

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

- For the reasons discussed in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add temporary § 165.T07–219 to read as follows:

§ 165.T07–219 Safety Zone; Ft. Myers Beach, Florida.

(a) *Location.* The Coast Guard is establishing a temporary safety zone on the waters of San Carlos Bay, Florida, in the vicinity of the Sanibel Island Bridge span “A”. This safety zone includes all waters from surface to bottom, within a 400 foot radius extending from the center portion of span “A” at the following coordinates: 26°28'59" N, 082°00'52" W. All coordinates referenced use datum: NAD 83.

(b) *Definitions.* The following definitions apply to this section:

Designated representative means Coast Guard Patrol Commanders including Coast Guard coxswains, petty officers and other officers operating Coast Guard vessels, and Federal, State, and local officers designated by or assisting the Captain of the Port Sector St. Petersburg, Florida, in the enforcement of regulated navigation areas and safety and security zones.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, no person or vessel may anchor, moor or transit the Regulated Area without the prior permission of the Captain of the Port Sector St. Petersburg, Florida, or his designated representative.

(d) *Dates.* This rule is effective from 6 a.m. on October 16, 2006 through 9 p.m. on March 31, 2007.

(e) *Enforcement period.* This regulated area will only be enforced during specific periods between the dates specified in paragraph (d), while construction operations are taking place. The Coast Guard does not know the exact dates of the construction operations at this time, however Sector St. Petersburg will announce each enforcement period by issuing

Broadcast Notice to Mariners 24 to 48 hours prior to the start of enforcement. Additionally, on-scene notice will be provided by Coast Guard or other local law enforcement maritime units enforcing the safety zone.

Dated: October 16, 2006.

J.A. Servidio,

Captain, U.S. Coast Guard, Captain of the Port Sector St. Petersburg, Florida.

[FR Doc. E6-18392 Filed 10-31-06; 8:45 am]

BILLING CODE 4910-15-P

POSTAL SERVICE**39 CFR Part 111****New Standards for Mailing Sharps and Other Regulated Medical Waste Containers**

AGENCY: Postal Service.

ACTION: Final rule.

SUMMARY: The Postal Service revises the standards for mailing sharps and other regulated medical waste containers. The new standards include improvements to the packaging, the package testing, and the process for authorizing and suspending authorization.

DATES: *Effective Date:* November 9, 2006.

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

SUPPLEMENTARY INFORMATION:**Background**

We published a proposed rule in the **Federal Register** (71 FR 19840, April 18, 2006) to revise the standards for mailing sharps and other regulated medical waste containers. Our proposal included the following changes:

1. To require container vendors to provide the Postal Service with the names and addresses of their distributors and to provide updates on a quarterly basis.

2. To revise the process for authorizing and suspending authorization for mailing sharps and other regulated medical waste containers to enhance monitoring and control of medical waste in the mail.

3. To revise container standards and container testing standards to ensure that container testing is performed on a consistent basis for all sharps and other regulated medical waste containers.

Comments Received

We received comments from four authorized sharps container vendors and one potential vendor. All commenters supported the concept of revising the rules to promote uniform

testing methods and to ensure the integrity of mailpieces containing sharps and other medical waste.

Documentation Requirements

Three commenters objected to the requirement that vendors provide a list of distributors to the Postal Service. All three commenters argued that requiring vendors to provide a quarterly list of distributors could lead to disclosure of sensitive proprietary vendor information. We agree that the Postal Service can identify a vendor's distributors, if needed, by requiring vendors to provide this information on request. Therefore, the final rule requires vendors to provide the names, addresses, and telephone numbers of their distributors to the Postal Service only on request.

Packaging

One commenter objected to a minimum size limit for the biohazard symbol placed on the outer shipping container. The commenter stated that requiring a 3 inch by 4 inch symbol would be excessively large on a small mailpiece. The Postal Service notes that currently no approved medical waste mailpieces are so small as to not easily accommodate a 3 inch by 4 inch biohazard symbol. The new standard will clarify that the 3 inch by 4 inch label requirement applies to the outer shipping container. For safety reasons, medical waste containers must be easily identified as containing biohazardous materials. Therefore, this final rule adopts the standard as published in the proposal.

