

Changes To CFR 49 Regulations

Walter Douglass
04-19-2007

Picture of Panic



Regulations As We Knew Them

- Infectious Substance UN2814
- Diagnostic Specimens UN3373
- Unregulated Specimens (No UN#)

Side By Side Comparison: New Terminology Vs Old

Old Terminology	New Terminology
■ Risk Group I Unregulated	■ Routine Screening Tests (Excepted Specimens) ■ Exempt Human specimen
■ Risk Group II & III Diagnostics Specimens (UN3373)	■ Biological Substances Category B ■ (UN3373)
■ Risk Group III & IV Infectious Substance (UN2814)	■ Infectious Substances Affecting Humans (UN2814)



EVERYTHING
[Handwritten notes and diagrams on a white sheet of paper, including a flowchart and various text annotations.]



TO:
CDC
1600 CLIFTON RD NE
ATTN: DASH
ATLANTA, GA 30333
404-438-1300

FROM:
ISAAC SALAZAR
TEXAS DEPT OF STATE HEALTH SERVICES
1100 W. 49TH ST
AUSTIN, TX 78756
512-438-7000

UN3373
DIAGNOSTIC SPECIMENS

TO:
CDC
1600 CLIFTON RD NE
ATTN: DASH
ATLANTA, GA 30333
404-438-1300

FROM:
ISAAC SALAZAR
TEXAS DEPT OF STATE HEALTH SERVICES
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UN3373

BIOLOGICAL SUBSTANCE
CATEGORY B



Why The Changes?

- To make standards consistent with United Nation's terminology.
- To clarify existing requirements.
- To promote compliance.
- Facilitate Domestic and International transportation

Benefits of Changes

Old Terminology	New Terminology
<ul style="list-style-type: none">■ Designed by laboratories, not transport experts	<ul style="list-style-type: none">■ Designed by United Nations Experts
<ul style="list-style-type: none">■ Includes laboratory handling concerns as well as transport concerns	<ul style="list-style-type: none">■ Considers transport concerns only

Definitions

- Category A Infectious Substance
 - Is an infectious substance transported in a form capable of causing permanent disability or life threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs.
 - And exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals.
 - Category A Infectious Substances are assigned to existing identification numbers UN2184 and UN2900.

Definitions Continued

- Category B Biological Substances
 - Does not meet the criteria for inclusion of a Category A Infectious Substance.
 - Does not cause permanent disability or life threatening or fatal disease to humans or animals when exposed to it.

Definitions Continued

- Excepted Specimens
 - Human or animal specimen transported for routine testing when the testing is not related to the diagnosis of an infectious disease and when there is no reason to suspect the sample is infectious.

Examples of Infectious Substances Category A

- *Mycobacterium tuberculosis* (cultures only)
- *Brucella abortus* (cultures only)
- Human immunodeficiency virus (cultures only)
- Dengue virus (cultures only)
- Herpes B virus (cultures only)
- *Rickettsia rickettsia* (cultures only)
- Rabies and other lyssaviruses (cultures only)

Examples of Category B substances

- Human immunodeficiency virus (Clinical specimens)
- Mycobacterium tuberculosis (Clinical specimens)
- Rabies virus (animal heads)
- Arbovirus (serum or CSF specimens)
- Syphilis (serum, blood, CSF)
- Hepatitis A, B , C (serum or blood)

Examples of Excepted Specimens

- Blood and urine not known or expected to have a pathogen
- Dried blood spots
- Routine samples not being tested for pathogens

Who Needs Training?

- 49 CFR defines a hazmat employee as a person who works for a hazmat employer and directly affects hazmat transportation safety.
 - Loads, unloads, or handles hazardous materials.
 - Prepares hazardous materials for transportation.
 - Is responsible for safety of transporting hazardous materials.
 - Operates a vehicle used to transport hazardous materials.

Training requirements for Ground transportation

- To ship Category B Biological Substances, the shipper must be familiar with the regulations.
- To Ship Category A infectious substances, the shipper must be trained and tested in CFR 49 regulations

Training requirements for air transportation

- To ship Category A and Category B, the shipper must be trained and tested in I.A.T.A. regulations.

Training Requirements for Excepted Specimens

- Familiar with packaging and labeling regulations


Category A Infectious Substance Labeling

- UN2814 and proper shipping name
- Infectious substance sticker
- Return address with name and telephone number
- Shipping address with name and telephone number
- 24 hour emergency number
- Directional indicator arrows

Shipper: Sandra Gomez
City of Houston
1115 S. Braeswood
Houston, TX 77030
PH: 713-558-3460 Re-Order Part # STP-887

SYPA

UN2814
Infectious Substance,
Affecting Humans
T. Pallidum


INFECTIOUS SUBSTANCE
IN CASE OF DAMAGE OR LEAKAGE
IMMEDIATELY NOTIFY
PUBLIC HEALTH AUTHORITY
IN U.S.A.
NOTIFY DIRECTOR - CDC
ATLANTA, GA
1-800-232-8124
6


Consignee: Miriam Johnson
Texas Dept of Health
1100 W. 49th Street
Austin, TX 78756-3194
PH: 512-458-7319 Re-Order Part # STP-888

QUANTITY:
DRY ICE
UN 1845
2.5 KG NET WT

PERSON RESPONSIBLE
(NAME & NUMBER): Cynthia Turner
713-558-3460


9

TC-125-1A/8-37
REGISTERED WITH TRANSPORT CANADA
ENREGISTRÉ À TRANSPORTS CANADA

 **4G CLASS 6.2/06**
CAN/8-37 SAF-T-PAK

Category B Biological Substance Labeling

- Un3373 sticker
- "Category B Biological Substance"
- Return address with name and phone number
- Shipping address with name and phone number
- Directional indicator arrows

TO:
DSHS Laboratory Services
1100 W. 49th St. MC-1947
Austin, Texas 78756-3199
512-458-7318

FROM:
Joanna Nichols, MIH
BIDS
601 W. Sesame Dr.
Harlingen, Texas 78550
956-444-3268

Shipper's Declaration not Required

Part B is required

Dry ice amount must be in kilograms.

