                         | <p><b>CLASS 4</b> Division<br/>4.3</p>  <p>Dangerous when wet</p> | <p><b>CLASS 5</b> Division<br/>5.1</p>  <p>Oxidizer</p>   | <p><b>CLASS 5</b> Division<br/>5.2</p>  <p>Organic peroxide</p> |
| <p><b>CLASS 6</b> Division<br/>6.1</p>  <p>Poison-Packing Group I and II</p>   | <p><b>CLASS 6</b> Division<br/>6.1</p>  <p>Poison-Packing III</p>                                | <p><b>CLASS 6</b> Division<br/>6.2</p>  <p>Infectious substance</p>  |  <p>42 CFR 72.3 Etiological agent label may apply.</p>   | <p><b>CLASS 7</b> I</p>   | <p><b>CLASS 7</b> II</p>    | <p><b>CLASS 7</b> III</p>                                       |
| <p><b>CLASS 8</b></p>  <p>Corrosive</p>  | <p><b>CLASS 9</b></p>    | <p><b>SUBSIDIARY RISK LABELS</b></p>  <p>Explosive<br/>Flammable gas<br/>Flammable liquid<br/>Flammable solid<br/>Corrosive<br/>Oxidizer<br/>Poison<br/>Spontaneously Combustible<br/>Dangerous when wet</p> <p>The class number may not be displayed on a subsidiary label (see Section 172.402).</p> |   | <p><b>EMPTY</b></p>  <p>Empty</p>                               | <p><b>FOR AIRCRAFT</b></p> <p>Cargo Aircraft Only</p>  <p>MAGNETIZED MATERIAL<br/>KEEP AWAY FROM AIRCRAFT COMPASS AND EQUIPMENT</p> |  |
| <p><b>TRANSITION-2001</b></p>    | <p><b>TRANSITION-2001</b></p>    | <p><b>TRANSITION-2001</b></p>    | <p><b>TRANSITION-2001</b></p>    | <p><b>TRANSITION-2001</b></p>  <p>CHLORINE</p>                  | <p><b>TRANSITION-2001</b></p>  <p>FLAMMABLE SOLID</p>   | <p><b>TRANSITION-2001</b></p>  <p>IRRITANT</p>                |

## HAZARDOUS MATERIALS PACKAGE MARKINGS

INNER PACKAGES COMPLY WITH PRESCRIBED SPECIFICATIONS

§172.25(a)(4)



§172.312(a)



§172.322



§172.325

**DANGER**  
The loading of this car has been FULCRATED or TREATED with \_\_\_\_\_  
(Name of poisonous liquid, solid, or gas)

BEFORE UNLOADING, open both doors and DO NOT BREATHE until car is free of gas. REMOVE ALL POISONOUS MATERIAL before release of empty car.

§173.9

**INHALATION HAZARD**

§172.313(a)

CONSUMER COMMODITY

**ORM-D**

§172.316(a)

