b. Other toxic substances and poisons are permitted to be sent between the authorized parties and under the conditions in 7.3 when they do not exceed 8 ounces per mailpiece and if: the material is held in a leak-resistant primary receptacle(s); sufficient absorbent and cushioning material completely surround each primary receptacle; the primary receptacle(s) and the absorbent and cushioning materials are firmly held within a secondary leakproof (for liquids) or siftproof (for solids) packaging; the secondary packaging is firmly and securely held within a strong outer packaging of 200-pound grade corrugated fiberboard or equivalent strength. The address side of each mailpiece must be marked with the proper shipping name and UN (or NA) identification number of the material (unless exempted by C024.11.2). Mailable materials sent via surface transportation must be marked on the address side as "Surface Mail Only." Each mailpiece must bear a shipping paper.

Irritating Material
7.5

Irritants are prohibited in international mail and domestic mail.

8.0 INFECTIOUS SUBSTANCES (HAZARD CLASS 6, DIVISION 6.2)

General
8.1

Infectious substances (i.e., etiologic agents), clinical specimens, and biological products 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 public health; and when it is determined that such items are properly prepared for mailing to withstand shocks, pressure changes, and other conditions incident to ordinary handling in transit. Mailable infectious substances sent as international mail must meet the standards in *International Mail Manual* (IMM) 135. For domestic mail, mailable infectious substances must meet the applicable standards in 8.0.

Definitions
8.2

The terms used in the standards for division 6.2 material are:

a. *Infectious substance* (etiologic agent) means a viable microorganism, or its toxin, that causes or may cause disease in human beings or animals, and includes those agents listed in 42 CFR 72.3 and any other agent that causes or may cause severe, disabling, or fatal disease. The terms infectious substance and etiologic agent are synonymous.

b. *Clinical (diagnostic) specimen* means any human or animal material including, but not limited to, excreta, secreta, blood, blood components, tissue, and tissue fluids, collected and being shipped for purposes of diagnosis.

c. *Biological product* means a material derived from a living organism that is prepared and manufactured in accordance with 9 CFR 102-104 (licenses for biological products; experimental products, distribution, and evaluation prior to licensing; and permits for biological products), 21 CFR 312 (investigational new drug application), or 21 CFR 600-680 (biologics) and that, under such provisions, may be shipped in interstate commerce. Biological products include, but are not limited to, products such as vaccines.

d. *Sharps* means any item of medical waste having a projecting cutting edge or fine point that was used in animal or human patient care or treatment or in medical research or industrial laboratories. The term includes, but is not limited to, hypodermic needles, syringes (with or without the attached needles), pasteur pipettes, scalpel blades, blood vials, needles with attached tubing, and culture dishes (regardless of the presence of infectious agents). Also included are other types of broken or unbroken glassware that were in contact with infectious agents, such as used slides or cover slips. The term does not include new unused medical devices such as hypodermic needles, syringes, and scalpel blades.

e. *Other medical devices* means all materials or devices used in animal or human patient care or treatment or in medical research that are not, or do not contain, a projecting sharp and are not known or not reasonably believed to contain an infectious substance (etiologic agent).

Packaging Infectious Substances (Etiologic Agents)
8.3

Packaging for all infectious substances (etiologic agents) is subject to these standards:

a. All infectious substances, clinical specimens, and biological products known or reasonably believed to contain an etiologic agent must meet the packaging requirements of 42 CFR 72.3 and must not exceed 50 ml per mailpiece. The primary receptacle or the secondary packaging must be capable of withstanding, without leakage, an internal pressure that produces a pressure differential of not less than 14 psi (95 kPa) and temperature 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 securely sealed, watertight, and durable secondary packaging. Several primary receptacles may be enclosed in a single secondary packaging if there is adequate shock-absorbent material between them to prevent breakage during ordinary handling and if the total liquid volume of all enclosed primary receptacles does not exceed 50 ml.

c. The space between the primary receptacle(s) and the secondary packaging at the top, bottom, and sides must contain enough material to absorb the entire content of the primary receptacle(s) in case of breakage or leakage.

