

**PURPOSE:**

Outline the process and procedure used to regulate the transportation of biological specimens.

**SCOPE:**

Processing Department

**RESPONSIBILITY:**

All processors are responsible for reading, understanding, and competently performing this procedure.

**EQUIPMENT: N/A**

**SUPPLIES: N/A**

**PROCEDURE:**

A. Transport Criteria


a. Shipping Categories

i. Materials shipped fall into one of these federally-defined categories

1. Category A Infectious Substances: known or suspected to contain high risk infectious substance containing a human or animal pathogen
  - a. E.g. rabies, smallpox, ebola
2. Category B Biological Substances: diagnostic specimens known to be infected with a substance that is in a form not generally capable of causing permanent disability or fatal disease in healthy humans or animals
  - a. Almost all specimens through the alb
  - b. Assigned ID number UN3373
3. Exempt Human Specimens: routine laboratory specimens known to not contain any infectious substance or a Category B in which the pathogen has been inactivated. Excluded from hazardous material regulation
4. Unregulated Biological Products: low risk medical specimens that are not subject to DOT or IATA shipping regulations
  - a. E.g. dried blood spots, fecal occult blood, blood components for transfusion, organs for transplant
5. GMO/GMMO: genetically altered. Require a Class 9 label and can fall into Category A or B. Must be verified before shipping
  - a. E.g. E. coli bacteria used in recombinant DNA research

6. Other (confidential documents, medical records, dry ice, etc)
- b. Temperature
    - i. Three temperature classifications are based on specimen stability
      1. Room Temp: 20-25C
      2. Refrigerated: 3-7C
      3. Frozen: below -20C
  - c. Labeling
    - i. Federal regulations require packages to be clearly marked based on hazards inside
      1. Biohazard: all biological materials
      2. Dry Ice: must include the weight of the dry ice
      3. Class 6: infectious substance
      4. UN 3373: Category B item
      5. Exempt Human Specimen: routine lab specimen known not to contain any infectious substance
      6. DANGER: air cargo over a specific volume
      7. Overpacks: combine several packages into a single shipment
  - d. Documentation
    - i. Can be in the form of a complete packing list, specimen control document
- B. Shipping Category B Biological Substances**
- a. Shipping by commercial carrier
    - i. Triple Packaged: leakproof primary container, leakproof secondary packaging, rigid outer packaging
      1. If shipping by aircraft, the primary receptacle cannot exceed 1L (34 oz)
    - ii. Outer container must display the full name and address of the sender and recipient and the name and phone number of the person responsible for the shipment
      1. If shipping by aircraft, the outer container cannot contain more than 4L or 4kg of samples
    - iii. According to IATA regulations, when using an Air Waybill, the Nature and Quantity of Goods box must show:
      1. UN3373
      2. The text "Biological Substance Category B"
      3. Number of packages in the shipment
    - iv. An itemized list of contents must be included between the secondary and outer container
    - v. Must be packed with packing material so that the contents do not shift during transport

- vi. Outer container must be sealed according to manufacturer instructions and withstand 1.2 meter drop
- vii. One side of outer container must be at least 100mm by 100mm
- b. Shipping by courier
  - i. Specimen is double bagged and carried in the courier transport tote
- C. Dry Ice
  - a. Requires special packaging and labeling if shipping by commercial carrier
    - i. Class 9 label, UN 1845, and dry ice weight
  - b. Package must be able to vent as the dry ice dissipates
- D. Shipping Exempt Human Specimens
  - a. Excluded from hazardous material regulations
  - b. EXEMPT HUMAN SPECIMEN label is placed on outer packaging
  - c. If there is not a hazardous material present (i.e. no dry ice) then no UN number is needed
- E. Transport of Medical Waste
  - a. Requires a Class 6 biohazard label and a UN 3291 number
- f. General Shipping Guidelines
  - a. All specimens are package with a double barrier to protect from spills (e.g., tube, specimen bag, and courier bag). In an instance where a biohazard spill has occurred, all couriers are to report to the manager immediately.
  - b. The following containerization procedures are mandatory under the Bloodborne Pathogens Standard, 29 CFR 1910. 1030. These procedures have been implemented by BBPL and must be followed by employees who are potentially exposed to bloodborne pathogens.
    - i. Specimens of blood of other potentially infectious materials shall be placed in containers, which prevent leakage during collection, handling, processing, storage, transport, or shipping. These containers must be closed prior to being stored, transported, or shipped. Containers for storage, transport, or shipping will be labeled in accordance with the standard and the procedures described in this document.
    - ii. If outside contamination of the primary container occurs (or if specimens contained within the primary container could puncture that container), the primary container will be placed within a secondary container, which prevents leakage during handling, processing, storage, transport, or shipping. The secondary container has to be puncture resistant and labeled/color coded under the requirements of the standard.
  - c. At any time if there is a concern or event the courier is to contact the manager

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immediately. All problems will be investigated and corrective action will be put forth as needed.

- d. Any blood spills or issues related to specimens during transit, the courier must contact the manager or safety officer immediately.
  - i. According to federal mandates, any spill or release of Category A or B infectious substances during any mode of transportation must be reported to the Department of Transportation. This is the responsibility of the Safety Officer at BBPL.

**SAFETY PRECAUTION:**

Follow guidelines within the Boyce and Bynum Pathology Laboratories safety manual.

**REFERENCES:**

N/A

**RELATED DOCUMENTS:**

N/A

**APPENDIXES:**

N/A