Three commenters did not want the Postal Service to eliminate the use of outer shipping containers with interlocking bottoms. All three commenters stated that current requirements that allow for the use of shipping containers with interlocking bottom flaps reinforced with tape are more than adequate, especially considering the overall rigorous testing mandates. After further consultation with package testing professionals, we conclude that interlocking bottom flaps sufficiently contain the primary receptacle, particularly when reinforced with tape. Therefore, we will maintain our current standards that allow interlocking bottoms when they are reinforced with water-resistant tape.

Two commenters requested clarification of the proposed changes to the secondary container requirements. The commenters stated that increasing the plastic bag thickness requirement from 3 mil to 4 mil was not necessary. In addition, they stated that it was not advantageous to require the plastic bag

to be placed around the secondary box. We believe that increasing the thickness of the plastic bag will help maintain the contents of the primary container should it break. Therefore, we will require plastic bags to be 4 mil thick. However, we will not require the plastic bag to be placed outside the secondary box.

Two commenters requested clarification of the proposed standards in section 601.10.17.7b4 of Mailing Standards of the United States Postal Service, Domestic Mail Manual (DMM). We revised this section to clarify that the absorbent material must be placed in the primary receptacle. Item e10 will serve as the required test to ensure that the secondary system is watertight.

One commenter suggested that the Postal Service require screw caps for primary containers. Historical data on safely mailing these mailpieces does not indicate a need to require screw caps. Therefore, this final rule adopts the standard as published in the proposal.

Mailpiece Testing

One commenter objected to the requirement that mailpieces be tested at the vendor's identified maximum weight and that the container's maximum allowable weight be printed on the outer shipping container. The commenter stated that it was impossible to predict the maximum weight of the materials that might be placed into a container and that end users would not have scales to weigh the mailpiece. We believe, in the interest of safety, that these mailpieces should be tested at the highest possible weight determined by the vendor, not to exceed 25 pounds, to ensure that the mailpiece can safely contain the maximum weight. Therefore, this final rule adopts the requirements as published in the proposal.

One commenter suggested that the Postal Service require accreditation of package testing facilities. Section 601.10.17.7d of the proposed rule states "the Postal Service may require proof of accreditation or other documentation to support the credentials of an independent testing facility." We believe that this standard provides the authority to require proof of credentials as necessary. Therefore, this final rule adopts the standard as published in the proposal.

One commenter questioned the need for a reference to 49 CFR 178.604, Leak-proof test. The commenter stated that we should not refer to the test because our pass/fail criteria were not the same as the criteria in 49 CFR. The test in 49 CFR 178.604 requires that the primary container hold 20 kPa without leakage.

Our criteria allow for air leakage around the opening of the primary container as long as there is no air leakage anywhere else and no leakage of water. We agree that it would be clearer, in this case, to eliminate the reference and to provide only the USPS test procedure and pass/fail criteria.

One commenter requested clarification on the height of the required drop tests. Our proposed rule requires 30-foot drops for the wet and cold tests as identified in 49 CFR 178.609e and f. The impact test requires a drop of 3 feet as identified in 49 CFR 178.609h. While we understand that the test identified in 49 CFR consists of requirements for packaging infectious substances, we believe that the Postal Service's handling and transportation systems are different from those of commercial carriers and require more stringent acceptance criteria. Therefore, this final rule adopts the standard as published in the proposal.

One commenter suggested that testing material should be simulated medical waste. We disagree. The testing material should consist of sharps or other regulated medical waste as defined in DMM 601.10.17.2e and g. Vendors are on notice that contaminated medical waste will not be used for testing purposes. Therefore, this final rule adopts the standard as published in the proposal.

Mailpiece Acceptance

One commenter objected to requirements that vendors retrieve improperly labeled containers when identified and held at plants. The commenter suggested that the Postal Service should confirm the mailpiece was properly marked and labeled before accepting it. While we continually educate employees on acceptance criteria, the mailer remains responsible for properly labeling the mailpiece. Therefore, this final rule adopts the requirement as published in the proposal.

