

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 authorized medical waste mailer.

(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 by an independent testing facility on one sample of each type of mailing container system to prove compliance with 8.7a. The sample mailing container system 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 container system 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 whenever a change is made to the design of the container system or every 24 months, whichever occurs first.

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, 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 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, Priority Mail, or Express Mail when packaged in a triple packaging, consisting of a

primary receptacle, secondary container, and outer shipping container as follows:

a. 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).

b. The primary receptacle and the absorbent and cushioning material must be enclosed in a watertight and securely sealed secondary container. The secondary container must also display the international biohazard symbol as shown in Exhibit 8.7c(2).

c. The secondary container must be firmly and snugly packed within a strong outer shipping container that is securely sealed. 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, Express 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. Either the primary receptacle or the inner packaging must be marked with the international