POSTAL SERVICE

39 CFR Part 111

Hazardous Materials: Proposed Domestic Mail Manual Revisions for Division 6.2 Infectious Substances and Other Related Changes

AGENCY: Postal Service.

ACTION: Proposed rule.

SUMMARY: The Postal Service is proposing to revise the mailing standards in *Domestic Mail Manual* (DMM) C023 related to the requirements and packaging standards for mailable types of Division 6.2 infectious substances. These DMM revisions would adopt some of the regulatory and packaging changes for infectious substances that the U. S. Department of Transportation (DOT) made to Title 49 *Code of Federal Regulations* (49 CFR) in the **Federal Register** final rule published on August 14, 2002 (67 FR 53118) and the subsequent change published on August 27, 2002 (67 FR 54967). If the revisions proposed by the Postal Service were adopted, they would provide a greater level of safety for handling and transporting mailable infectious substances in the mailstream.

The proposed changes would also facilitate domestic and international air transportation by aligning the changes with the current international standards for the transport of hazardous materials via air.

Other minor changes and clarifications are proposed to the hazardous materials mailing standards in DMM C021, C023, C024, and F010 to improve clarity and reduce misunderstanding; to ensure the packaging integrity of mailable hazardous materials during Postal Service handling; and to provide a greater level of safety for Postal Service employees and the public.

DATES: Comments must be received on or before January 21, 2003.

ADDRESSES: Mail or deliver written comments to the Manager, Mail Preparation and Standards, U.S. Postal Service, 1735 North Lynn Street, Room 3025, Arlington, VA 22209–6038. Written comments may be submitted via fax to 703–292–4058. Copies of all written comments will be available for inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, at the Postal Service Headquarters Library, 475 L'Enfant Plaza SW., Room 11800, Washington, DC 20260–1540.

FOR FURTHER INFORMATION CONTACT: Jane Stefaniak (703) 292–3548, Mail Preparation and Standards, United States Postal Service.

SUPPLEMENTARY INFORMATION: The carriage of U.S. mail by the United States Postal Service (Postal Service) is regulated by Title 39 *Code of Federal Regulations* (39 CFR). Unlike commercial carriers, the Postal Service is not subject to the Federal regulations of the U.S. Department of Transportation (DOT) in Title 49 *Code of Federal Regulations* (49 CFR). The Postal Service is, however, subject to the legal restrictions in Title 18 *United States Code* 1716 (18 U.S.C. 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 matter is outwardly or of its own force dangerous to life, health, or property. Accordingly, for legal and safety reasons, the mailing standards for hazardous materials in the *Domestic Mail Manual* (DMM) not only closely adhere to the DOT regulations in 49 CFR, but also include many additional limitations and prohibitions.

In many instances, the Postal Service standards are more restrictive than the DOT requirements that apply to shipments being transported in domestic commerce. As an example, commercial shippers are permitted under the DOT regulations in 49 CFR to send certain types of flammable materials via air transportation. In contrast, the Postal Service prohibits the mailing of all flammable materials via air transportation.

Under Postal Service mailing standards, most hazardous materials are nonmailable. With few exceptions, the Postal Service generally limits the mailing of hazardous materials to only those materials that can be reclassified as an ORM–D material under the DOT Federal regulations in 49 CFR 173.144 and that can be renamed with the proper shipping name of ''Consumer Commodity.'' Additionally, mailable hazardous materials must meet the Postal Service quantity and packaging requirements, which in many instances are more restrictive than the DOT requirements in 49 CFR. Of all regulated hazardous materials, ORM–D materials present the lowest level of risk during handling and transportation.

Over the past few years, the Postal Service has encountered increasing difficulties with the commercial carriers who are contracted to provide air transportation services for the carriage of U.S. mail. Many carriers have refused to transport mailpieces containing mailable hazardous materials. In some instances, an air carrier has established a corporate policy not to carry hazardous materials. In other cases, an air carrier has refused to carry a specific type of hazardous material (*e.g.*, diagnostic specimens) because Postal Service packaging standards, which met Federal standards, did not meet the international standards followed by the air carrier industry.

To ensure an acceptable level of safety and to facilitate domestic and international transportation, the Postal Service is proposing to adopt some of the regulatory and packaging changes for Division 6.2 infectious substances that DOT adopted as revisions to 49 CFR in the **Federal Register** (67 FR 53118 and 67 FR 54967). The DOT changes are consistent with the current international standards found in the *Technical Instructions for the Safe Transport of Dangerous Goods* published by the International Civil Aviation Organization (ICAO).

It should also be noted that many of the DOT Federal regulations in 49 CFR involve requirements for the transport of hazardous materials that have moderate, high, or very high risk levels and that are shipped in very large quantities (exceeding 70 pounds in weight). Such hazardous materials are not permitted in the U.S. mail due to the legal restrictions in 18 U.S.C. 1716, concerns for employee and public safety, and Postal Service size and weight limitations. Accordingly, the Postal Service proposes to adopt only the new DOT regulations for Division 6.2 infectious substances that apply to materials that can be safely handled in the U.S. mail. As an example, the Postal Service would not adopt the new DOT bulk packaging options for regulated medical waste because under DOT regulations in 49 CFR, a bulk packaging is defined as a receptacle that has a capacity greater than 450L (119 gallons) for liquid materials or a net mass greater than 400 kg (882 pounds) for solid materials. As established by law, the maximum size and weight limits per mailpiece are 70 pounds and 108 inches in combined length and girth (130 inches for Parcel Post). A bulk packaging receptacle as defined by DOT would be nonmailable in the U.S. mail because it would exceed the maximum size and weight limits for mailing, while also posing an unacceptable risk level during Postal Service transport and handling.

In this proposed rule, the Postal Service proposes the adoption of the following changes to the mailing standards for Division 6.2 infectious substances:

• New classification criteria for Division 6.2 infectious substances based on the defining criteria developed by the World Health Organization (WHO) and consistent with the DOT Federal regulations in 49 CFR for domestic transport and the ICAO technical instructions for international transport.

• New DOT packaging requirements that are applicable to the mailable types of Division 6.2 materials and consistent with the ICAO technical instructions. For safety reasons, the proposed Postal Service volume limits may be lower than the DOT limits in some instances.

• New DOT Federal requirements that regulate diagnostic specimens in Risk Group 2, 3, or 4 as hazardous materials.

• Revisions and modifications in the new DOT Federal regulations related to the definitions of Division 6.2 materials and use of the biohazard symbol.

In addition, the Postal Service is also proposing a few minor clarifications and changes to the hazardous materials standards and certain related standards in DMM C021, C023, C024, and F010. These proposed clarifications and changes would improve clarity in the standards and reduce misunderstanding. They would also improve packaging integrity for medical and sharps waste and provide a greater level of safety during handling for both Postal Service employees and the public. These proposed changes include:

• Minor revisions to the text in DMM C021 to improve clarity.

• Minor clarifications to the definitions in DMM C023.1.1 including added text in the definition for ''air'' transportation requirements to note that the Postal Service does not guarantee air transportation service for any class of mail. Air transportation service is usually provided for First-Class Mail®, Priority Mail®, and Express Mail® destined to zones 5 through 8, however, it is dependent on the ability of the Postal Service to procure an air carrier.

• Standardization of the terminology used in DMM C023 for identifying the different components required for the proper packaging of mailable hazardous materials.