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

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 content to the environment and no significant reduction in the effectiveness of the packaging.

f. [05-06-99] 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 by Express Mail, Priority Mail, or First-Class Mail. Those specific etiologic agents listed in 42 CFR 72.3(f) must be sent registered mail. Each mailpiece must be marked on the address side with the proper shipping name and UN number of the material (e.g., "Infectious Substances Affecting Humans, UN2814," or "Infectious Substances Affecting Animals, UN2900"). Each mailpiece must bear a DOT Class 6 label for infectious substances (etiologic agents), proper UN package specification markings, and orientation markings.

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(e)(2)(ii).

Packaging Clinical Specimens and Biological Products
8.4

A clinical specimen or biological product known or reasonably believed to contain an infectious substance (etiologic agent) must be packaged under 8.3. The packaging of a clinical specimen (e.g., a urine or blood specimen used in drug-testing programs or for insurance purposes) or a biological product (e.g., polio vaccine) that is not known or not reasonably believed to contain an infectious substance (etiologic agent) is subject to these packaging standards:

a. *Not Exceeding 50 ml.* A clinical specimen or biological product consisting of 50 ml or less per mailpiece must be packaged in a securely sealed primary receptacle. Sufficient shock-resistant material to withstand shock and pressure changes and absorbent material must surround the primary receptacle, or be otherwise configured to take up the content in case of leakage. The primary receptacle and the absorbent cushioning must be enclosed in a secondary packaging having a leakproof barrier that can prevent failure of the secondary packaging should there be leakage of the primary receptacle during shipment. The secondary packaging may serve as the outer packaging.

b. *Exceeding 50 ml.* In addition to meeting the requirements in 8.4a, a clinical specimen or biological product that exceeds 50 ml per mailpiece also is subject to these requirements:
   (1) 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 packaging.
   (2) The secondary packaging cannot serve as the outer packaging; the secondary packaging must be enclosed in a fiberboard box or container of equivalent strength; the maximum amount of a specimen that may be enclosed in a single outer packaging must not exceed 4,000 ml.

c. *Markings.* Mailable material must be marked as specified in 8.7.

Sharps
8.5

The types of used sharps waste defined in 8.2d are permitted for mailing only using merchandise return service (see S923) in conjunction with First-Class Mail or Priority Mail, subject to these standards:

a. *Authorization.* Each distributor or manufacturer of a complete sharps mailing kit or packaging assembly, including containers, cartons, and any other related material to be used to mail sharps to a storage or disposal facility, must obtain authorization from the USPS. Before applying for authorization, each type of mailing kit must be tested and certified against the standards in 8.5d by an independent party. A written request for authorization is sent to the Manager, Business Mail Acceptance, USPS Headquarters (see G043 for address). The request must contain the following:
   (1) A $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.
   (2) Address of the headquarters or general business office of the distributor or manufacturer.
   (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 8.5d.
(5) Copy of the proposed manifest to be used with all mailings.
(6) 24-hour telephone number for emergencies.
(7) List of the types of sharps waste to be mailed for disposal.

b. *Packaging.* The packaging for used sharps waste and unsterilized containers is subject to these standards:
(1) Used sharps waste must be packaged in a securely sealed, leak-resistant, and puncture-resistant primary receptacle that may not contain more than 50 ml of residual waste liquid. 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 packaging or containment system. The secondary packaging may consist of more than one component. If one of the components is a plastic bag, it must be at least 3.0 mils thick and reinforced with a fiberboard sleeve having a minimum thickness of 40-point. A plastic bag by itself does not meet the requirement for a secondary packaging. Several primary receptacles may be enclosed in a secondary packaging.
(3) The secondary packaging must be enclosed in an outer packaging or shipping container constructed of 200-pound grade corrugated fiberboard or similar material of equivalent strength. The secondary packaging must fit securely within the outer packaging 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 35 pounds.
(6) In each sharps mailing kit, the manufacturer or distributor must include a step-by-step instruction sheet that clearly details the proper sequence and methods of kit assembly prior to mailing to prevent package failure during transport due to improper assembly.

