

FACILITY: Veterans Affairs Medical Center: Pathology and Laboratory Medicine
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Safety

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SOP HISTORICAL RECORD

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Introduction

Proper instruction on the packaging, labeling, transportation, and storage of biological specimens is essential in the laboratory.

Policy

1. The U S Department of Transportation (DOT), Centers for Disease Control (CDC), U.S. Postal Service (USPS) and U.S. Department of Agriculture (USDA) have defined packaging requirements and definitions of etiological agents (infectious substances), clinical/diagnostic specimens, and biological materials based on the following:

a. Diagnostic specimens are currently defined as any human or animal materials including, but not limited to excreta, secretions, blood and its components, tissue, and tissue fluids that may or may not contain an infectious agent.

b. Infectious substances are defined as those substances containing viable microorganisms or their toxins which are known, or suspected to cause disease in animals or humans.

2. Biological products are those substances that meet one of the following criteria:

a) Biological products for human use manufactured in accordance with the requirements of national public health authorities and being transported under special approval or license from such authorities.

b) Biological products shipped prior to licensing for development or investigational purposes for use in humans.

3. Packaging:

a. The method of packaging and shipment of these specimens depend upon whether the shipper reasonably believes that the material does or does not contain etiologic agents or falls under the guidelines of the U.S. DOT as regulated medical waste. Biological products and "diagnostic specimens" are not considered to be dangerous goods, provided they do not contain, or are reasonably believed not to contain, an infectious substance, or do not contain any other dangerous substance. These must then be packaged in accordance with civil (ICAO) and international air traffic (IATA) and DOT packing instructions depending on its final destination.

b. In general, if materials are to be shipped off site to another facility by air or carriers using public roads the recommendation of the Health and Safety Division is that clinical specimens, including any diagnostic specimens and other biological materials of human origin, be packaged in accordance with DOT/IATA, as described below. This directive may change if and when the revision of 42 CFR Part 72, Interstate Shipment of Etiologic Agents; becomes finalized.

4. Shipping/labeling by air or public carriers:

a. The following packaging instructions are in accordance with IATA and/or DOT and will be followed for shipping of biological products or diagnostic specimens reasonably believed not to contain infectious or any other dangerous substance. Specimens of human blood, potentially infectious materials of human origin, or other bio-hazardous materials will be placed in an appropriately sized, watertight, primary container which prevents leakage during handling, processing, storage, transport, or shipping. Care shall be taken by the person collecting the material or specimen not to contaminate the outside of the primary container.

b. The sealed, watertight, primary container will be placed into an appropriate watertight, secondary container. The sturdy, watertight, secondary container will be constructed to prevent leakage during handling, processing, storage, transport or shipping. The secondary container should be lined with sufficient absorbent material (i.e., paper towels, absorbent pad) to absorb the contents of the primary container in the event of leakage or breakage of the primary container.

c. The secondary container must be placed in a strong outer shipping container.

d. The outer packaging container shall be of adequate strength (DOT approved) and size (4" minimum) and labeled with a red-orange/red label with a black biohazard symbol and closed prior to being stored, transported, or shipped. (Recommended materials for outer packaging include fiberboard, wood, metal or sturdy plastic.)

e. All shipping containers are to be secured using heavy duty security straps or key accessed lock.

f. Labeling: Some form of labeling will be used to identify a specimen or material. Whether the material or specimen is packaged/contained for laboratory purposes or for shipment or transport to a distant location, the material will be sufficiently labeled as to identify its contents.