• Expansion of the Registered Mail® service requirement in DMM C023.8.0 for use with mailable infectious substances to provide added security and safety during Postal Service handling. Currently only the infectious substances listed in 42 CFR 72.3(f) are required to be sent as Registered Mail. This proposal would require that all mailable Risk Group 4 infectious substances be sent as Registered Mail.

• Expansion of the requirements in DMM C023.8.0 to establish that regulated medical waste would be subject to the same authorization requirements as sharps waste.

• Clarifications and minor changes to the requirements in DMM C023.8.0 for sharps waste containers to enhance the accuracy of the regulations and reduce misunderstanding of the standards. In addition, the Postal Service proposes additional limitations for sharps waste containers to ensure packaging integrity during Postal Service handling and to provide a greater level of safety for Postal Service employees and the public.

• Clarification of the required placement of the biohazard symbol in DMM C023.8.0 for mailable regulated and nonregulated Division 6.2 materials that are permitted in the mail.

• Standardization of the maximum weight limit in DMM C023 for several different types of mailable hazardous materials as 25 pounds or less. This change would affect nonflammable compressed gasses, matches, medical waste, sharps, and nonspillable wet batteries.

• Reinstatement of former DMM C024.18.0 (DMM Issue 56) with revised text to clarify the mailability of odd-shaped items in paper envelopes and to support the restrictions for harmful matter in DMM C021.

• Revisions to DMM F010 that would prohibit the use of the ancillary service endorsement ''Change Service Requested'' on Priority Mail, First-Class Mail, Standard Mail, and Package Services mail containing mailable perishable matter (including live animals) under DMM C022, hazardous materials under DMM C023, and restricted matter under DMM C024. Also, a revision to require a return or forwarding endorsement on Standard Mail containing mailable perishable matter, hazardous materials, or restricted matter.

A phase-in period through April 30, 2003 is proposed for mailer implementation of the new packaging requirements for diagnostic specimen mailpieces using a business reply mail format and sharps waste mailpieces using a merchandise return service format. This time period will allow mailers to exhaust any existing packaging stock presently in circulation.

The Postal Service believes that the adoption of the changes in this proposed rule would help to ensure an acceptable level of security and safety during Postal Service handling for the types and quantities of hazardous materials that are permitted in the U.S. mail.

Although exempt from the notice and comment requirements of the Administrative Procedure Act [5 U.S.C. 553(b), (c)] regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites comments on the following proposed revisions of the *Domestic Mail Manual* (DMM) incorporated by reference in the *Code of Federal Regulations.* See 39 CFR part 111.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

PART 111—[AMENDED]

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, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

2. Revise the following sections of the *Domestic Mail Manual* (DMM) as follows:

Domestic Mail Manual (DMM)

* * * * *

C Characteristics and Content

C000 General Information

* * * * *

C020 Restricted or Nonmailable Articles and Substances

C021 Articles and Substances Generally

* * * * *

2.0 NONMAILABLE ARTICLES AND SUBSTANCES—GENERAL

2.1 Basic Information

[Delete the last two sentences of 2.1 and insert the following text to read as follows:]

* * * The mailability standards that apply to perishable, hazardous, and restricted matter are detailed in C022, C023, and C024, respectively. Publication 52, *Hazardous, Restricted, and Perishable Mail,* contains additional clarification and further describes the conditions of preparation and packaging under which the USPS accepts for mailing potentially harmful matter that is otherwise nonmailable. Publication 52 also contains detailed information on the mailability of specific hazardous materials.

* * * * *

3.0 INJURIOUS AND HARMFUL ARTICLES

3.1 General

* * * * *

[Revise item b to read as follows:]

b. All poisonous animals, except scorpions mailed for medical research purposes or for the manufacture of

antivenom; all poisonous insects; all poisonous reptiles; and all types of snakes, turtles, and spiders.

* * * * *

3.2 Hazardous Materials

[Revise the first sentence to read as follows:]

Harmful matter also includes regulated hazardous materials as defined in C023 that are likely to harm USPS employees or to destroy, deface, or otherwise damage mail or postal equipment.* * *

4.0 MARKING

* * * * *

4.2 Addressing

[Revise 4.2 to read as follows:]

For any matter mailed under the provisions in C020, the recipient's name and address must be affixed or applied directly to the mailpiece using a material or method that is not water-soluble and not easily smeared or rubbed off. Except for diagnostic specimen mailpieces using a business reply mail format and nonregulated materials, a return address that includes the sender's name and address must appear on all matter mailed under C020. The return address, when required, must be applied using a material or method that is not water-soluble and not easily smeared or rubbed off.

4.3 Warning Label

[Revise the last sentence in 4.3 to read as follows:]

* * * See C023 for the warning label requirements that apply to the mailing of hazardous materials.

* * * * *

C023 Hazardous Materials

Summary

[Revise the Summary to read as follows:]

C023 describes the general standards, restrictions, and prohibitions that apply to the mailability of hazardous materials.

1.0 GENERAL

1.1 Definitions

* * * * *

[Revise the last sentence in item a to read as follows:]

a. * * * In international commerce, hazardous materials are known as dangerous goods.

[At the end of item b, add a new sentence to read as follows:]

b. * * * Almost all limited quantity materials are nonmailable.

[At the end of item c, add a new sentence to read as follows:]

c. * * * ORM–D materials having the proper shipping name of ''consumer commodity'' are mailable subject to USPS quantity and packaging standards.

* * * * *

[Revise items e and f to read as follows:]

e. *Air transportation requirements,* for the purposes of C023 only, apply to all mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates. All mailable hazardous materials sent at those rates must meet the requirements that apply to air transportation. Mailable hazardous materials sent at any of those rates may or may not be transported via air depending on the distance between the point of origination and the point of destination, and the ability of the USPS to obtain an air carrier between those points.

f. *Surface transportation requirements,* for the purposes of C023 only, apply to all mailable hazardous materials sent at the Standard Mail or Package Services rates. All mailable hazardous materials sent at the Standard Mail or Package Services rates must meet the requirements that apply to surface transportation.

* * * * *

[Revise item h to read as follows:]

h. *Secondary container* is the packaging component into which the primary receptacle(s) and any required absorbent and cushioning material is securely placed. The packaging of certain mailable hazardous materials do not require the use of a secondary container.

[Revise item i to read as follows:]

i. *Outer shipping container* is the exterior packaging component into which a primary receptacle, along with any required absorbent and cushioning material, and the secondary container (if required), are securely placed. The outer shipping container bears the addressing information along with all required markings.

1.2 U.S. Department of Transportation

[Revise 1.2 to read as follows:]

The U.S. Department of Transportation (DOT) regulates the surface and air carriage of hazardous materials within the United States via any means of transportation. The DOT regulations for the transport of hazardous materials are codified in Title 49, *Code of Federal Regulations* (49 CFR) 100–185. USPS mailing standards for hazardous materials generally adhere to 49 CFR, but also include many additional limitations and prohibitions.

[Renumber 1.3 through 1.9 as 1.4 through 1.10 and insert new 1.3 to read as follows:]

1.3 USPS Standards

The USPS standards generally restrict the mailing of hazardous materials to ORM–D materials with the proper shipping name of ''consumer commodity'' that meet USPS quantity limitations and packaging requirements. The few non-ORM–D materials permitted to be mailed are subject to the standards in C023. Detailed information on the mailability of specific hazardous materials is contained in Publication 52, *Hazardous, Restricted, and Perishable Mail.*

1.4 Hazard Class

* * * * *

[Renumber ''Exhibit 1.3 DOT Hazard Classes and Mailability Summary'' as ''Exhibit 1.4 DOT Hazard Classes and Mailability Summary.'']

