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

Regulated medical waste and sharps medical waste known or suspected to contain a Category A infectious substance is not mailable. Regulated medical waste and sharps medical waste as defined in [10.17.2f](#) and [10.17.2g](#), and containing materials classified as Category B infectious substances, must be marked UN 3291 and are permitted for mailing only using merchandise return service (see [507.11.0](#)) with First-Class Mail or Priority Mail service, subject to the following requirements:

a. *Authorization.* Each vendor of a complete regulated medical waste or sharps waste mailing container system (including all component parts required to safely mail 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 container system must be tested and certified under the standards in [10.17.5e](#) by an independent testing facility. The vendor in whose name the authorization is being sought must submit a written request to the manager, Mailing Standards, USPS Headquarters (see [608.8.0](#), *USPS Contact Information*, 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 vendor ceases doing business before all its waste container systems 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 vendor seeking the authorization and must name the USPS as the beneficiary or obligee. 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.
2. Address of the headquarters or general business office of the vendor seeking the authorization.
3. Name, address, and phone number of each storage and disposal site.
4. List of all types of mailing container systems to be covered by the request, a complete sample of each mailing container system, and proof of package testing certifications performed by the independent testing facility that subjected the packaging materials to the testing requirements in [10.17.5e](#).
5. Copy of the proposed waste shipping paper to be used with each mailing container system.
6. 24-hour toll free telephone number for emergencies.
7. List of the types of waste to be mailed for disposal in each mailing container system.
8. Copy of the merchandise return service label to be used with each mailing container system and verification that the merchandise return service permit fee and accounting fee have been paid.
9. Address of the Post Office or postage due unit where the containers are delivered.

b. *Packaging.* Regulated medical waste and sharps medical waste that also meets the definition of a Category A infectious substance is not mailable. A medical waste material treated by steam sterilization, chemical disinfections, or other appropriate method so that it no longer contains a Category A or Category B infectious substance must be packaged under [10.17.8](#). The packaging for regulated medical waste and sharps medical waste containing or suspected of containing a Category B infectious substance is subject to these standards:

1. Sharps medical waste and regulated medical waste meeting the definitions in [10.17.2e](#) and [10.17.2g](#) must be collected in a rigid, securely sealed, and leakproof primary receptacle. For sharps waste, the primary receptacle must also be puncture-resistant and may not have a maximum capacity that exceeds 3 gallons in volume. For regulated medical waste, the primary receptacle may not have a maximum capacity that exceeds 5 gallons in volume. Each primary receptacle may not contain more than 50 ml (1.66 ounces) of residual waste liquid. Each primary receptacle must display the international biohazard symbol shown in [Exhibit 10.17.5d3](#). Package testing results must show that the contents 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.

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, the bag must be at least 4 mil in thickness and must be used in conjunction with a 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. The primary receptacle(s) must fit securely and snugly within the secondary container to prevent breakage during ordinary processing.

3. The secondary container must be enclosed in a strong outer shipping container constructed of 200-pound grade corrugated fiberboard. 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 unless reinforced with water-resistant tape. The secondary container must fit securely and snugly within the outer shipping container to prevent breakage during ordinary processing.

4. There must be enough material within the primary receptacle 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. Medical Professional Packages as identified in 10.17.5c, may not weigh more than 35 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.

6. In each mailing container system, the authorized vendor must include a step-by-step instruction sheet that clearly details the proper sequence and method of container system assembly prior to mailing to prevent package failure during transport due to improper assembly. The instruction sheet must also include a customer service telephone number, or provide specific information on where such a telephone number is located elsewhere on the container system, for third-party end users to contact if they have assembly questions or find a component part is missing.

*c. Medical Professional Packages. Medical Professional Packages, while intended for use by small medical offices, is not limited to use by medical offices only. One primary receptacle larger than 5 gallons in volume may be used for mailing pre-primary sharps receptacles (sharps receptacles normally used in doctors' offices) and other regulated medical waste under the following conditions:*

*1. The mailpiece must meet all the requirements in 10.17.5 except for the primary receptacle capacity limits of 10.17.5b1.*

*2. Only rigid, securely closed, puncture and leak-resistant pre-primary sharps receptacles that meet or exceed Occupational Safety and Health Administration standards as identified in 29 CFR 1910.1030, may be placed inside the primary receptacle. Each pre-primary sharps container may contain no more than 50 ml (1.66 ounces) of residual waste liquid. Several pre-primary sharps receptacles may be enclosed in the single primary receptacle.*

