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# Packaging and Shipping of Biomedical Material

Centers for Disease Control and Prevention  
Office of Health and Safety, Biosafety Branch  
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## Introduction

The regulation that describes the requirements for the proper packaging and shipping of biomedical material is found in 42 CFR Part 72- Interstate Shipment of Etiologic Agents. This regulation has been the responsibility of the Public Health Service since 1971 when the authority for governing the interstate shipment of etiologic agents was delegated to CDC. The regulation now in effect was published in 1980. It is currently in the process of being revised and you will be notified of any changes when they become law. It is the intent of the regulation that biomedical material that may contain etiologic agents will be packaged and shipped in such a way that the contents will not leak and will arrive in good condition. What follows is a set of instructions extracted from the regulation.

Any questions should be directed to the **Office of Health and Safety** in Atlanta at **404 639-3235**, or Fax **404 639-2294**.

## Definitions

Biomedical materials that are known to contain, or could contain, etiologic agents are divided into two groups:

- **"Diagnostic specimens and biological products"** on the one hand and
  - **"materials containing certain etiologic agents"** on the other.
- The former are packaged according to Part 72.2 and the latter according to Part 72.3.

**"Etiologic agent"** means a viable microorganism or its own toxin that causes, or may cause, human disease.

**"Diagnostic specimen"** means excreta, secreta, blood and its components, tissue, tissue fluids, etc., "which (the shipper) reasonably believes may contain an etiologic agent" and that is "being shipped for purposes of diagnosis."

**"Biological product"** means a product prepared in accordance with regulations that govern the manufacture of vaccines, reagents, etc.

**"Materials containing certain etiologic agents"** means "material known to contain or reasonable believed (by the shipper) to contain" an etiologic agent from a list included in the regulation. The list contains most of the Class 2, 3, and 4 agents but any etiologic agent should be handled according to the regulation even if it is not on the list. Patient specimens that would be expected to contain an etiologic agent should be shipped according to the requirements in Part 72.3.

**"Interstate"** shipping is interpreted to include intrastate shipping.

***Packaging of diagnostic specimens and biological products (42 CFR Part 72.2)***

Such material must be "packaged to withstand leakage of contents, shocks, pressure changes, and other conditions incident to ordinary handling in transportation." This should be interpreted to mean that the contents should not leak to the outside of the shipping container, even if there should be leakage of the primary container(s) during transit, unless the package is severely damaged, e.g., like being run over by a transport vehicle. These packages should, on the other hand, withstand rough handling and passage through cancellation machines, sorters, conveyors, etc.

***Packaging of materials containing.... etiologic agents (42 CFR Part 72.3)***

A.

There are two sets of instructions for this material, depending upon the volume shipped.

1.

**Volume not exceeding 50 ml.:**

- (a) The material to be shipped shall be placed in a securely closed, watertight tube, vial, ampule or the like that is referred to as primary container.
- (b) The primary container is then placed in a durable watertight container referred to as the secondary container.
- (c) Several primary containers can be placed in a single secondary container, so long as total contents of the primary containers does not exceed 50 ml.
- (d) Absorbent material must be placed in the space at top, bottom, and sides between the primary and secondary containers. There must be enough absorbent material to absorb the entire contents of the primary container(s) in case of breakage or leakage and should not be nonparticulate, i.e., not sawdust, vermiculite, etc.
- (e) Each set of primary and secondary containers is then placed in an outer shipping container constructed of corrugated fiberboard, cardboard,

wood, or other material of equivalent strength. This means that most, if not all, bags, envelopes, and the like are not acceptable outer shipping containers.

2.

**Volume greater than 50 ml.:**

Packaging of these larger volumes of material must comply with all of the foregoing requirements, but in addition:

(a)

Shock absorbent material, in volume at least equal to that of the absorbent material between the primary and secondary containers, shall be placed at the top, bottom, and sides between the secondary container and outer shipping container.

(b)

Single primary containers shall not contain more than 1,000 ml of material, however two or more primary containers, whose volumes do not exceed 1,000 ml, may be placed in a single secondary container.

(c)

The maximum amount of etiological agent that may be enclosed within a single outer shipping container may not exceed 4,000 ml.

B.

If dry ice is used, it must be placed between the secondary container(s) and the outer shipping container and the shock absorbent material placed so that the secondary container(s) do not become loose within the outer shipping container as the dry ice sublimates.

C.

A special label, illustrated on page 3, must be placed on the outer shipping container. This label identifies the package as containing etiologic agents and directs anyone observing damage to the package or leakage of contents to call CDC.

D.

The regulation also contains a list of etiological agents that require special handling in addition to that stated above. These are, by and large, Class 3 and Class 4 agents. The requirement is that they be shipped by "registered mail or an equivalent system which requires or provides for sending notification of receipt to the sender immediately upon delivery."

**When this notice of receipt is not received "within 5 days following anticipated delivery" the sender must notify CDC.**

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