

POSTAL SERVICE

39 CFR Part 111

New Mailing Standards for Division 6.2 Infectious Substances

AGENCY: Postal Service.

ACTION: Interim rule with request for comments.

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**SUMMARY:** The Postal Service is revising its mailing standards and packaging requirements for Division 6.2 infectious substances based on the criteria published by the World Health Organization. Our revised standards adopt many of the changes the Department of Transportation made to its regulations for the shipment and packaging of hazardous materials. We also harmonize our standards with the World Health Organization Guidance on Regulations for the Transport of Infectious Substances and the International Civil Aviation Organization Technical Instructions for the Safe Transport of Dangerous Goods by Air. In addition, we prohibit Category A infectious substances in the mail.

**DATES:** These changes are effective November 1, 2006. We will accept your comments on or before December 1, 2006.

**ADDRESSES:** Mail or deliver written comments to the Manager, Mailing Standards, U.S. Postal Service, 475 L'Enfant Plaza, SW., Room 3436, Washington, DC 20260-3436. You may inspect and photocopy all written comments at USPS Headquarters Library, 475 L'Enfant Plaza, SW., 11th Floor N, Washington, DC between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Bert Olsen, 202-268-7276.

**SUPPLEMENTARY INFORMATION:** The Postal Service is subject to the legal restrictions in Title 18 of United States Code 1716, which prohibits the mailing of "all disease, germs, or scabs, and all other natural or artificial articles, compositions, or material which may kill or injure another, or injure the mails or other property" if that material is outwardly or of its own force dangerous to life, health, or property. For legal and safety reasons, the mailing standards for hazardous materials in Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM) closely adhere to Department of Transportation (DOT) regulations in 49 CFR, and include additional limitations and prohibitions.

On June 6, 2003, we published a final rule in the Federal Register (68 FR 33858) to revise the standards for mailing infectious substances. The revision harmonized our standards with many of the DOT regulations in effect at that time for the transportation of infectious substances. On June 2, 2006, DOT published new regulations (71 FR 32244) to revise the transportation requirements for infectious substances and adopt new classification criteria, new exceptions, and new packaging and hazard communication requirements consistent with revised international standards.

This interim rule harmonizes our mailing standards with the packaging category system for infectious substances developed by the World Health Organization (WHO) in 2005. Our revisions are largely consistent with DOT regulations for shipping and packaging hazardous materials and with the International Civil Aviation Organization (ICAO) Technical Instructions for the Safe Transport of Dangerous Goods by Air. We also prohibit Category A infectious substances in the mail. Category A includes infectious substances transported in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy people or animals if exposure occurs. Our prohibition of Category A infectious substances is consistent with ICAO's recommendation that Category A substances not be carried by mail.

Our interim rule:

Revises the classification system from the current four-tiered risk group classification system to a two-tiered system. Infectious substances are now classified as "Category A" and

Category B," depending on the type of substance.

Identifies Category A infectious substances as nonmailable.

Replaces the shipping name "Diagnostic Specimen" with "Biological substance, Category B."

Adopts packaging requirements for Category B infectious substances consistent with those in the DOT regulations, the WHO Guidance, and the ICAO Technical Instructions.

These revisions to our mailing standards will provide a greater level of safety for handling and transporting mailable infectious substances. These changes will also facilitate domestic and international transportation by aligning our mailing standards with the current international standards for the transport of hazardous materials.

We provide the new standards below. We will publish a final rule and may further revise the standards based on the comments we receive.

Although we are exempt from the notice and comment requirements of the Administrative Procedure Act regarding proposed rulemaking (see 5 U.S.C. 553(b), (c)), we invite public comments on the following revisions to Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM), incorporated by reference in the Code of Federal Regulations. See 39 CFR 111.1.

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#### List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

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Accordingly, 39 CFR part 111 is amended as follows:

#### PART 111--[AMENDED]

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1. The authority citation for 39 CFR part 111 continues to read as follows:

Authority: 5 U.S.C. 552(a); 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001-3011, 3201-3219, 3403-3406, 3621, 3626, 5001.

