NEW SHIPPING REGULATIONS MAKE IT EASIER TO SHIP SURVEILANCE SAMPLES

IN JULY 2005 CHANGES WERE MADE TO THE INTERNATIONAL AIR TRANSPORTATION ASSOCIATIONS REGULATIONS REGARDING SHIPPING OF BIOLOGICAL SUBSTANCES THAT HAVE OR ARE BEING ADOPTED BY THE WORLD HEALTH ORGANIZATION AND THE US DEPARTMENT O TRANSPORTATION.

THE EASIEST LINK TO THESE CHNAGES IS: www.saftpak.com/2005-07-05announcement.htm. CLICK ON THE RELEVANT LINK AT THE BOTTON "IATA 46TH EDITION ADDENDUM III"

A SUMMARY OF THESE CHANGES AND HOW THEY AFFECT YOU AS THE SHIPPER FOLLOWS. REMEMBER, YOU AS THE SHIPPER, ARE THE RESPONSIBLE PARTY TO ASSURE THAT THE SAMPLES ARE PACKAGED AND SHIPPED CORRECTLY.

DEFINITIONS

Cultures are the result of a process by which pathogens are intentionally propagated. This definition does not include patient specimens as defined below.

Patient specimens are those collected directly from humans or animals, including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Exemptions

Substances which do not contain infectious substances and or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class (explosive, flammable, radioactive substances, etc.)

Substances containing micro-organisms, which are non-pathogenic to humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Environmental samples (including food and water samples), which are not considered to pose a significant risk of infection, are not subject to these Regulations unless they meet the criteria for inclusion in another class.

Patient specimens for which there is minimal likelihood that pathogens are present are not subject to these Regulations if the specimen is transported in a packaging which will prevent any leakage and which is marked with the words "Exempt Animal Specimen" or "Exempt Human Specimen", as appropriate. The packaging must meet the following conditions:

- (a) The packaging must consist of three components:
 - (1) a leak-proof primary receptacle(s) (blood collection tube)
 - (2) a leak-proof secondary packaging (zip lock bag); and
 - (3) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm °— 100 mm (4 inches by 4 inches) (syrofoam mailer);
- (b) For liquids, absorbent material (paper towels, cotton, etc.) in sufficient quantity to absorb the entire contents must be placed between the primary receptacle(s) (I) and the secondary packaging (zip lock bag) so that, during transport, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;

(c) When multiple fragile primary receptacles (*blood collection tubes*) are placed in a single secondary packaging, they must be either individually wrapped or separated to prevent contact between them.

NOTE:

In determining whether a patient specimen has a minimal likelihood that pathogens are present, an element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be transported under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antigens (PSA); tests required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or therapeutic drug monitoring; tests conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy tests; biopsies to detect cancer; and antibody detection in humans or animals.

The following is recommended when submitting animal samples for routine surveillance or testing to the laboratory.

- 1. If the intended test sample is serum, the whole blood should be allowed to clot and the serum removed. The serum sample can then be placed in a clean test tube or vial and the lid secured. (Primary container)
- 2. Place the blood or serum tube(s) in a Styrofoam shipping container. Each sample should be contained in its own slot in the container or the samples should be separated or wrapped individually. Tape the styrofoam container shut.
- 3. Place the closed Styrofoam container inside a zip lock storage bag. (Secondary container)
- 4. Add sufficient toweling or absorbent material to the zip lock bag to absorb all of the liquid if the container were crushed (Absorbent material).
- 5. Seal the zip-lock bag.
- 6. Place the bag or bags inside a cardboard box or insulated shipping container (Outer packaging).
- 7. Place the submission form(s) in a separate envelope or plastic bag and place inside the box or shipping container.
- 8. If needed, place one or more frozen gel packs inside additional zip-lock bags and seal the bags shut. (Most of the "spills" reported to us from the mailroom have been leaking gel packs).
- 9. Place the frozen gel packs inside the cardboard box or shipping container.
- 10. Add cushioning material if needed to keep the packages from moving inside the box.
- 11. Seal the box shut.
- 12. If reusing cardboard boxes, be sure to remove or black out any attached labels that would indicate that the box contained biological or hazardous substances.
- 13. Place the shipping label and a return address label on the box.
- 14. Print or label the box or shipping container with "Exempt Animal Specimen".