CONSUMER COMMODITY

**ORM-D-AIR**

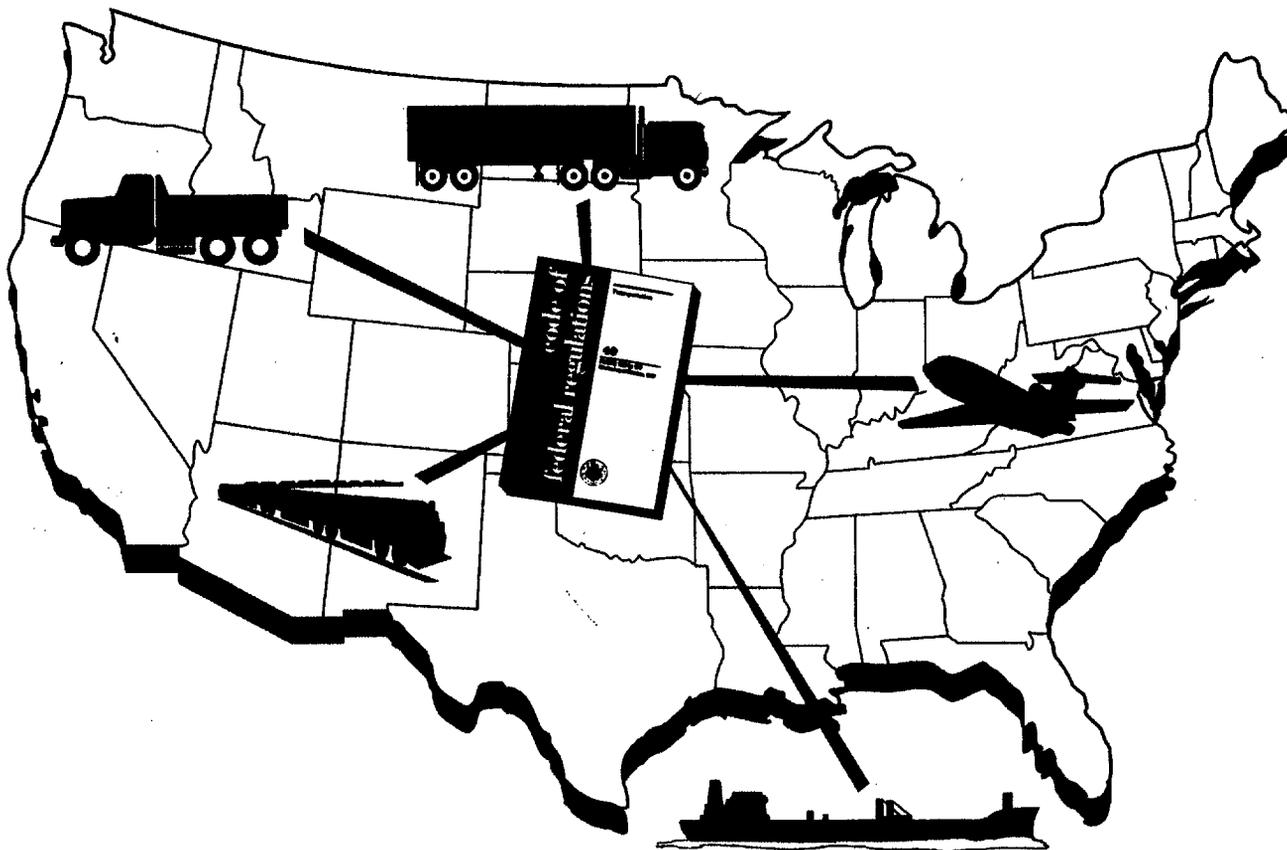
§172.316(a)(1)

Keep a copy of the DOT Emergency Response Guidebook handy!



U.S. Department of  
Transportation  
Research and  
Special Programs  
Administration

# Hazardous Materials Marking, Labeling & Placarding Guide



Refer to 49 CFR, Part 172:

Marking - Subpart D

Labeling - Subpart E

Placarding - Subpart F

Emergency Response - Subpart G

**NOTE:**

# Hazardous Materials Warning Labels

|  |  |  |   |  |  |   |
|--|--|--|---|--|--|---|
| <p>CLASS 1 Explosive<br/>1.1<br/>1.2<br/>1.3</p> <p>*Include appropriate division number and compatibility group letter.</p> | <p>CLASS 1 Explosive<br/>1.4</p> <p>*Include appropriate compatibility group letter.</p>   | <p>CLASS 1 Explosive<br/>1.5</p> <p>*Include appropriate compatibility group letter.</p> | <p>CLASS 1 Explosive<br/>1.6</p> <p>*Include appropriate compatibility group letter.</p>  | <p>CLASS 2 Division<br/>2.1</p> <p>Flammable gas</p>                                     | <p>CLASS 2 Division<br/>2.2</p> <p>Non-flammable gas</p> | <p>CLASS 2 Division<br/>2.2</p> <p>Oxygen</p>           |
| <p>CLASS 2 Division<br/>2.3</p> <p>Poison gas</p>  | <p>CLASS 3</p> <p>Flammable liquid</p>   | <p>CLASS 4 Division<br/>4.1</p> <p>Flammable solid</p>                                   | <p>CLASS 4 Division<br/>4.2</p> <p>Spontaneously Combustible</p>  | <p>CLASS 4 Division<br/>4.3</p> <p>Dangerous when wet</p>                                | <p>CLASS 5 Division<br/>5.1</p> <p>Oxidizer</p>          | <p>CLASS 5 Division<br/>5.2</p> <p>Organic peroxide</p> |
| <p>CLASS 6 Division<br/>6.1</p> <p>Poison-Inhalation Hazard only, Zone A or B.</p>   | <p>CLASS 6 Division<br/>6.1</p> <p>POISON<br/>Placard 454 kg (1,001 lbs) or more of PG I or II, other than Zone A or B, Inhalation hazard.</p> | <p>CLASS 6 Division<br/>6.1</p> <p>Poison-PG III</p>                                     | <p>CLASS 6 Division<br/>6.2</p> <p>Infectious substance</p>   | <p>29 CFR 1910.1030 BIOHAZARD marking may be used for Regulated Medical Waste (RMW).</p> | <p>CLASS 7</p> <p>Radioactive WHITE-I</p>                | <p>CLASS 7</p> <p>Radioactive YELLOW-II</p>             |
| <p>CLASS 7</p> <p>Radioactive YELLOW-III</p>   | <p>CLASS 8</p> <p>Corrosive</p>  | <p>CLASS 9</p> <p>Miscellaneous</p>  | <p>SUBSIDIARY RISK LABELS</p> <ul style="list-style-type: none"> <li>Explosive</li> <li>Flammable gas</li> <li>Flammable liquid</li> <li>Flammable solid</li> <li>Corrosive</li> <li>Oxidizer</li> <li>Poison</li> <li>Spontaneously Combustible</li> <li>Dangerous when wet</li> </ul> <p>The class number may not be displayed on a subsidiary label (see Section 172.402).</p> |  | <p>EMPTY</p> <p>Empty-Radioactive</p>                    | <p>FOR AIRCRAFT</p> <p>Cargo Aircraft Only</p>          |
| <p>TRANSITION-2001</p>   | <p>TRANSITION-2001</p>   | <p>TRANSITION-2001</p>   | <p>TRANSITION-2001</p>  | <p>TRANSITION-2001</p>   | <p>TRANSITION-2001</p>                                   |   |