* * * * *

1.6 Mailability Rulings

[In the first sentence, change ''package'' to ''mailpiece.'']

1.7 Warning Labels

[Change ''division 6.2 materials under 8.3'' and ''as required in 1.7'' to ''Division 6.2 materials under 8.5'' and ''as required in 1.8''.]

1.8 Package Markings

[Delete the last sentence in 1.8 and insert two new sentences to read as follows:]

* * * The designation ''ORM-D'' or ''ORM–D AIR'', as required, must be placed within a rectangle that is approximately 6.3 mm (¼ inch) larger on each side than the designation. Mailable ORM–D materials sent as Standard Mail or Package Services must also be marked on the address side as ''Surface Only'' or ''Surface Mail Only.''

1.9 Shipping Papers

[Revise 1.9 to read as follows:]

A shipper's declaration for dangerous goods (*i.e.*, shipping paper) prepared under 49 CFR 172.200 through 172.205 is required for certain types of hazardous materials when mailed. The shipping paper must be completed and signed in triplicate by the mailer. It must be affixed to the outside of the mailpiece within an envelope or similar carrier that can be easily opened and resealed to allow viewing of the document. Shipping papers are required as follows:

a. *Air transportation requirements.* Except for nonregulated materials sent under 8.3 or 8.10 and diagnostic specimens sent under 8.6, mailpieces containing mailable hazardous materials sent at the First-Class Mail, Priority

Mail, or Express Mail rates must include a shipping paper.

b. *Surface transportation requirements.* Except for nonregulated materials sent under 8.3 or 8.10 and mailable ORM–D materials, mailpieces containing mailable hazardous materials sent at the Standard Mail or Package Services rates must include a shipping paper.

1.10 Air Transportation Prohibitions

[Revise the first two sentences in 1.10 to read as follows (the remainder of 1.10 is unchanged):]

All mailable hazardous materials sent at the First-Class Mail, Priority Mail, or Express Mail rates must meet air transportation requirements. The following types of hazardous materials that are prohibited from carriage on air transportation must not be sent at the First-Class Mail, Priority Mail, or Express Mail rates:

* * * * *

2.0 EXPLOSIVES (HAZARD CLASS 1)

2.1 Definition

[In the second sentence, change ''Exhibit 1.3'' to ''Exhibit 1.4''.]

2.2 Mailability

[In the second sentence, change ''division 1.4'' to ''Division 1.4S.'']

3.0 GASES (HAZARD CLASS 2)

3.1 Definition

[In item b, change ''division 2.1 or 2.3'' to ''Division 2.1 or 2.3''.]

3.2 Mailability

[In the second, third, and fourth sentences, change ''division'' to ''Division.'']

3.3 Container

[Revise 3.3 to read as follows:]

An other-than-metal primary receptacle containing a mailable gas may be acceptable if the water capacity of the primary receptacle is 4 fluid ounces (7.22 cubic inches) or less per mailpiece and the primary receptacle meets 49 CFR requirements. Mailable nonflammable and flammable compressed gases are acceptable in metal primary receptacles that have a water capacity up to 33.8 fluid ounces (1 liter or 61.0 cubic inches), depending on their internal pressure. A DOT 2P container must be used as the primary receptacle if the internal pressure is from 140 to 160 psig at 130°F (55°C). A DOT 2Q container must be used as the primary receptacle if the pressure is from 161 to 180 psig at 130°F (55°C). A container with an internal pressure over 180 psig at 130°F (55°C) is prohibited from mailing. Mailable flammable compressed gases are restricted to 33.8 fluid ounces (1 liter) per mailpiece. Mailable nonflammable compressed gasses are permitted in individual 33.8 fluid ounce (1 liter) containers that must be securely packed within an outer shipping container. Each mailpiece must not exceed a total of weight of 25 pounds.

3.4 Marking

[In the first sentence, change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

4.0 FLAMMABLE AND COMBUSTIBLE LIQUIDS (HAZARD CLASS 3)

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4.2 Flammable Liquid Mailability

[In items a and b, change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

4.3 Combustible Liquid Mailability

[In items a and b, change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

[Revise item c to read as follows:]

c. For air or surface transportation, if the flashpoint is above 200°F (93°C) the material is not regulated as a hazardous material. Such nonregulated materials must be properly and securely packaged to prevent leakage under the general packaging requirements in C010.

4.4 Cigarette Lighters

[In the second sentence, change ''division 2.1'' to ''Division 2.1''.]

[In item c, change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

5.0 FLAMMABLE SOLIDS (HAZARD CLASS 4)

* * * * *

5.2 Mailability

[Change ''outer packaging'' to ''outer shipping container'' and change ''Surface Mail Only'' to '' ''Surface Only'' or ''Surface Mail Only.'' '']

5.3 Matches

* * * * *

[Revise items c and d to read as follows:]

c. They are tightly packed in a securely sealed primary receptacle to prevent any shifting or movement that could cause accidental ignition by rubbing against adjoining items. The primary receptacle(s) is placed securely within an outer shipping container made of fiberboard, wood, or other equivalent material. Multiple primary receptacles may be placed in a single outer shipping container. The address side of the mailpiece must be marked ''Surface Only'' or ''Surface Mail Only'' and ''Book Matches,'' ''Strike-on-Card Matches,'' or ''Card Matches,'' as appropriate. A shipping paper is not required.

d. The gross weight of each mailpiece is not more than 25 pounds.

6.0 OXIDIZING SUBSTANCES, ORGANIC PEROXIDES (HAZARD CLASS 5)

* * * * *

6.2 Mailability

[Revise 6.2 to read as follows:]

Oxidizing substances and organic peroxides are prohibited in international mail. For domestic mail, a material that can qualify as an ORM–D material is permitted via air or surface transportation. Liquid materials must be enclosed within a primary receptacle having a capacity of 1 pint or less; the primary receptacle(s) must be surrounded by absorbent cushioning material and held within a leak-resistant secondary container that is packed within a strong outer shipping container. Solid materials must be contained within a primary receptacle having a weight capacity of 1 pound or less; the primary receptacle(s) must be surrounded with cushioning material and packed within a strong outer shipping container. Each mailpiece may not exceed a total weight of 25 pounds. The address side of each mailpiece must be plainly and durably marked with ''ORM–D AIR'' or ''ORM–D,'' as applicable, immediately following or below the proper shipping name. A mailable Class 5 material sent via surface transportation must be marked ''Surface Mail'' or ''Surface Mail Only'' on the address side. A mailable material sent via air transportation must bear a shipper's declaration for dangerous goods.

7.0 TOXIC SUBSTANCES (HAZARD CLASS 6, DIVISION 6.1)

7.1 Definitions

[In the first sentence, change ''division 6.1'' to ''Division 6.1''.]

7.2 Mailability

[In the second sentence, change ''division 6.1'' to ''Division 6.1''.]

7.3 Authorized Parties

[In the first sentence, change ''division 6.1'' to ''Division 6.1''.]