This final rule will be effective on November 9, 2006. Sharps and other regulated medical waste containers that are currently approved for mailing can maintain their authorization until it expires (24 months from the most recent approval). Containers must meet the new standards if they are submitted for authorization (or renewal of authorization) on or after November 9.

We adopt the following amendments 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.

List of Subjects in 39 CFR Part 111

Administrative practice and procedure, Postal Service.

- Accordingly, 39 CFR part 111 is amended as follows:

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, 416, 3001–3011, 3201–3219, 3403–3406, 3621, 3626, 5001.

- 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

* * * * *

10.0 Hazardous Materials

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10.17 Infectious Substances (Hazard Class 6, Division 6.2)

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[Revise title of 10.17.7 as follows:]

10.17.7 Sharps Medical Waste and Regulated Medical Waste Containers

[Replace "distributor or manufacturer" with "vendor" throughout 10.17.7.]

* * * * *

[Add new authorization information to the end of item a1 as follows:]

1. * * * Vendors that market their containers to distributors are responsible for disposal and cleanup costs attributed to those containers. In addition, vendors must provide a list of distributors, including firm names, addresses, and telephone numbers, to the Postal Service on request.

* * * * *

[Revise item a3 to add "name" and "phone number" as follows:]

3. Name, address, and phone number of each storage and disposal site.

* * * * *

[Add text at the end of item a8 as follows:]

8. * * * and verification that the merchandise return service (MRS) permit fee and accounting fee have been paid.

[Add new item a9 as follows:]

9. Address of the post office or postage due unit where the containers are delivered.

* * * * *

[Revise the package testing information in item b1 by replacing the last sentence as follows:]

1. * * * Package testing results must show that the contents of the primary container did not penetrate through the primary container during package testing and that the primary container can maintain its integrity at temperatures as low as 0°F and as high as 120°F.

[Revise the third sentence of item b2 to read "4 mil" as follows:]

2. * * * If one of the components is a plastic bag, the bag must be at least 4 mil in thickness and must be used in conjunction with a fiberboard box.
* * *

* * * * * [Revise item b4 by replacing "a watertight barrier" with "the primary receptacle" as follows:]

4. There must be enough material within the primary receptacle * * *

[Revise item b5 as follows:]

5. Each mailpiece must not weigh more than 25 pounds. The container's maximum allowable weight must be printed on the outside of the box and on the assembly and closure instructions included with each mailpiece. The mailpiece must be tested at the maximum allowable weight identified by the vendor.
* * * * *

[Add a new sentence at the end of item c1 as follows:]

1. * * * Place the label on the top or on a side of the container.

[Add a new sentence at the end of item c2 as follows:]

2. * * * The symbol on the outer shipping container must be at least 3 inches high and 4 inches wide.
* * * * *

[Add new item c7 as follows:]

7. Vendors must retrieve mailpieces held at processing facilities due to improper labeling such as no return address or due to improperly completed shipping papers.
* * * * *

[Revise item d as follows:]

d. *Package Testing*. Vendors must submit to the manager, Mailing Standards (see 608.8 for address), package testing results from an independent testing facility for each package for which the vendor is requesting authorization. In addition, vendors must submit package testing results from an independent testing facility when the design of a container system changes or every 24 months, whichever occurs first. The test results must show that if every mailpiece prepared for mailing were subject to the environmental and test conditions in 49 CFR and the additional test requirements in 10.17.7e, no contents would be released into the environment

and the effectiveness of the packaging would not be significantly reduced. The Postal Service may require proof of accreditation or other documentation to support the credentials of an independent testing facility.

[Add new item e as follows:]

e. *Testing Criteria*. Each mailpiece must pass each of the tests described below:

1. *Leak-proof test*. The test must be conducted on one primary receptacle with the lid in place, without the secondary and outer packaging. The test duration must be at least 5 minutes and must be conducted at 20 kPa (3 psi). The pass/fail criterion is: No air leakage from anywhere other than the closure of the primary receptacle. Air leakage at the closure is not considered a failure if the primary receptacle passes the test for watertightness as determined by placing 50 ml of deionized water into the primary receptacle, securing the closure, and then turning the container on its side and observing for any evidence of leakage. Any evidence of water leaking from the primary receptacle is a failure.