## HAZARDOUS MATERIALS MARKINGS

|  |                 |  |                    |   |
|--|-----------------|--|--------------------|---|
| <p>INNER PACKAGES COMPLY WITH PRESCRIBED SPECIFICATIONS</p> <p>§173.25(a)(4)</p> | <p>§172.322</p> | <p>THIS UNIT IS UNDER FUMIGATION WITH _____ APPLIED ON _____ DATE _____</p> <p><b>DO NOT ENTER</b></p> <p>§172.302(g) and §173.9</p> | <p>§172.313(a)</p> | <p>CONSUMER COMMODITY</p> <p><b>ORM-D</b></p> <p>§172.316(a)</p>        |
| <p>§172.312(a)</p>   | <p>§172.325</p> |  |                    | <p>CONSUMER COMMODITY</p> <p><b>ORM-D-AIR</b></p> <p>§172.316(a)(1)</p> |

Keep a copy of the North American Emergency Respons

**OSHA**Occupational Safety & Health Administration  
U.S. Department of Labor

## OSHA Regulations (Standards - 29 CFR) Bloodborne pathogens. - 1910.1030

### ← OSHA Regulations (Standards - 29 CFR) - Table of Contents

- **Standard Number:** 1910.1030
- **Standard Title:** Bloodborne pathogens.
- **SubPart Number:** Z
- **SubPart Title:** Toxic and Hazardous Substances

#### Interpretation(s)

(a)

Scope and Application. This section applies to all occupational exposure to blood or other potentially infectious materials as defined by paragraph (b) of this section.

(b)

Definitions. For purposes of this section, the following shall apply:

"Assistant Secretary" means the Assistant Secretary of Labor for Occupational Safety and Health, or designated representative.

"Blood" means human blood, human blood components, and products made from human blood.

"Bloodborne Pathogens" means pathogenic microorganisms that are present in human blood and can cause disease in humans. These pathogens include, but are not limited to, hepatitis B virus (HBV) and human immunodeficiency virus (HIV).

"Clinical Laboratory" means a workplace where diagnostic or other screening procedures are performed on blood or other potentially infectious materials.

"Contaminated" means the presence or the reasonably anticipated presence of blood or other potentially infectious materials on an item or surface.

"Contaminated Laundry" means laundry which has been soiled with blood or other potentially infectious materials or may contain sharps.

"Contaminated Sharps" means any contaminated object that can penetrate the skin including, but not limited to, needles, scalpels, broken glass, broken capillary tubes, and exposed ends of dental wires.

"Decontamination" means the use of physical or chemical means to remove, inactivate, or destroy bloodborne pathogens on a surface or item to the point where they are no longer capable of transmitting infectious particles and the surface or item is rendered safe for handling, use, or disposal.



**BIOHAZARD**