7.4 Packaging and Marking

[In item a, change ''inner receptacle(s)'' to ''primary receptacle(s)''; change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to ''''Surface Only'' or ''Surface Mail Only.'' '']

[In item b, change ''secondary leakproof (for liquids) or siftproof (for solids) packaging'' to ''leakproof (for liquids) or siftproof (for solids) secondary container''; change ''secondary packaging'' to ''secondary container''; change ''outer packaging'' to ''outer shipping container''; and change ''Surface Mail Only'' to ''''Surface Only'' or ''Surface Mail Only.'' '']

* * * * *

8.0 INFECTIOUS SUBSTANCES (HAZARD CLASS 6, DIVISION 6.2)

[*Revise 8.0 to read as follows:*]

8.1 General

Division 6.2 includes infectious substances (*i.e.*, etiologic agents), biological products, cultures and stocks, diagnostic (clinical) specimens, regulated medical waste, sharps waste, toxins, and used health care products. Division 6.2 materials are not permitted in international mail or domestic mail, except when they are intended for medical or veterinary use, research, or laboratory certification related to the public health; and only when such materials are properly prepared for mailing to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit. Mailable Division 6.2 materials sent as international mail must meet the standards in *International Mail Manual* 135. For domestic mail, mailable Division 6.2 materials must meet the applicable standards in 8.0. Unless otherwise noted, all mailable Division 6.2 materials in Risk Group 2, 3, or 4 must be prepared to meet air transportation requirements.

8.2 Definitions

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

a. *Division 6.2 (infectious substance)* means a material known to contain or suspected of containing a pathogen. A pathogen is a virus or microorganism (including its viruses, plasmids, or other genetic elements, if any) or a proteinaceous infectious particle (prion) that has the potential to cause disease in humans or animals. A Division 6.2 material must be assigned to a risk group as defined in 8.2f. Assignment to a risk group is based on the known medical condition and history of the source patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal. Infectious substances are subject to applicable requirements in 42 CFR 72 (Interstate Shipment of Etiologic Agents).

b. *Biological product* means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. A biological product includes a material manufactured and distributed in accordance with one of the following provisions: 9 CFR 102 (Licenses for Biological Products); 9 CFR 103 (Experimental Products, Distribution, and Evaluation of Biological Products Prior to Licensing); 9 CFR 104 (Permits for Biological Products); 21 CFR 312 (Investigational New Drug Application); 21 CFR 314 (Applications for FDA Approval to Market a New Drug); 21 CFR 600–680 (Biologics); or 21 CFR 812 (Investigational Device Exemptions). A biological product known to contain or suspected of containing a pathogen in Risk Group 2, 3, or 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate, unless otherwise excepted by standard.

c. *Cultures and stocks* means a material prepared and maintained for growth and storage and containing a Risk Group 2, 3, or 4 infectious substance.

d. *Diagnostic (clinical) specimen* means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes, but excluding live infected animals. A diagnostic specimen is not assigned a UN identification number unless the source patient or animal has or may have a serious human or animal disease from a Risk Group 4 pathogen, in which case it must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Assignment to UN 2814 or UN 2900 is based on known medical condition and history of the patient or animal, endemic local conditions, symptoms of the source patient or animal, or professional judgment concerning individual circumstances of the source patient or animal.

e. *Regulated medical waste* means a waste material (other than a sharp) known to contain or suspected of containing an infectious substance in Risk Group 2 or 3 and generated in the diagnosis, treatment, or immunization of human beings or animals; research on the diagnosis, treatment, or immunization of human beings or animals; or the production or testing of biological products. Regulated medical waste containing an infectious substance in Risk Group 4 must be classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate. Regulated medical waste classified in Risk Group 4 (including sharps waste) is nonmailable.

f. *Risk group* means a ranking of a microorganism's ability to cause injury through disease. A risk group is defined by criteria developed by the World Health Organization (WHO) that are based on the severity of the disease caused by the organism, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of the disease through the availability of known and effective preventive agents and treatment. There is no relationship between a risk group and a DOT packing group. The mailer is responsible for accurately ranking a mailable material within the correct risk group. Exhibit 8.2f details the criteria for each risk group according to the level of risk.

Exhibit 8.2f Risk Group Criteria

Risk group	Pathogen	Risk to individuals	Risk to community
4	A pathogen that usually causes serious human or animal disease and that can be readily transmitted from one individual to another, directly or indirectly, and for which effective treatments and preventive measures are not usually available..	High	High

Risk group	Pathogen	Risk to individuals	Risk to community
3	A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventive measures are available..	High	Low.
2	A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventive measures available and the risk of spread of infection is limited..	Moderate	Low.
1	A microorganism that is unlikely to cause human or animal disease. A material containing only such microorganisms is not subject to regulation as a hazardous material, but it is subject to the packaging requirements in 8.10, unless otherwise noted in 8.0..	None or Very Low	None or Very Low.

g. *Sharps* means any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and that is also capable of cutting or penetrating skin or a packaging material. 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. Sharps waste classified in Risk Group 4 is nonmailable.

h. *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 classed as Division 6.2, described as an infectious substance, and assigned to UN 2814 or UN 2900, as appropriate.

i. *Used health care product* means a medical, diagnostic, or research device or piece of equipment, or a personal care product used by consumers, medical professionals, or pharmaceutical providers that does not meet the definition of a diagnostic specimen, biological product, or regulated medical waste, is contaminated with potentially infectious body fluids or materials, and is not decontaminated or disinfected to remove or mitigate the infectious hazard prior to transportation. A used health care product classified in Risk Group 4 is nonmailable.

8.3 Nonregulated Materials

The following materials are not subject to regulation as Division 6.2 hazardous materials and are mailable when the packaging requirements in 8.10 are met:

a. A diagnostic (clinical) specimen known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also, a diagnostic specimen in which the pathogen has been neutralized or inactivated so that exposure to it cannot cause disease.

b. A biological product known to contain or suspected of containing a microorganism in Risk Group 1, or that does not contain a pathogen. Also any biological product, including an experimental product or component of a product, subject to federal approval, permit, or licensing requirements, such as those required by the Food and Drug Administration (FDA) of the Department of Health and Human Services (HHS) or the U.S. Department of Agriculture (USDA).

c. Blood collected for blood transfusion or the preparation of blood products; blood products; tissues intended for use in surgical procedures; and human cell, tissues, and cellular and tissue-based products regulated under authority of the Public Health Service Act and/or the Food, Drug, and Cosmetic Act. Also, blood collected for 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 pathogen in Risk Group 2 or 3, in which case the test sample must be packaged under 8.6.

d. A material, including a Division 6.2 waste, that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4.

e. Forensic material in Risk Group 1 transported on behalf of a U.S. government, state, local, or Indian tribal government agency.

8.4 Packaging—General

All materials mailable under the provisions in 8.0 must be properly packaged. Exhibit 8.4a lists the specific reference in 8.0 under which each type of mailable material must be packaged.