*3. Multiple tie-closed plastic bags of regulated medical waste may be placed inside the single primary receptacle.*

*4. The primary receptacle must be lined with a plastic bag at least 4 mil in thickness and must include sufficient absorbent material within the liner to absorb all residual liquid in the primary receptacle.*

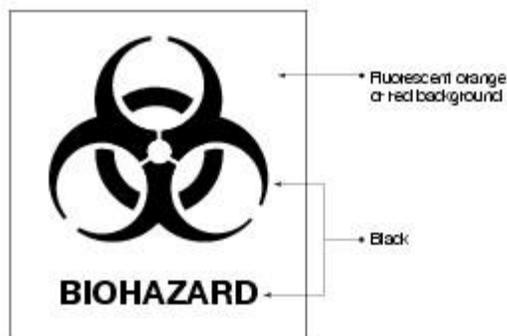
*5. The mailpiece must not weigh more than 35 pounds.*

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

*1. For Medical Professional Packages, the additional marking "Medical Professional Packaging" must be clearly printed in lettering at least 2 inches high on the address side of the outer shipping container.*

*2. Each primary receptacle and outer shipping container must bear a label, which cannot be detached intact, showing: (a) the company name of the vendor to which the mailing authorization is issued; (b) the USPS Authorization Number, and; (c) the container ID number (or unique model number) signifying that the packaging material is certified and that the vendor obtained the authorization required by 10.17.5a. Place the label on the top or on a side of the container.*

3. 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 10.17.5d3](#). The symbol on the outer shipping container must be at least 3 inches high and 4 inches wide.



**Exhibit 10.17.5d3 International Biohazard Symbol**

4. Each mailpiece must have a four-part waste shipping paper. The shipping paper 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 shipping paper must comply with all applicable requirements imposed by the laws of the state from which the container system is mailed. At a minimum, the information in [Exhibit 10.17.5d4](#) must be on the shipping paper.

**Exhibit 10.17.5d4 Shipping Paper for Regulated Medical Waste and Sharps Waste Containers**

SECTION	INFORMATION REQUIRED
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 of.
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 the shipping paper: "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 USC 1716 WHICH MAY RESULT FROM PLACING

	<p>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."</p> <p>This statement must be followed by printed or typewritten name of generator (mailer), signature of generator, and date signed.</p>
4. Destination Facility (Storage or Disposal Site)	<p>The following certification statement of receipt, treatment, and disposal must be printed on the shipping paper: "I certify that the contents of this container have been received, treated, and disposed of in accordance with all local, state, and federal regulations."</p> <p>This statement must be followed by printed or typewritten name of an authorized recipient at destination facility, signature of authorized recipient, and date signed.</p>
5. Transporter Intermediate Handler Other Than the Postal Service (If Different From Destination Facility)	<p>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.</p>
6. Serialized Waste Shipping Papers	<p>Each waste shipping paper or mail disposal service shipping record must be serialized using a unique numbering system for identification purposes.</p>
7. Comment Area	<p>Each shipping paper must contain an area designated for entering comments or noting discrepancies.</p>
8. Completion and Distribution of Waste Shipping Paper	<p>Each shipping paper 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.</p>
9. Emergency Telephone Number	<p>Each shipping paper must bear the following statement with appropriate information:</p>

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**"IN CASE OF EMERGENCY, OR THE DISCOVERY OF  
DAMAGE OR LEAKAGE, CALL  
1-800-###-####."**

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5.The outer shipping container must bear a properly prepared merchandise return service label (see [507.11.0](#)). The merchandise return service permit must be held in the same name as that of the authorized medical waste vendor.

6.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.

7.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").

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

e.Package Testing. Vendors must submit to the manager, Mailing Standards (see [608.8.0](#) 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 [10.17.5f](#), 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.

f.Testing Criteria. Packages tested for approval as Medical Professional Packages may not be tested using pre-primary containers that are currently, or have previously been, approved as USPS primary containers. Test reports must identify by brand name the pre-primary containers used during testing. 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 receptacle, 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 a 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 receptacle.

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.

g.Suspension of Authorization. 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 [608.8.0](#) 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. 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.

#### **10.17.6 Packaging Used Health Care Products**

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

- 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 10.17.5d3](#).
- 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 10.17.5d3](#).

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.