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2. Revise the following sections of Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM), as follows:

#### 600 Basic Standards for All Mailing Services

##### 601 Mailability

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##### 10.0 Hazardous Materials

\* \* \* \* \*

##### 10.17 Infectious Substances (Hazard Class 6, Division 6.2)

###### 10.17.1 General

[Revise the first and last sentences in 10.17.1 as follows:]

Division 6.2 materials include infectious substances, biological products, regulated medical waste, sharps medical waste, used health care products, and forensic materials. \* \* \* Unless otherwise noted, all mailable Division 6.2 materials must meet the mail preparation requirements for air transportation.

###### 10.17.2 Definitions

The terms used in the standards for Division 6.2 materials are defined as follows:

[Revise item a as follows:]

a. Infectious substance means a material known or reasonably expected to contain a pathogen. A pathogen is a microorganism that can cause disease in humans or animals. Examples of pathogens include bacteria, viruses, fungi, and other infectious agents. An infectious substance must be assigned to one of the following two categories:

1. Category A: An infectious substance transported in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure occurs. Category A infectious substances are not mailable. A Category A

infectious substance is assigned the identification number UN 2814 or UN 2900, based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal.

2. Category B: An infectious substance that does not meet the criteria for inclusion in Category A. A mailpiece known or suspected to contain a Category B infectious substance must bear the proper shipping name "Biological substance, Category B" on the address side of the mailpiece and must be assigned to and marked with identification number UN 3373 or, for regulated medical waste and sharps medical waste, identification number UN 3291.

[Revise item b as follows:]

b. Biological product means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product or arsphenamine or derivative of arsphenamine (or any other trivalent arsenic compound) intended to prevent, treat, or cure a disease or condition of humans or animals. A biological product includes a material subject to regulation under 42 U.S.C. 262 or 21 U.S.C. 151-159. Unless otherwise excepted, mark these mailpieces with identification number UN 3373 when they contain a biological product known or reasonably expected to contain a pathogen that meets the definition of a Category B infectious substance.

[Revise item c as follows:]

c. Cultures are infectious substances that result from a process by which pathogens are intentionally propagated. This definition does not include a human or animal patient specimen as defined in 10.17.2e.

[Replace item d with new item d as follows:]

d. Exempt human or animal specimen means a human or animal sample (including, but not limited to, secretta, excreta, blood and its components, tissue and tissue fluids, and body parts) transported for routine testing not related to the diagnosis of an infectious disease. Typically, exempt human specimens are specimens for which there is a low probability that the sample is infectious, such as specimens for drug or alcohol testing; cholesterol testing; blood glucose level testing; prostate-specific antigens (PSA) testing; testing to monitor heart, kidney, or liver function; pregnancy testing; and testing for diagnosis of noninfectious diseases such as cancer biopsies. Exempt human or animal specimens are not subject to regulations as hazardous materials but must be packaged according to 10.17.10.

[Replace item e with new item e as follows:]

e. Patient specimen means material that is collected directly from humans or animals and transported for purposes such as diagnosis and research. Patient specimens include excreta, secretta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media (such as transwabs, culture media, and blood culture bottles).

[Replace item f with new item f as follows:]

f. Regulated medical waste, for USPS purposes, means a soft waste material (other than a sharp) derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Soft medical waste includes items such as used rubber gloves, swabs, gauze, tongue depressors, and other similar material. Mark these mailpieces with identification number UN 3291.

[Delete Exhibit 10.17.2f, Risk Group Criteria. Revise item g as follows:]

g. Sharps medical waste, for USPS purposes, means a medical waste object that is capable of cutting or penetrating skin or packaging material and that is contaminated with a pathogen or may become contaminated with a pathogen derived from the medical treatment, diagnosis, immunization, or biomedical research of a human or animal. Sharps include used medical waste such as needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires. Mark these mailpieces with identification number UN 3291.

