

Fact Sheet

SPECIMEN PACKAGING CHANGES FOR 2003

On August 14th the US DOT revised its regulation governing the packaging of Diagnostic Specimens and Infectious Substances. ICAO and IATA have made similar revisions taking effect in January 2003. This fact sheet presents an overview of the recent changes to the US DOT and ICAO/IATA requirements for specimen packaging and shipment, and discusses resultant cost-saving opportunities for shippers.

WHO ARE THE US DOT, ICAO AND IATA, AND HOW DO THEY REGULATE PACKAGING AND SHIPMENT?

US DOT is the Department of Transportation, which governs, among many things, the packaging and shipment of hazardous materials or dangerous goods by all modes of transportation. On August 14, 2002, the US DOT revised its regulation governing the packaging and shipment of medical specimens. The revision was necessary to align US requirements with those of the international community, including ICAO and IATA requirements. The applicable US DOT regulations are found at 49 CFR 171-178.

ICAO is the International Civil Aviation Organization that sets technical packaging standards for dangerous goods based on recommendations from the United Nations Committee of Experts.

The IATA is the International Air Transport Association that adopts the ICAO standards, as well as more restrictive requirements that reflect airline industry standard practices or operational considerations. The IATA requirements are published in the well-known "Dangerous Goods Regulations".

WHAT CHANGE HAS TAKEN PLACE?

The US DOT, ICAO and IATA regulations have clarified those types of pathogen-containing specimens that must be packaged and shipped as Infectious Substances, and those that must be shipped as Diagnostic Specimens. The change concerns the classification of pathogens into the World Health Organization (WHO) Risk Groups. The Risk Groups are a ranking system developed by WHO, to describe the severity of a disease caused by a pathogen, the mode and relative ease of transmission, the degree of risk to both an individual and a community, and the reversibility of a disease through the availability of known and effective preventative agents and treatment.

Risk Group 4

A pathogen that usually causes serious human or animal disease and that can be readily transmitted

from one individual to another, directly or indirectly, and for which effective treatments and preventative measures are not usually available.

Risk Group 3

A pathogen that usually causes serious human or animal disease but does not ordinarily spread from one infected individual to another, and for which effective treatments and preventative measures are available.

Risk Group 2

A pathogen that can cause human or animal disease but is unlikely to be a serious hazard, and, while capable of causing serious infection on exposure, for which there are effective treatments and preventative measures are available and the risk of spread of infection is limited.

Risk Group 1

A micro-organism that is unlikely to cause human or animal disease. A material containing only such organisms is generally not subject to transport regulation.

HOW DOES THIS AFFECT SPECIMEN PACKAGING AND SHIPMENT?

The change now authorizes the packaging and shipment of pathogen-containing specimens, that meet WHO Risk Group 2 & 3 criteria, to be packaged and shipped as Diagnostic Specimens. Shippers are no longer required to package and ship such specimens as Infectious Substances. This is consistent with IATA Packaging Instruction 602 and/or US DOT 49 CFR 173.196. Diagnostic Specimens must be packaged and shipped consistent with IATA Packaging Instruction 650 and/or US DOT 49 CFR 173.199.

Although the instructions and regulations for packaging and shipment of Infectious Substances and Diagnostic Specimens have many similarities, they do differ with regard to performance testing. Diagnostic Specimen packaging must be capable of passing a 1.2 meter drop test, as opposed to the 9 meter drop test required for Infectious Substances.

This means that shippers who continue to purchase

Infectious Substance packaging for specimens, which should now be packaged as Diagnostic Specimens, **are paying too much to comply.**

WHAT ARE CHANGES TO THE “MATERIALS OF TRADE” EXCEPTION?

The US DOT has provided domestic shippers with regulatory relief by expanding the Materials of Trade exception at 49 CFR 173.6 to include Diagnostic Specimens in Risk Groups 2 & 3, when transported in dedicated motor vehicles by private or contract carriers.

This change will significantly benefit laboratories that have their own designated couriers to transport specimens via a motor vehicle.

Required packaging for specimens shipped as Diagnostic Specimens under the exception require:

- ❑ Leakproof inner packaging
- ❑ Outer packaging with sufficient absorbent material to absorb the entire contents on the inner packagings
- ❑ Outer packaging must be strong, tight packaging securely closed and secured against movement.
- ❑ Capacity limitation:
With one or more inner packagings, each inner package does not exceed 0.5 L and outer package does not exceed 4.0 L;
With one single inner packaging, single outer package is limited to 4.0 L.

WHAT SHOULD SHIPPERS DO TO ENSURE COMPLIANCE AND BEGIN TO SAVE?

Shippers should review their current specimen management schemes to identify cost saving and compliant opportunities resulting from the rule changes. Laboratories, hospitals and research facilities that continue with existing packaging materials are probably paying too much for a level of performance packaging that is no longer needed or required for Diagnostic Specimens. Custom Pack, Inc. can assist you with this task, offering expertise both in customized packaging design and regulatory compliance.

Give us a call at 800-722-7005 to speak with a *Specimen Shipping Compliance Specialist* who can work with you to identify opportunities and implement solutions. You can visit our web site at www.cpispecimen.com for additional information on Custom Pack, Inc.

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