Exhibit 8.4a Packaging References for Materials Mailable Under 8.0

Material	Risk group			
	1	2	3	4
Blood for Transfusion	8.10	8.6	8.6	NM
Biological Product	8.10	8.5	8.5	8.5
Culture or Stock	8.10	8.5	8.5	8.5
Diagnostic Specimen	8.10	8.6	8.6	8.5
Division 6.2 (Infectious Substance)	8.10	8.5	8.5	8.5
Forensic Material	8.10	8.9	8.9	8.5
Regulated Medical Waste	8.7	8.7	8.7	NM
Sharps	8.7	8.7	8.7	NM
Toxin (Division 6.2)	8.10	8.5	8.5	8.5
Treated Medical Waste	8.10	n/a	n/a	n/a
Used Health Care Product	8.8	8.8	8.8	NM

NM means nonmailable; n/a mean not applicable

8.5 Packaging of Division 6.2 Infectious Substances

Division 6.2 materials include infectious substances (etiologic agents), biological products, cultures or stocks, and toxins known or suspected to contain a Risk Group 2, 3, or 4 pathogen. It also includes diagnostic specimens known or suspected to contain a Risk Group 4 pathogen. The packaging of Division 6.2 infectious substances is subject to these standards:

a. All Division 6.2 materials must meet the packaging requirements in 49 CFR 173.196 and 42 CFR 72.3. Either the primary receptacle or the secondary container must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 0.95 bar, 14 psi (95 kPa), and temperatures in the range of −40°F to 131°F (−40°C to 55°C) as required by 49 CFR 173.196.

b. The material must be packaged in a securely sealed and watertight primary receptacle (test tube, vial, etc.) that is enclosed in another watertight and durable secondary container that is securely sealed. Several primary receptacles may be enclosed in the secondary container if there is adequate cushioning material between them to prevent breakage during ordinary handling, and if the total volume of the material in all enclosed primary receptacles does not exceed 50 ml for liquids and 50 g for solids. The primary receptacle(s) and the secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The space between the primary receptacle(s) and the secondary container at the top, bottom, and sides must contain enough absorbent material to take up the entire contents of the primary receptacle(s) in case of breakage or leakage.

d. The primary receptacle(s) and the secondary container must be securely enclosed in an outer shipping container constructed of fiberboard or other equivalent material. No external surface of the outer shipping container may be less than 3.9 inches (100 mm) as required by 49 CFR 173.196. An itemized list of the contents of the primary receptacle(s) must be enclosed between the secondary container and the outer shipping container.

e. Each mailpiece must be designed and constructed so that, if it were subject to the environmental and test conditions in 49 CFR 178.609, there would be no release of the contents to the environment and no significant reduction in the effectiveness of the packaging.

f. The address side of the mailpiece must bear the ''Etiologic Agents/Biohazard Material'' label required by 42 CFR 72.3(d) and must be sent First-Class Mail or Priority Mail using Registered Mail service. Each mailpiece must be marked on the address side with the proper shipping name and UN number of the material (*e.g.*, ''UN 2814, Infectious Substances, Affecting Humans'' or ''UN 2900, Infectious Substances, Affecting Animals''). Each mailpiece must bear a DOT Class 6 label for infectious substances (etiologic agents), proper UN package specification markings, and orientation markings. A shipping paper is required.

g. Articles that include dry ice as a refrigerant for the infectious substance must meet the requirements of 42 CFR 72.3(c) and 49 CFR 173.196(b)(2)(ii).

8.6 Packaging for Diagnostic Specimens in Risk Group 2 or 3

A diagnostic (clinical) specimen known or suspected to contain a Risk Group 4 pathogen must be packaged under 8.5. A diagnostic specimen classified in Risk Group 1 must be packaged under 8.10. A diagnostic specimen classified in Risk Group 2 or 3 and that meets the definition in 8.2d must be sent as First-Class Mail or Priority Mail. Such materials must be packaged in a triple packaging, consisting of a primary receptacle, secondary container, and outer shipping container. The following specific packaging requirements apply:

a. *Liquid Diagnostic (Clinical) Specimens.*

(1) The specimen must be contained in a leakproof and securely sealed primary receptacle. A single primary receptacle may not contain more than 500 ml of a specimen. Multiple primary receptacles are permitted in a single mailpiece if the mailpiece does not contain more than 4,000 ml. The primary receptacle(s) must be surrounded by absorbent material capable of taking up the entire liquid contents if the primary receptacle(s) leak.

(2) The primary receptacle(s) and the absorbent material must be securely packed within a secondary container in such a way that, under normal conditions of transport, the primary receptacle cannot break, be punctured, or leak its contents into the secondary container. Each primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(3) The secondary container must be leakproof, securely sealed, and placed within a strong outer shipping container having suitable cushioning material such that any leakage of the contents does not impair the protective properties of the cushioning material or the outer shipping container.

(4) The primary receptacle(s) or the secondary container must be capable of withstanding, without leakage, an internal pressure producing a pressure differential of not less than 0.95 bar, 14 psi (95 kPA). The completed mailpiece must be capable of successfully passing the drop test in 49 CFR 178.603 at a drop height of at least 1.2 meters (3.9 feet). The address side of the outer shipping container must be clearly and durably marked ''Diagnostic Specimen.'' A shipping paper is not required.

b. *Solid Diagnostic Specimens.*

(1) The primary receptacle must be siftproof with a capacity of not more than 500 g (1.1 pounds). The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(2) If several fragile primary receptacles are placed in a single secondary container, they must be individually wrapped or separated to prevent contact between them. The secondary container must be siftproof to contain the contents if the primary receptacle(s) leak.

(3) The outer shipping container may not exceed 4 kg (8.8 pounds) capacity. The outer shipping container must be clearly and durably marked ''Diagnostic Specimen.'' A shipping paper is not required.

8.7 Regulated Medical Waste and Sharps Waste

Regulated medical waste and sharps waste known to contain or suspected of containing an infectious substance in Risk Group 4 are nonmailable. Regulated medical waste and sharps waste as defined in 8.2e and 8.2g, respectively, and classified in Risk Group 1, 2 or 3 are permitted for mailing only using merchandise return service (see S923) with First-Class Mail or Priority Mail, subject to the following requirements:

a. *Authorization.* Each distributor or manufacturer of a complete regulated medical waste or sharps waste mailing kit, including containers, cartons, and any other related components intended for mailing such waste to a storage or disposal facility, must obtain authorization from the USPS prior to mailing. Before applying for authorization, each type of mailing kit must be tested and certified under the standards in 8.7d by an independent party. The manufacturer or distributor in whose name the authorization is

being sought must submit a written request to the Mail Preparation and Standards manager, USPS Headquarters (see G043 for address). The request for authorization must contain the following:

(1) An irrevocable 50,000 surety bond or letter of credit as proof of sufficient financial responsibility to cover disposal costs if the manufacturer (or distributor) ceases doing business before all its shipping containers are disposed of or to cover cleanup costs if spills occur while the containers are in USPS possession. The surety bond or letter of credit must be issued in the name of the manufacturer or distributor seeking the authorization and must name the USPS as the beneficiary or obligee, as appropriate.

(2) Address of the headquarters or general business office of the distributor or manufacturer seeking the authorization.

(3) Address of each disposal and storage site.

(4) List of all types of mailing kits to be covered by the request, a complete sample of each mailing kit, and proof of package testing certifications performed by the independent testing facility that subjected the packaging materials to the testing requirements in 8.7d.

(5) Copy of the proposed manifest to be used with all mailings.

(6) 24-hour toll free telephone number for emergencies.

(7) List of the types of waste to be mailed for disposal.