[Revise the last part of item h as follows:]

h. \* \* \* UN 2814, UN 2900, or UN 3373, as appropriate. A toxin known or suspected to contain a Category A infectious substance is not mailable. A toxin known or suspected to contain a Category B infectious substance must be marked UN 3373 and packaged under 10.17.5. Toxins from plant, animal, or bacterial sources that do not contain an infectious substance, and are not contained in an infectious substance, may be considered for classification as Division 6.1 toxic substances under 10.16.

[Delete the last sentence in item i. Revise the last part of the new last sentence as follows:]

i. \* \* \* to remove or mitigate the infectious hazard prior to transport.

### 10.17.3 Nonregulated Materials

[Revise 10.17.3 as follows:]

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable

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when the packaging requirements in 10.17.9 are met:

a. A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture. A biological product known or suspected to contain a Category B infectious substance must be marked UN 3373 and packaged under 10.17.5. A biological product known or suspected to contain a Category A infectious substance is not mailable.

b. Blood collected for the purpose of blood transfusion or the preparation of blood products; blood products; plasma; plasma derivatives; blood components; tissues or organs intended for use in transplant operations; and human cell, tissues, and cellular and tissue-based products regulated under the Public Health Service Act (42 U.S.C. 264-272) or the Food, Drug, and Cosmetic Act (21 U.S.C. 332 et seq.).

c. Blood, blood plasma, and blood components collected for the purpose of blood transfusion or the preparation of blood products and sent for testing as part of the collection process, except where the person collecting the blood has reason to believe it contains a Category B infectious substance, in which case the test sample must be shipped as a Category B infectious substance. Materials known or suspected to contain a Category A infectious substance are not mailable.

d. Dried blood spots, collected by applying a drop of blood to absorbent material, or dried specimens for fecal occult blood detection. (These materials are not classified as exempt human or animal specimens.)

e. Forensic material containing a biological material, such as tissue, body fluid, excreta, or secretions, not expected to contain a Category A or Category B infectious substance and transported on behalf of a U.S. Government agency or a state, local, or Indian tribal government agency. A forensic material known or suspected to contain a Category B infectious substance must be shipped as a Category B infectious substance. A forensic material known or suspected to contain a Category A infectious substance is not mailable.

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[Revise Exhibit 10.17.4 as follows:]

Exhibit 10.17.4 Packaging Standards for Division 6.2 Infectious Substances

Material being mailed	Packaging standards		
	Nonregulated	Category A	Category B
Blood for Transfusion.....	10.17.9	nm	10.17.5
Biological Product.....	10.17.9	nm	10.17.5
Culture or Stock.....	10.17.9	nm	10.17.5
Patient Specimen.....	na	nm	10.17.5
Exempt Human or Animal Specimen.....	10.17.10	na	na
Forensic Material.....	10.17.9	nm	10.17.5
Regulated Medical Waste.....	10.17.6	nm	10.17.6
Sharps Waste.....	10.17.6	nm	10.17.6
Toxin *.....	10.16.4	nm	10.17.5
Treated Medical Waste.....	10.17.9	n/a	n/a
Used Health Care Product.....	10.17.7	nm	10.17.7

nm = Not mailable. n/a = Not applicable.

\* Toxin means a Division 6.1 material from a plant, animal, or bacterial source. A toxin containing an infectious substance or a toxin contained in an infectious substance must be classified as Division 6.2; described as an infectious substance; and assigned to UN 2814, UN 2900, or UN 3373, as appropriate. A Division 6.1 toxin that can qualify as an ORM-D material is permitted when packaged under 10.16.3 or 10.16.4.