The label will ensure that the analytical results are properly recorded and reported. Label the container as follows:

1. The primary container will be labeled to allow for material identification. For internal lab purposes, minimally the label will include, a) material ID, b) investigator ID, and c) date. A biohazard symbol is not always required as long as Universal Precautions are practiced with all clinical samples and other samples containing potentially infectious materials.
 2. The label shall include material ID, investigator ID, lab ID, and date. Biohazard labeling is required when the material is suspected of containing etiologic agents and when such specimens/containers leave the facility. This includes the transport of materials from floor to floor of a building as well as across a public street, i.e., from the Hospital of the University of Pennsylvania to Philadelphia VA Medical Center. Freight elevators must be used when transporting potentially infectious materials.
 3. It is recommended that when transporting multiple samples of biological materials, that personnel use a cart, basket or other appropriate container.
- g. Manifesting/Form completion: If you must ship infectious materials off site, DOT requires appropriate training be completed by the shipper. The trained shipper must complete the proper shipping papers, including the proper shipping names and numbers of the shipped materials. The DOT, IATA, or ICAO regulations must be referred to for this information. To properly ship infectious materials, contact the UCHSC Health and Safety Division for the appropriate documents.
5. Transport by courier:

A. Personnel who transport biological materials shall be knowledgeable in safe handling practices and decontamination procedures in the event of a spill. Whenever infectious materials or infectious waste is to be transferred from one room to another the material/waste must be properly contained. For example, if you are transporting infectious materials/waste from your laboratory to the autoclave, the materials/waste must be placed in a sealed, leak proof container. The health of employees, visitors, and the general public are dependent upon the infectious waste container not leaking or shedding harmful agents. Handle the infectious materials/waste in the following manner whenever it is transported:

- a. Infectious waste bags or containers will be sealed tightly before moving. Bags are typically twisted shut and sealed with filament tape.
- b. All red bags are doubled to insure that they are leak proof.
- c. Infectious materials, such as culture stocks or blood, will be transported in an appropriate primary container, i.e., tube, culture flask, etc., and then placed into a leak proof biohazard plastic bag or a small, leak proof rigid carrying container, as appropriate.
- d. Infectious waste bags must be placed into either a sealed cardboard box or a covered plastic container before transporting. Red bags cannot be transported without secondary containment.
- e. Plastic buckets, secondary containers, and carts used in handling infectious waste must be marked with a universal biohazard label.
- f. Secondary containers and carts must be disinfected on a regular basis, i.e., at the end of the work shift or end of the workday.
- g. Carts and containers used to transport infectious materials or waste will not be used for other purposes.
- h. The time and transportation route will be carefully selected to minimize the potential exposure of others.

6. Receipt of container:

Upon receipt of the container, lab personnel will inspect the container for compromise of security. If the security straps or tape have been compromised, personnel will notify the Lab Manager or designee.

- a. Specimens will be counted and inspected for damage, leaks, and identity compromise.
- b. Any evidence of compromise will be documented and forwarded to The Privacy Officer.

7. Storage:

In general, infectious materials will only be stored under refrigeration in a refrigerator or freezer to prevent the rapid growth of the infectious agent. Infectious wastes, on the other hand, will only be stored for a minimum amount of time to prevent the rapid growth of bacteria and objectionable odors. When the infectious waste boxes are full, the laboratory worker will remove them from the

laboratory area and they are then stored in the on-site infectious waste trailer. The designated storage area for infectious materials will:

- a. Be segregated for the storage of the infectious materials only. Biohazard signs will be posted on doors, waste containers, refrigerators, and freezers.
- b. Be located in an area that has limited traffic flow and is not subject to being crushed or knocked over.
- c. Be in an area that will not exceed room temperature.
- d. Be cleaned on a regular basis with a suitable hospital approved detergent-germicide.
- e. While on site storage of infectious waste for more than 48 hours is not recommended, there may be times when a longer storage time may be necessary.
- f. All organs and other large pieces of tissue will be refrigerated immediately to control objectionable odors.
- g. If bacterial growth or objectionable odors are a concern, the infectious waste will be stored in a freezer or refrigerator until disposal. Note: Infectious waste is prohibited from being placed into a refrigerator or freezer where food, medical supplies, and other sensitive materials are ordinarily stored.

REFERENCES:

- a. 42 CFR Part 72, Interstate Shipment of Etiologic Agents.
- b. CAP question 01-7100.