c. *Package documentation, marking, and labeling.*
(1) Each primary receptacle and outer packaging must bear a label, which cannot be detached intact, showing: (a) company name of the manufacturer or the distributor; (b) U.S. Postal Service Authorization Number; and (c) container ID number (or unique model number) signifying that the packaging material is certified and the manufacturer or distributor obtained an authorization required by 8.5a.
(2) The outer packaging must bear the international biohazard symbol with either a fluorescent orange or fluorescent red background as shown in Exhibit 8.5c(2).
(3) All mailpieces containing used sharps must be accompanied by a four-part manifest or mail disposal service shipping record. The manifest must be placed in an envelope affixed to the outside of the mailpiece. The manifest must comply with all applicable requirements imposed by the laws of the state from which the package is mailed. At a minimum, the information shown in Exhibit 8.5c(3) must be on the manifest.

(4) The outer packaging must bear a properly prepared merchandise return service label (see S923).
(5) Mailable material must be marked as specified in 8.7.

d. *Package testing.* Testing must be performed on one sample of each type of kit to prove compliance with 8.5a. The sample packaging kit must withstand the tests in 49 CFR 178.604 (leakproof test), 178.606 (stacking test), 178.608 (vibration standard), and 178.609 (test requirements for packaging for infectious substances/etiologic agents). In addition, the outer packaging must be subjected to the bursting test in 49 CFR 178.609(h)(2) and an absorbency test for the absorbent material commensurate with the requirements in 8.5b(4) must be performed. The test results must show that if every packaging 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 whenever a change is made to the packaging design or every 24 months, whichever occurs first.

Other Used Medical Devices
8.6

USPS authorization is not required to mail other used medical devices and waste as defined in 8.2e. Packaging for other used medical devices is subject to these standards:

a. Other used medical devices must be mailed as First-Class Mail, Priority Mail, or Express Mail.

b. Other used medical devices must be packaged in a securely sealed, leak-resistant primary receptacle, the total liquid volume of which must not exceed 50 ml unless the devices are shipped in formalin or its equivalent. The primary receptacle must maintain its integrity when exposed to temperatures between 0° and 120°F.

c. The primary receptacle must be enclosed in an outer packaging constructed of 200-pound grade corrugated fiberboard or similar material of equivalent strength. The primary receptacle must fit securely within the outer packaging to prevent breakage during ordinary processing.

d. There must be enough absorbent material and secondary leakproof material between the primary receptacle and the outer packaging to absorb three times the total liquid allowed. If the device is mailed in a formalin solution or its equivalent, there must be enough absorbent material and secondary leakproof material to absorb the entire liquid contents in case of leakage.

e. Each parcel containing other used medical devices must bear a complete street return address (not a post office box) and cannot exceed 35 pounds.

f. Mailable material must be marked as specified in 8.7.

International Biohazard Symbol
Exhibit 8.5c(2)

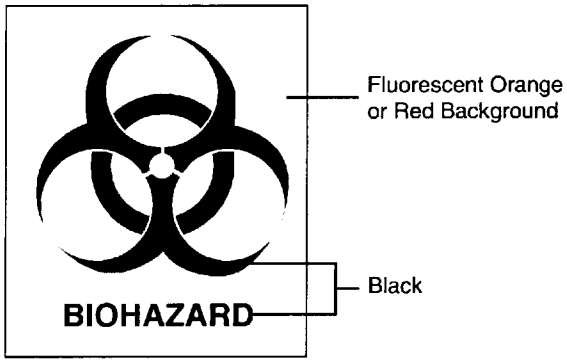

Exhibit 8.5c(3) **Manifest for Sharps Containers**

1. Generator (Mailer)

a. Name.
b. Complete address (not a post office box).
c. Telephone number.
d. Description of contents of shipping container; "Used Medical Sharps" is required.
e. Date shipping 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

"I certify that this carton has been approved for the mailing of used medical sharps, 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 regulations. I AM AWARE THAT FULL RESPONSIBILITY RESTS WITH THE GENERATOR (MAILER) FOR ANY VIOLATION OF 18 USC 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 applicable national governmental regulations."
This printed statement is to be followed by printed name of generator (mailer), signature of generator, and date when manifest was signed.