[Revise 10.7.5 as follows:]

10.17.5 Packaging Category B Infectious Substances

A material that is classified as a Category B infectious substance and that meets the definition in 10.17.2a2 must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199, and sent as First-Class Mail, Priority Mail, or Express Mail. Each primary receptacle containing a liquid must be leakproof and surrounded by absorbent material sufficient to protect the primary receptacle and

absorb the total amount of liquid should the primary receptacle leak or break. Each primary receptacle containing a solid must be siftproof. Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The primary and secondary packaging must be enclosed in a rigid outer shipping container. A single primary receptacle must not contain more than 1 liter (34 ounces) of a liquid specimen or 4 kg (8.8 pounds) of a solid specimen. Two or more primary receptacles whose combined volume does not exceed 4 liters (1 gallon) for liquids or 4 kg (8.8 pounds) for solids may be enclosed in a single secondary container. In addition:

- a. The secondary container must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2.
- b. The primary receptacle or secondary packaging must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 95 kPa (0.95 bar, 14 psi) in the range of -40[deg]C to 55[deg]C (-40[deg]F to 130[deg]F).
- c. All mailpieces sent under 10.17.5 must be marked on the address side with the shipping name "Biological substance, Category B" and "UN 3373" as outlined in 49 CFR 173.199 (a)(5). Regulated medical waste and sharps medical waste as defined in 10.17.2f and 10.17.2g must be marked UN 3291. See 10.17.6.
- d. Orientation arrows are not required on these mailpieces but may be used.
- e. The outer packaging must show the name and telephone number of a person who is knowledgeable about the material shipped and has comprehensive emergency response and incident mitigation information, or of someone who has immediate access to the person with such knowledge and information.

[Delete 10.17.6 and renumber 10.17.7 through 10.17.10 as 10.17.6 through 10.17.9.]

#### 10.17.6 Sharps Waste and Other Mailable Regulated Medical Waste

[Revise the introductory text as follows:]

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Regulated medical waste and sharps medical waste known or suspected to contain a Category A infectious substance is not mailable. Regulated medical waste and sharps medical waste as defined in 10.17.2f and 10.17.2g, and containing materials classified as Category B infectious substances, must be marked UN 3291 and is permitted for mailing only using merchandise return service (see 507.10.0) with First-Class Mail or Priority Mail service, subject to the following requirements:

\* \* \* \* \*

[Revise item b as follows:]

b. Packaging. Regulated medical waste and sharps medical waste that also meets the definition of a Category A infectious substance is not mailable. A medical waste material treated by steam sterilization, chemical disinfections, or other appropriate method so that it no longer contains a Category A or Category B infectious substance must be packaged under 10.17.9. The packaging for regulated medical waste and sharps medical waste containing or suspected of containing a Category B infectious substance is subject to these standards:

\* \* \* \* \*

#### 10.17.7 Packaging Used Health Care Products

[Revise the introductory text as follows:]

A used health care product known or reasonably suspected to contain a Category A material is not mailable. A used health care product not suspected to contain an infectious material, or that is known or suspected to contain a Category B infectious substance, and is being returned to the manufacturer or manufacturer's designee is mailable as First-Class Mail, Priority Mail, or Express Mail subject to the following packaging requirements:

\* \* \* \* \*

[Revise the heading and introductory text in renumbered 10.17.8 as follows:]

#### 10.17.8 Packaging Forensic Material

Forensic material containing a biological material, such as tissue, body fluid, excreta, or secreta, and sent on behalf of a U.S. Government agency or a State, local, or Indian tribal government agency must be packaged under 10.17.9 when it is not known or suspected to contain a Category A or Category B infectious substance. Forensic material known or suspected to contain a Category A infectious substance is not mailable. Forensic material known or suspected to contain a Category B infectious substance as identified in 10.17.5 is

mailable as First-Class Mail, Priority Mail, or Express Mail when triple-packaged in a primary receptacle, secondary container, and a rigid outer shipping container as follows:

\* \* \* \* \*

[Revise the heading and text in renumbered 10.17.9 as follows:]