(8) Copy of the merchandise return service label to be used with each mailing kit.

b. *Packaging.* Regulated medical waste and sharps waste in Risk Group 4 are nonmailable. A waste material treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance in Risk Group 2, 3, or 4 must be packaged under 8.10. The packaging for regulated medical waste and sharps waste in Risk Group 1, 2, or 3 is subject to these standards:

(1) Regulated medical waste and sharps waste must be collected in a rigid, securely sealed, and leakproof primary receptacle. For sharps waste, the primary receptacle must also be puncture-resistant. The primary receptacle may not contain more than 50 ml (1.66 ounces) of residual waste liquid and may not have a maximum capacity that exceeds 3 gallons in volume. The primary receptacle must display the international biohazard symbol shown in Exhibit 8.7c(2). The primary receptacle must maintain its integrity when exposed to temperatures between 0° and 120°F.

(2) The primary receptacle must be packaged within a watertight secondary container or containment system. The secondary container may consist of more than one component. If one of the components is a plastic bag, it must be at least 3 ml in thickness and be used in conjunction with a strong fiberboard box. A plastic bag by itself does not meet the requirement for a secondary container. Several primary receptacles may be enclosed in a secondary container.

(3) The secondary container must be enclosed in a strong outer shipping container constructed of 200-pound grade corrugated fiberboard. The box certification must be displayed on the bottom of the fiberboard box. The joints and flaps of the outer shipping container must be securely taped, glued, or stitched to maintain the integrity of the container. When tape or glue is used to secure an outer shipping container, the material must be water-resistant. Fiberboard boxes with interlock bottom flaps (*i.e.*, easy-fold) are not permitted as outer shipping containers. The secondary container must fit securely within the outer shipping container to prevent breakage during ordinary processing.

(4) There must be enough material within a watertight barrier to absorb and retain three times the total liquid allowed within the primary receptacle (150 ml per primary receptacle) in case of leakage.

(5) Each mailpiece must not weigh more than 25 pounds.

(6) In each mailing kit, the authorized manufacturer or distributor must include a step-by-step instruction sheet that clearly details the proper sequence and method of kit assembly prior to mailing to prevent package failure during transport due to improper assembly.

c. *Mailpiece Labeling, Marking, and Documentation.* Regulated medical waste and sharps waste must meet the following requirements:

(1) Each primary receptacle and outer shipping container must bear a label, which cannot be detached intact, showing:

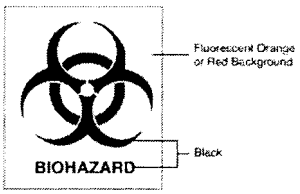
(a) The company name of the manufacturer or the distributor to which the mailing authorization is issued.

(b) The USPS Authorization Number.

(c) The container ID number (or unique model number) signifying that the packaging material is certified and that the manufacturer or distributor obtained the authorization required by 8.7a.

(2) The primary receptacle(s) and the outer shipping container must bear the international biohazard symbol in black with either a fluorescent orange or fluorescent red background as shown in Exhibit 8.7c(2).

Exhibit 8.7c(2) International Biohazard Symbol



(3) Each mailpiece must have a four-part waste manifest, which also serves as a shipping paper. The manifest must be affixed to the outside of the mailpiece in an envelope or similar carrier that can be easily opened and resealed to allow review of the document. The manifest must comply with all applicable requirements imposed by the laws of the state from which the kit is mailed. At a minimum, the information in Exhibit 8.7c(3) must be on the manifest.

Exhibit 8.7c(3)

Manifest for Regulated Medical Waste and Sharps Waste Containers

1. Generator (Mailer)
   a. Name.
   b. Complete address (not a Post Office box).
   c. Telephone number.
   d. Description of contents of mailing container. ''Regulated Medical Waste'' or ''Regulated Medical Waste—Sharps'' is required as appropriate.
   e. Date container was mailed.
   f. State permit number of approved facility in which contents are to be disposed.
2. Destination Facility (Disposal Site)
   Complete address (not a Post Office box).
3. Generator's (Mailer's) Certification
   The following certification statement must be printed on manifest:
   ''I certify that this container has been approved for the mailing of [insert either ''regulated medical waste'' or ''sharps waste,'' as appropriate], has been prepared for mailing in accordance with the directions for that purpose, and does not contain excess liquid or nonmailable material in violation of the applicable Postal Service regulations. I AM AWARE THAT FULL RESPONSIBILITY RESTS WITH THE GENERATOR (MAILER) FOR ANY VIOLATION OF 18

U.S.C. 1716 WHICH MAY RESULT FROM PLACING IMPROPERLY PACKAGED ITEMS IN THE MAIL. I also certify that the contents of this consignment are fully and accurately described above by proper shipping name and are classified, packed, marked, and labeled, and in proper condition for carriage by air according to the national governmental regulations.''

This statement must be followed by printed or typewritten name of generator (mailer), signature of generator, and date signed.

4. Destination Facility (Storage or Disposal Site)

The following certification statement of receipt, treatment, and disposal must be printed on manifest:

''I certify that the contents of this container have been received, treated, and disposed of in accordance with all local, State, and Federal regulations.''

This statement must be followed by printed or typewritten name of an authorized recipient at destination facility, signature of authorized recipient, and date signed.

5. Transporter Intermediate Handler Other Than the Postal Service (If Different From Destination Facility)

a. Name.

b. Complete address (not a Post Office box).

c. Printed or typewritten name of transporter or intermediate handler.

d. Signature of transporter or intermediate handler and date signed.

6. Serialized Waste Manifests

Each waste manifest or mail disposal service shipping record must be serialized using a unique numbering system for identification purposes.

7. Comment Area

Each manifest must contain an area designated for entering comments or noting discrepancies.

8. Completion and Distribution of Waste Manifest

Each manifest must contain instructions for properly completing the four-part form. Copies of the form must be distributed as follows:

a. One copy must be kept by generator (mailer).

b. One copy must be kept by transporter or intermediate handler for 90 days.

c. One copy must be kept by destination facility for 90 days.

d. One copy must be mailed to generator by destination facility.

9. Emergency Telephone Number

Each manifest must bear the following statement with appropriate information:

''IN CASE OF EMERGENCY, OR THE DISCOVERY OF DAMAGE OR LEAKAGE, CALL 1–800–###–####.''

(4) The outer shipping container must bear a properly prepared merchandise return service label (*see* S923). The merchandise return service permit must be held in the same name as that of the authorization.

(5) The outer shipping container must be marked on two opposite side walls with the package orientation marking in 49 CFR 173.312 to identify the proper upright position of the mailpiece during handling.

(6) Mailpieces containing regulated medical waste or sharps waste must be marked on the address side with the correct UN number and proper shipping name (*e.g.*, ''Regulated Medical Waste, UN 3291'' or ''Regulated Medical Waste—Sharps, UN 3291'').

d. *Package Testing.* Testing must be performed on one sample of each type of kit to prove compliance with 8.7a. The sample mailing kit must withstand the tests in 49 CFR 178.604 (leakproof test), 178.606 (stacking test), 178.608 (vibration standard), and 178.609(e), (f), and (h) (test requirements for packaging for infectious substances). In addition, the absorbent material must withstand an absorbency test that satisfies the requirements in 8.7b(4). The test results must show that if every kit prepared for mailing were to be subject to the environmental and test conditions in 49 CFR, there would be no release of the contents to the environment and no significant reduction in the effectiveness of the packaging. Periodic retesting must be performed at least once every 24 months.