4. Destination Facility (Storage or Disposal Site)

a. Printed certification of receipt, treatment, and disposal stating: "I certify that the contents of this package have been received, treated, and disposed of in accordance with all local, state, and federal regulations."
b. Printed or typewritten name of an authorized recipient at destination facility.
c. Signature of authorized recipient at destination facility.
d. Date representative of destination facility signed manifest.

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

a. Name.
b. Complete street address (not a post office box).
c. Printed name of transporter or intermediate handler.
d. Signature of transporter or intermediate handler.

6. Serialized Manifests

Manifest or mail disposal service shipping forms must be serialized.

7. Area Reserved for Comments

Manifest must contain an area designated for entering discrepancies and comments, especially if an alternative destination facility is used.

8. Completion and Distribution of Manifest

Manifest must contain instructions for properly completing manifest and distributing copies.
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

Manifest must bear following statement with appropriate information:
"IN CASE OF EMERGENCY, OR THE DISCOVERY OF DAMAGE OR LEAKAGE,
CALL 1-800-XXX-XXXX."

Marking and Labeling of Division 6.2 Material
8.7

[05-06-99] All mailable division 6.2 materials, except those prepared under 8.4, must be sent via air transportation. The following markings and labels are required, as applicable:

a. Infectious Substances (Etiologic Agents). Materials mailable under 8.3 must be marked and labeled as specified in 8.3f. A shipper's declaration for dangerous goods is required.

b. Clinical Specimens and Biological Products. Materials mailable under 8.4 must be marked on the address side with "Clinical Specimen—Blood Sample," "Clinical Specimen—Urine Sample," "Clinical Specimen—Saliva Sample," "Biological Product," etc., as appropriate. The universal biohazard symbol shown in Exhibit 8.5c(2) may appear on the address side. A shipping paper is not required for material sent under 8.4.

c. Sharps Wastes. Packages containing sharps waste mailable under 8.5 must be marked on the address side with the proper shipping name and correct UN number (e.g., "Regulated Medical Waste—Sharps, UN3291"). The universal biohazard symbol shown in Exhibit 8.5c(2) must appear on the outside of the mailpiece. The manifest required in 8.5c serves as the shipping paper.

d. Other Used Medical Devices. Parcels containing other used medical devices mailable under 8.6 must be marked on the address side with the proper shipping name and correct UN number (e.g., "Regulated Medical Waste, UN 3291"). The universal biohazard symbol shown in Exhibit 8.5c(2) must appear on the outside of the mailpiece. A shipping paper is required.

9.0 RADIOACTIVE MATERIALS (HAZARD CLASS 7)

Radioactive materials are prohibited in international mail and domestic mail if required to bear the DOT Radioactive White-I, Radioactive Yellow-II, or Radioactive Yellow-III label (49 CFR 172.436, 172.438, or 172.440, respectively) or if it contains quantities of radioactive material in excess of those authorized in Publication 52, *Acceptance of Hazardous, Restricted, or Perishable Matter.* Radioactive materials are prohibited in domestic mail via air transportation. For international mail, the standards in IMM 135 apply.

10.0 CORROSIVES (HAZARD CLASS 8)

Definition
10.1

A *corrosive* is any liquid or solid that causes visible destruction or irreversible alteration in human skin tissue at the site of contact or a liquid that has a severe corrosion rate on steel.

Mailability
10.2

Corrosives are prohibited in international mail. A corrosive that can qualify as an ORM-D material is permitted in domestic mail via air or surface transportation subject to these limitations:

a. *Liquid Corrosive.* A liquid mixture must be 1 pint or less and must contain 15% or less corrosive material with the remainder of the mixture not being a hazardous material, unless otherwise specified for a specific corrosive material. Primary receptacles must be securely sealed compatible glass bottles that are enclosed within securely sealed metal or plastic secondary packagings. The secondary packaging must be packed within a strong outer packaging that does not exceed 25 pounds per mailpiece.