#### 10.17.9 Packaging Nonregulated Materials

Nonregulated materials as defined in 10.17.3 are not subject to regulation as hazardous materials but must be properly packaged when presented for mailing. Regulated medical waste, sharps medical waste, and used health care products must be packaged and mailed under 10.17.6 and 10.17.7. Exempt human and animal specimens must be packaged under 10.17.10. Nonregulated materials are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services mail. Such materials must be held within a securely sealed primary receptacle. The primary receptacle must be surrounded by sufficient absorbent material (for liquids) and cushioning material to protect the primary receptacle from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. Either the primary receptacle or the inner packaging must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2. The primary receptacle and the absorbent and cushioning material must be snugly enclosed in a rigid outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping container are not required. Nonregulated material specimens and biological products are subject to the following packaging standards:

a. Liquid Patient Specimens and Biological Products. Mailers must package a liquid nonregulated patient specimen, a forensic specimen, or a biological product (such as polio vaccine) as follows:

1. Not exceeding 50 ml. A patient specimen or biological product consisting of 50 ml or less per mailpiece must be packaged in a securely sealed primary receptacle. Two or more primary receptacles whose combined volume does not exceed 50 ml may be enclosed within a single mailpiece. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container with a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container must be securely sealed, and it may serve as the outer shipping container if it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2, except when the secondary container also serves as the outer shipping container. In that case, the biohazard symbol must appear on the inner packaging or on the primary container. A shipping paper and a content marking on the outer shipping container are not required.

2. Exceeding 50 ml. A liquid patient specimen, forensic material, or biological product that exceeds 50 ml must be packaged in a securely sealed primary receptacle. A single primary receptacle must not contain more than 500 ml of specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml may be enclosed in a single secondary container. Sufficient absorbent material and cushioning material to withstand shock and pressure changes must surround the primary receptacle(s), or be otherwise configured to take up the entire liquid contents in case of leakage. The primary receptacle(s) and the absorbent cushioning must be enclosed in a secondary container with a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) should leak during transport. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2. The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

b. Solid (or Dry) Specimen. A solid or dry specimen, such as a saliva swab, blood spot, fecal smear, culture or stock, or forensic material, must be completely dried before packaging in a mailing container or envelope. Cushioning material to withstand shock and pressure changes is required only if the dry specimen is placed in a breakable primary receptacle. When required, the cushioning material must surround the primary receptacle. The primary receptacle (and cushioning material, if required) must be enclosed in a secondary container with a siftproof

barrier that can prevent failure of the secondary container if the primary receptacle breaks during shipment. The secondary container must be securely sealed, and it may serve as the outer shipping container if it has sufficient strength to withstand ordinary postal processing. The secondary container must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2, except when the secondary container also serves as the outer shipping container. In that case, the biohazard symbol must appear either on the inner packaging or on the primary container receptacle. A shipping paper and a content marking on the outer shipping container are not required.

[Insert new 10.17.10 as follows:]

#### 10.17.10 Packaging Exempt Human or Animal Specimens

Exempt human or animal specimens as defined in 10.17.2d are not subject to regulation as hazardous materials but when presented for mailing must be triple-packaged in leakproof (for liquids) or siftproof (for solids) primary receptacles. Sufficient cushioning and absorbent materials must surround each primary receptacle containing liquid. Secondary containers for liquids must be leakproof. Secondary containers for solids must be siftproof. The primary and secondary packaging must be enclosed in a rigid outer shipping container. A single primary receptacle must not contain more than 500 ml of a liquid specimen or 500 grams of a solid specimen. Two or more primary receptacles whose combined volume does not exceed 500 ml (for liquids) or 500 grams (for solids) may be enclosed in a single secondary container. The secondary container cannot serve as the outer shipping container. The secondary container must be marked with the international biohazard symbol shown in Exhibit 10.17.6c2. The secondary container must be securely and snugly enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container. A shipping paper is not required. The outer shipping container must be marked on the address side with the words "Exempt human specimen" or "Exempt animal specimen," as appropriate. In addition, at least one surface of the outer packaging must have a minimum dimension of 3.9 inches x 3.9 inches (100 mm x 100 mm). Exempt human and animal specimens are mailable as First-Class Mail, Priority Mail, Express Mail, or Package Services mail.

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