8.8 Packaging of Used Health Care Products

A used health care product known or suspected to contain a Risk Group 4 pathogen is nonmailable. A used health care product meeting the definition in 8.2i, classified in Risk Group 1, 2, or 3, and being returned to the manufacturer or manufacturer's designee is mailable as First-Class Mail or Priority Mail subject to the following packaging requirements:

a. Each used health care product must be drained of liquid to the extent possible and placed in a watertight primary receptacle designed and constructed to ensure that it remains intact under normal conditions of transport. For a used health care product capable of cutting or penetrating skin or packaging material, the primary receptacle must be capable of retaining the product without puncture of the packaging under normal conditions of transport. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

b. Each primary receptacle must be placed inside a watertight secondary container designed and constructed to ensure that it remains intact under normal conditions of transport. The secondary container must also be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The secondary container must be placed inside an outer shipping container with sufficient cushioning material to prevent movement between the secondary container and the outer shipping container. An itemized list of the contents of the primary receptacle and information concerning possible contamination with a Division 6.2 material, including its possible location on the product, must be placed between the secondary container and the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

8.9 Packaging of Forensic Material in Risk Groups 2 and 3

Forensic material in Risk Group 1 sent on behalf of a U.S. government, state, local, or Indian tribal government agency must be packaged under 8.10. Forensic material known or suspected to contain a Risk Group 4 infectious substance must be packaged under 8.5. Forensic material known or suspected to contain a Risk Group 2 or 3 pathogen is mailable as First-Class Mail or Priority Mail when packaged in a triple packaging, consisting of a primary receptacle, secondary container, and outer shipping container. The forensic material 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 container from breakage. The absorbent material must be capable of taking up the entire liquid contents of the primary receptacle in case of leakage. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2). The primary receptacle and the absorbent and cushioning material must be enclosed in a watertight and securely sealed secondary container that is snugly packed within a strong and securely sealed outer shipping container. The secondary container must also display the international biohazard symbol as shown in Exhibit 8.7c(2). A shipping paper and a content

marking on the outer shipping container are not required.

8.10 Packaging for Risk Group 1 Materials

Division 6.2 materials in Risk Group 1 are not subject to regulation as hazardous materials (see 8.3), but when presented for mailing they must be properly packaged. Regulated medical waste, sharps waste, and used health care products classified in Risk Group 1 must be packaged and mailed under the applicable requirements in 8.7 or 8.8. All other Risk Group 1 materials are mailable as First-Class Mail, Priority Mail, or Package Services. 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. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2). The primary receptacle and the absorbent and cushioning material must be snugly enclosed in a strong outer shipping container that is securely sealed. A shipping paper and a content marking on the outer shipping container are not required. Risk Group 1 diagnostic specimens and biological products are subject to the following packaging standards:

a. *Liquid Diagnostic (Clinical) Specimens and Biological Products.* A diagnostic (clinical) specimen in Risk Group 4 or a biological product in Risk Group 2, 3, or 4 must be packaged under 8.5. A diagnostic specimen in Risk Group 2 or 3 must be packaged under 8.6. The packaging of a diagnostic specimen (*e.g.*, a urine specimen or blood specimen used in drug-testing programs or insurance purposes) or a biological product (*e.g.*, polio vaccine) in Risk Group 1 is subject to the following standards:

(1) *Not Exceeding 50 ml.* A diagnostic 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. The primary receptacle(s) must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2). 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 having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle(s) leaks during shipment. The secondary container may serve as the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

(2) *Exceeding 50 ml.* In addition to meeting the requirements in 8.10a(1), a clinical specimen or biological product that exceeds 50 ml per mailpiece also is subject to these requirements:

(a) A single primary receptacle must not contain more than 1,000 ml of specimen; two or more primary receptacles whose combined volume does not exceed 1,000 ml may be enclosed in a single secondary container.

(b) The secondary container cannot serve as the outer shipping container; the secondary container must be enclosed in a fiberboard box or container of equivalent strength that serves as the outer shipping container; the maximum amount of a specimen that may be enclosed in a single mailpiece must not exceed 4,000 ml.

b. *Dry Specimens.* A dry specimen, such as a blood spot or fecal smear in Risk Group 1 must be completely dried prior to enclosing it in a securely sealed primary receptacle. The primary receptacle must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2). Cushioning material to withstand shock and pressure changes is only required if the dry specimen is held within a breakable receptacle or on a glass slide. When required, the cushioning material must surround the primary receptacle to prevent breakage or damage to the primary receptacle. The primary receptacle (and cushioning material, if required) must be enclosed in a secondary container having a leakproof barrier that can prevent failure of the secondary container if the primary receptacle breaks during shipment. The secondary container may serve as the outer shipping container. A shipping paper and a content marking on the outer shipping container are not required.

9.0 RADIOACTIVE MATERIALS (HAZARD CLASS 7)

[*Change ''Publication 52,* Acceptance of Hazardous, Restricted, or Perishable Matter'' *to ''Publication 52,* Hazardous, Restricted, or Perishable Mail.'']

10.0 CORROSIVES (HAZARD CLASS 8)

* * * * *

10.2 Mailability

[*In item a, change ''secondary packagings'' to ''secondary container''; change ''secondary packaging'' to ''secondary container''; and change ''outer packaging'' to ''outer shipping container''.*]

[*In item b, change ''secondary packaging'' to ''secondary container'' and change ''outer packaging'' to ''outer shipping container''.*]

10.3 Marking

[*In the first sentence, change ''Surface Mail Only'' to ''Surface Only'' or ''Surface Mail Only.''*]

10.4 Nonspillable Wet Electric Storage Batteries

* * * * *

[*Revise item a to read as follows:*]

a. The nonspillable battery must be protected from short circuits, surrounded with sufficient cushioning material, and securely packaged in a strong fiberboard box that serves as the outer shipping container. [*In item b, change ''outer packaging'' to ''outer shipping container''.*]

* * * * *

[*In item d, change ''50 pounds'' to ''25 pounds.''*]

11.0 MISCELLANEOUS HAZARDOUS MATERIALS (HAZARD CLASS 9)

11.1 Definition

[*In the second sentence, delete ''magnetized materials,''.*]

* * * * *

11.3 Marking

[*In the first sentence, change ''Surface Mail Only'' to ''Surface Only'' or ''Surface Mail Only.''*]

11.4 Dry Ice

[*In item a, change the heading ''Air Transportation'' to ''Air Transportation Requirements.''*]

[*In item b, change the heading ''Surface Transportation'' to ''Surface Transportation Requirements''. Also change ''Surface Mail Only'' to ''Surface Only'' or ''Surface Mail Only.''*]

* * * * *

[*Renumber 11.5 as 12.0 and change the heading to read as follows:*]

12.0 OTHER REGULATED MATERIALS

12.1 Magnetized Materials

[*Change the first sentence in 12.1 to read as follows (the remainder of 12.1 is unchanged):*]

A magnetized material is not classified within any of the nine hazard classes. Such material is regulated as a hazardous material only if offered for carriage on air transportation and when it has a magnetic field strength capable of causing the deviation of aircraft instruments. Regulated magnetized materials are mailable subject to the following limitations:

a. Definition.

[*In the second sentence, change ''a hazard class 9 material'' to ''a hazardous material.''*]

b. Mailability.

