

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 Waste	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—nonmailable.

n/a—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. 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 normal handling, and if the total volume of the material in all enclosed primary receptacles does not exceed 50 ml for liquids or 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. All mailpieces sent under 8.5 must be sent First-Class Mail or Priority Mail and 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. Any mailpiece classified as a Risk Group 4 material and that contains any of the select agents or toxins listed in 42 CFR 73.4 or 73.5 must meet all requirements in 42 CFR 72 and must also be sent using Registered Mail service.

g. Articles that include dry ice as a refrigerant for the infectious substance must meet the requirements in 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, Priority Mail, or Express Mail. Such materials must be packaged in a triple packaging, consisting of a primary receptacle, secondary container, and outer shipping container, subject to the following specific requirements:

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 with sufficient cushioning material to withstand shock and pressure changes and with absorbent material capable of taking up the entire liquid contents should 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.

(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. The secondary container must be marked with the international biohazard symbol as shown in Exhibit 8.7c(2).

(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