Note: 2 lbs. = 1 kg.

Airwaybill/airbills must have the following:

1. "Dangerous Goods-Shipper's Declaration not required"
2. Dry Ice: 5 UN1845
3. Net weight: 4 kg (9 lbs)



DRY ICE,
_____ kg.

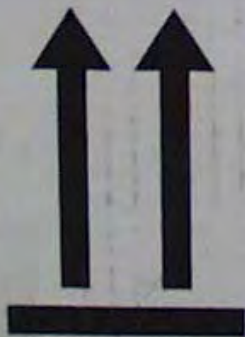
Shipper's name and Address

9

UN1845

Consignee Name and Address

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BIOLOGICAL SUBSTANCE
CATEGORY B

EP tubes
- MC ends MC starts
- MIU/MEV = MC
- MC ends C starts
- MEV
- UNSATS

CLINICAL DIAGNOSTIC SPECIMEN
BUSINESS REPLY LABEL
 FIRST CLASS MAIL PERMIT NO. 228 AUSTIN TX
 POSTAGE WILL BE PAID BY ADDRESSEE

DEPARTMENT OF STATE HEALTH SERVICES
 LABORATORY
 WALTER DOUGLASS
 PO BOX 149143
 AUSTIN TX 78714-9903

(Department of State Health Services)

NO POSTAGE
 NECESSARY
 IF MAILED
 IN THE
 UNITED STATES

X

NAME, TEL, RETURN ADDRESS OF CONTACT PERSON

UN3373
 BIOLOGICAL SUBSTANCE
 CATEGORY B
 THIS
 (371) 808-7111 X 7199

BUSINESS REPLY LABEL
 FIRST CLASS MAIL PERMIT NO. 228 AUSTIN TX
 POSTAGE WILL BE PAID BY ADDRESSEE

DEPARTMENT OF STATE HEALTH SERVICES
 LABORATORY
 WALTER DOUGLASS
 PO BOX 149143
 AUSTIN TX 78714-9903

NO POSTAGE
 NECESSARY
 IF MAILED
 IN THE
 UNITED STATES

FROM

CLINICAL DIAGNOSTIC SPECIMEN

TO
 DEPARTMENT OF STATE HEALTH SERVICES
 Laboratory
 1100 West 49th Street
 AUSTIN, TEXAS 78756-3194

To Avoid Delay
 Use Proper
 Postage

NAME, TEL, RETURN ADDRESS OF CONTACT PERSON

UN3373
 BIOLOGICAL SUBSTANCE
 CATEGORY B
 (371) 808-7111 X 7199

DEPARTMENT OF STATE HEALTH SERVICES
 LABORATORY
 WALTER DOUGLASS
 1100 WEST 49TH STREET
 AUSTIN TX 78756-3194

TO AVOID DELAY
 USE PROPER
 POSTAGE

Excepted Human and Animal Specimens

- “Exempt human specimen”
- “Exempt animal specimen”
- Return address
- Shipping address
- No “Biohazard” label

Transport by Private or Contract Carrier

- The HMR currently does not regulate infectious substance transported by a private carrier or contract carrier in a motor vehicle used exclusively to transport these items

Changes to Dangerous Goods Shipper's Declaration

- The "UN number" is now in the first column.
- Column for "Subsidiary Risk" is eliminated.
- "Proper Shipping Name" is now second column.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

(Provide at least three copies to the airline.)

Shipper	Air Waybill No. Page of Pages Shipper's Reference Number
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Consignee	
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Two completed and signed copies of this Declaration must be handed to the operator

WARNING

Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: <i>(delete non applicable)</i>	Airport of Departure		
<table border="1" style="display: inline-table;"> <tr> <td style="padding: 2px;">PASSENGER AND CARGO AIRCRAFT</td> <td style="padding: 2px;">CARGO AIRCRAFT ONLY</td> </tr> </table>	PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY	
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY		
Airport of Destination:			

Shipment type: *(delete non-applicable)*
 NON-RADIOACTIVE RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification				Quantity and type of packaging	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack-ing Group			

Additional Handling Information

Emergency Telephone Number

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable International and National Governmental Regulations. I declare that all of the applicable air transport requirements have been met.

Name/Title of Signatory

Place and Date

Signature
(see warning above)

FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS, OR TREATMENT.

Returning Shipping Packers

- DSHS does not pay to return other lab's shipping packers.
- Postage stamps or a carrier's account number is required before DSHS lab will return empty packers.
- Hazmat labeling must be covered.



El Paso City-County Health Laboratory
4505 Alberta Drive – 2nd floor
El Paso, Texas 79905

Helpful Websites

- <http://hazmat.dot.gov>
- <http://www.dshs.state.tx.us/lab>
- <http://www.fedex.com/us/services/options/dangerousgoods/declarationforms.html>
- <http://www.dhl-usa.com/home/home.asp>