[*In the third sentence, change ''Publication 52'' to ''Publication 52, Hazardous, Restricted, and Perishable Mail.''*]

* * * * *

C024 Other Restricted or Nonmailable Matter

* * * * *

[Renumber 18.0 and 19.0 as19.0 and 20.0, and insert new 18.0 to read as follows:]

18.0 ODD-SHAPED ITEMS IN PAPER ENVELOPES

Pens, pencils, key rings, bottle caps, and other similar odd-shaped items are not permitted in letter-size or flat-size paper envelopes unless they are wrapped within the other contents of the envelope to streamline the shape of the mailpiece and prevent damage during postal processing. If an odd-shaped item is not properly wrapped, it could burst through the envelope and cause injury to employees and damage to USPS processing equipment. Odd-shaped items that are properly wrapped within paper envelopes and are sent at the First-Class Mail or Standard Mail nonautomation rates may be subject to the nonmachinable surcharge under E130 or E620, as applicable. Properly wrapped odd-shaped items in automation rate letter-size mail are subject to the standards in C810. Flat-size automation rate mail is subject to the uniform thickness requirement in C820.

* * * * *

F Forwarding and Related Services

F000 Basic Services

F010 Basic Information

* * * * *

5.0 CLASS TREATMENT FOR ANCILLARY SERVICES

5.1 First-Class Mail and Priority Mail

* * * * *

[Revise item e to read as follows:]

e. First-Class Mail or Priority Mail bearing ''Change Service Requested'' must include the appropriate Address Change Service (ACS) participant code from an authorized ACS participant. ''Change Service Requested'' is not permitted for the following:

(1) Priority Mail, except for Priority Mail containing perishable matter under C022 (other than live animals).

(2) First-Class Mail or Priority Mail containing live animals under C022, hazardous materials under C023, or restricted matter underC024.

(3) First-Class Mail or Priority Mail with a special service other than Delivery Confirmation or Signature Confirmation.

Exhibit 5.1 Treatment of Undeliverable First-Class Mail and Priority Mail

[Revise the listing for ''Change Service Requested'' to read as follows:]

Mailer endorsement	USPS treatment of UAA pieces
	* * * * *
''Change service requested'' [2].	In all cases: Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS. Restrictions: This endorsement may be used only by mailers authorized to participate in Address Change Service (ACS) and only for: (1) First-Class Mail (excluding live animals, hazardous materials, and restricted matter) bearing a proper ACS participant code. (2) Priority Mail containing perishable matter (other than live animals) and bearing a proper ACS participant code and the marking ''Perishable.'' Delivery Confirmation and Signature Confirmation are the only special services permitted with this endorsement. Prohibitions: This endorsement is not permitted for First-Class Mail or Priority Mail containing live animals, hazardous materials, or restricted matter.
	* * * * *

* * * * *

[Revise the text of footnote 2 to read as follows:]

2. Valid only for ACS participating pieces, other than pieces containing live animals, hazardous materials, or restricted matter.

* * * * *

5.3 Standard Mail

* * * * *

[Reletter items c through j as d though k, and insert new item c to read as follows:]

c. The endorsement ''Change Service Requested'' is not permitted for Standard Mail containing perishable matter under C022, hazardous materials under C023, or restricted matter under C024. Standard Mail containing perishable matter, hazardous materials, or restricted matter must bear the endorsement ''Address Service Requested,'' ''Forwarding Service Requested,'' or ''Return Service Requested.''

* * * * *

Exhibit 5.3a Treatment of Undeliverable Standard Mail

[*Revise the listing for ''Change Service Requested'' to read as follows:*]

Mailer endorsement	USPS Treatment of UAA Pieces
No endorsement [1].	In all cases: Piece0 disposed of by USPS. Prohibitions: Standard Mail containing perishable matter, hazardous materials, or restricted matter must bear a permissible endorsement.

Mailer endorsement	USPS Treatment of UAA Pieces
''Address Service Requested'' [2].	* * * * *
* * * * *	* * * * *
''Change Service Requested'' [3].	In all cases: Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS. Restrictions: Delivery Confirmation is the only special service permitted with this endorsement. Prohibitions: This endorsement is not permitted for Standard Mail containing perishable matter, hazardous materials, or restricted matter.

[*Revise footnote 1 and add new footnotes 2 and 3 to read as follows:*]

1. Not valid for pieces containing perishable matter, hazardous materials, or restricted matter.

2. Valid for all pieces, including Address Change Service (ACS) participating pieces.

3. Not valid for pieces containing perishable matter, hazardous materials, or restricted matter. Valid for all other pieces, including Address Change Service (ACS) participating pieces.

* * * * *

5.4 Package Services

* * * * *

[*Reletter items c through e as d through f, and insert new item c to read as follows:*]

c. The endorsement ''Change Service Requested'' is not permitted for Package Services mail containing perishable matter under C022, hazardous materials under C023, or restricted matter under C024.

* * * * *

Exhibit 5.4 Treatment of Undeliverable Package Services Mail

[*Revise the listing for ''Change Service Requested'' to read as follows:*]

Mailer endorsement	USPS Treatment of UAA Pieces
* * * * *	* * * * *
''Change Service Requested'' [2].	In all cases: Separate notice of new address or reason for nondelivery provided (in either case, address correction fee charged); piece disposed of by USPS.
	Restrictions: Delivery Confirmation and Signature Confirmation are the only special services permitted with this endorsement. Prohibitions: This endorsement is not permitted for Package Services Mail containing perishable matter, hazardous materials, or restricted matter.

[*Add new footnote 2 to read as follows:*]

2. Not valid for pieces containing perishable matter, hazardous materials, or restricted matter. Valid for all other pieces, including Address Change Service (ACS) participating pieces.

* * * * *

An appropriate amendment to 39 CFR part 111 to reflect these changes will be published if the proposal is adopted.

Stanley F. Mires,

Chief Counsel, Legislative.

[FR Doc. 02–31990 Filed 12–18–02; 8:45 am]

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DEPARTMENT OF VETERANS AFFAIRS

38 CFR Part 1

RIN 2900–AL33

Privacy Act of 1974—Implementation

AGENCY: Department of Veterans Affairs.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend Department of Veterans Affairs (VA) regulations governing the confidentiality and release of VA records subject to the Privacy Act, 5 U.S.C. 552a. We propose to revise regulation, which exempts certain records from the provisions of the Privacy Act authorized under 5 U.S.C. 552a (j)(2) and (k)(2). This revision would have the intended effect of permitting VA to exempt a new Privacy Act systems of records relating to police and security records.

DATES: Comments must be received on or before February 18, 2003.

ADDRESSES: Mail or hand deliver written comments to: Director, Office of Regulations Management (02D), Department of Veterans Affairs, 810 Vermont Avenue, NW, Room 1154, Washington, DC 20420; or fax comments to (202) 273–9289; or e-mail comments to *OGCRegulations@mail.va.gov*. Comments should indicate that they are submitted in response to ''RIN 2900–AL33.'' All written comments received will be available for public inspection at the above address in the Office of Regulations Management, Room 1158, between the hours of 8 a.m. and 4:30 p.m., Monday through Friday (except holidays).

FOR FURTHER INFORMATION CONTACT: Director Police and Security Service (07B), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420, telephone (202) 273–5544.

SUPPLEMENTARY INFORMATION: Currently, VA regulations only exempt from certain provisions of the Privacy Act two VA Privacy Act systems of records (see, 38 CFR 1.582). This document proposes to add a new system of records, ''Police and Security Records—VA (103VA07B),'' to those already exempt under § 1.582.

Under title 5 United States Code (U.S.C.) 552a(j)(2), the head of any agency may exempt any system of records within the agency from certain provisions of the Privacy Act, if the agency or component that maintains the