2. *Stacking test*. One mailpiece must withstand the test in 49 CFR 178.606. The dynamic compression test must be conducted on the empty, unsealed mailpiece assembled for mailing, without the primary receptacle(s). The test mass is the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. A compensation factor of 1.5 must be used to compute the test load, based on the vendor-identified weight. The pass/fail criteria are: No buckling of the sidewalls sufficient to cause damage to the contents in the primary container, and in no case does the deflection exceed 1 inch.

3. *Vibration test*. One mailpiece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.608. The test mailpiece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions. The test sample is prepared as it would be for mailing. The pass/fail criterion is: No rupture, cracking, or splitting of any primary receptacle.

4. *Wet drop test*. Five mailpieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609e. Each test mailpiece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer

shipping container and on the assembly and closing instructions included with each mailpiece. Each mailpiece is prepared as it would be for mailing and subjected to the water spray as described in the test. A separate, untested mailpiece is used for each drop orientation: Top, longest side, shortest side, and corner. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.

5. *Cold drop test*. Five mailpieces filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609f. Each test mailpiece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mailpiece. Each mailpiece is prepared as it would be for mailing and chilled as described in the test. A separate, untested mailpiece is used for each drop orientation: Top, longest side, shortest side, and corner. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.

6. *Impact test*. One mailpiece filled with sharps or other regulated medical waste must withstand the test in 49 CFR 178.609h. The test mailpiece is filled with sharps or other regulated medical waste to the vendor-identified maximum weight, not to exceed 25 pounds, as indicated on the outer shipping container and on the assembly and closing instructions included with each mailpiece. The mailpiece is prepared as it would be for mailing. The pass/fail criteria are: No rupture, cracking, or splitting of any primary receptacle, and no contents may penetrate into or through the body or lid of any primary receptacle.

7. *Puncture-resistant test*. Package testing results must show that during all of the previous tests, the contents did not penetrate through the primary container.

8. *Temperature test*. Package testing results must show that each primary receptacle maintained its integrity when exposed to temperatures as low as 0°F and as high as 120°F.

9. *Absorbency test*. Package testing results must show that the primary receptacle(s) contain enough absorbent material to absorb three times the total liquid allowed within the primary receptacle in case of leakage. Absorbency is determined by pouring 150 ml of deionized water into the

primary receptacle(s), then turning the receptacle(s) upside down and observing for any evidence of free liquid not absorbed on contact. Any evidence of free liquid is a failure.

10. Watertight test. Package testing results must show that no leakage occurred when 50 ml of deionized water was placed into the secondary containment system and the entire system turned upside down for 5 minutes.

[Add new item f as follows:]

f. Suspension of Authorization.

1. The Postal Service may suspend a vendor's authorization based on information that a mailpiece no longer meets the standards for mailing sharps medical waste and regulated medical waste containers, or that the mailpiece poses an unreasonable safety risk to Postal Service employees or the public. The suspension can be made immediately, making the mailpiece nonmailable immediately. The vendor may contest a decision to suspend authorization by writing to the manager, Mailing Standards (see 608.8 for address), within 7 days from the date of the letter of suspension. The appeal should provide evidence demonstrating why the decision should be reconsidered. Any order suspending authorization remains in effect during an appeal or other challenge.

2. When a vendor is notified that its authorization to mail sharps or other regulated medical waste containers has been suspended, the vendor must immediately: (1) Recall all identified containers. (2) Notify all customers that they cannot mail the identified containers. (3) Suspend sales and distribution of all identified containers. (4) Collect the identified containers from distributors, consumers, and the Postal Service without using the mail and in accordance with all Federal and State regulations.

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Neva R. Watson,

Attorney, Legislative.

[FR Doc. E6-18063 Filed 10-31-06; 8:45 am]

BILLING CODE 7710-12-P

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.

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.