

IATA Dangerous Goods Regulations Update

Making Sense of the New Regulations for Shipping Specimens

The International Air Transport Association (IATA) made significant changes to the regulations for shipping specimens in 2005. Also, the US Department of Transportation (DOT) has a proposal to harmonize their regulations with the international regulations which should make everything a little easier once you catch up with the new regulations. Here are the highlights:

Gone are Risk Groups, new categorical classification has been identified in the IATA addendums. Four Risk Groups which were somewhat ambiguous have been redefined into Category A and Category B. **Going** is the term “Diagnostic Specimen” to be replaced by “Biological Substance, Category B”. **New** under IATA is “Exempt Human Specimens”

Category A- An infectious substance that is transported in a form that is capable of causing permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. There is now a published list of those pathogens and cultures considered to be Category A. Category A requires Infectious Substance packaging, IATA Packing Instruction 602. [Category A infectious substances list click here](#)

Category B- This is the term given to specimens that do not meet the criteria for inclusion in Category A (does **not** cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs). This is what is now to be called “Biological Substance, Category B” (effective 1-1-2007) and to be packaged according to IATA Packing Instruction 650. Regulators are encouraging the use of the new label immediately. [New Biological Substance, Category B label click here](#)

Exempt Human Specimens- Patient specimens for which there is minimal likelihood that pathogens are present. Examples are: blood or urine for cholesterol levels, hormone levels, prostate specific antigens (PSA), tests to monitor organ function (heart, liver, kidney), tests conducted for insurance or employment, pregnancy, biopsies for cancer, drug or alcohol presence testing.

This is an international (IATA) regulation and not adopted by DOT. Some experts are recommending that it be packaged according to PI650 though at a minimum the packaging requirements are as follows:

- 100mm x 100mm dimension on one side
- leak-proof primary
- leak-proof secondary
- absorbent sufficient for total contents
- outer box of adequate strength for it's capacity
- marking “Exempt Human Specimens” or “Exempt Animal Specimens”

Note: Information has been compiled by Therapak Corporation. Please verify regulation changes with your common carrier regarding specimen shipments (Fedex, DHL, etc...). It is unclear how carriers will integrate “Exempt Human Specimens” shipments while they are mainly focusing laboratories on using IATA Packing Instruction 650 which is becoming “Biological Substance, Category B” as opposed to Diagnostic Specimens. Please inquire with Therapak if you would like to purchase new labels set forth by these regulation changes.