

## **2005 Diagnostic Specimen Transport Requirements**

There are some serious new IATA Dangerous Goods Regulations affecting the classification of clinical specimens and the preparation of packages of DIAGNOSTIC SPECIMENS for transport, effective January 1, 2005.

Diagnostic Specimens are defined as: human or animal material including, but not limited to excreta, secreta, blood and its components, tissue and tissue fluids, and body parts being transported for purposes such as research, diagnosis, investigational activities, disease treatment or prevention.

Infectious Substances are defined as substances which are known or are reasonably expected to contain pathogens. In the recent past, infectious substances have been classified by reference to World Health Organization Risk Groups.

The new regulations are as follows:

### **CLASSIFICATION OF INFECTIOUS SUBSTANCES AND DIAGNOSTIC SPECIMENS**

The new rules no longer recognize the concept of risk groups. Instead, they identify pathogens by category: A or B. There is a list of indicative examples of infectious substances included in Category A, but there is no list for Category B.

Pathogens in Category A must be shipped as INFECTIOUS SUBSTANCE, AFFECTING HUMANS, UN 2814 or ANIMALS, UN 2900. They must be packed as Class 6.2 and must be accompanied by a Shipper's Declaration, as has always been the case.

All others are considered to be in Category B, and they are to be shipped as DIAGNOSTIC SPECIMEN or CLINICAL SPECIMEN, UN 3373. This means, for example, that we can ship HIV blood samples (but not laboratory cultures) as Diagnostic Specimens, because HIV (not in cultures) is not listed as a Category A pathogen. It is therefore in Category B and is to be shipped as Diagnostic Specimen, UN 3373.

The new rules make shipping clinical trial and investigatory specimens easier, in that most commonly shipped infectious pathogens occurring in human bodily fluid samples are not found in Category A.

### **PREPARATION OF DIAGNOSTIC SPECIMEN PACKAGES**

As always, Diagnostic Specimens must be packed in compliance with IATA DGR Packing Instruction 650. The following important package marking changes to

PI 650 appear in the 2005 Regulations:

The outermost shipping container must bear:

the Proper Shipping Name DIAGNOSTIC SPECIMENS or CLINICAL SPECIMENS

a new marking consisting of a diamond within which appears UN 3373, such as in the example below:



In addition, if the Diagnostic Specimens contain infectious pathogens, the package or the Air Waybill must contain the name, address, and phone number of a Responsible Person.

Please refer to Packing Instruction 650 for details of these new regulations.

[ Marie, the **SECOND PAGE** of the website article is still ok as it stands]