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Filter Devices • Medical & Cleanroom Disposables

It's in the Bag:

Shipping Diagnostic Specimens : Made Easy

Developments in the past few years have multiplied the number of occasions when the need arises to ship diagnostic specimens over long distances. This is a direct result of globalisation and internationalisation. It was not until 1989 that the first packaging system anywhere in the world to be certified by a national authority for this purpose came on stream in Canada.

Unfortunately, despite progressively more stringent regulation worldwide since 1989 and the availability of an ever widening range of shipper options, there is still a widespread ignorance about their availability, of training given to ensure their appropriate use, and of the regulations which control the movement of diagnostic specimens generally.

The result has been a growing number of disasters and near disasters involving this kind of activity. Regulation changes are visible when looking at how diagnostic specimens can be mailed. The biggest change of all comes with the necessity to meet air transport requirements. That now demands that the secondary container must be capable of withstanding, without leakage, an internal pressure of not less than 95kPa. This is no easy task: in fact an independent test on current mainstream shippers has demonstrated a failure rate in excess of 90 per cent. This means that a lot of traditional solutions go out of the window. Aluminium canisters, quilted bags, cardboard tubes and zipper bags now all belong to yesterday.

New US regulations are tougher than the IATA Packing Instruction 650, which requires that packaging for infectious substances and diagnostic specimens should consist of an inner and an outer packaging. The inner packaging must comprise a watertight primary receptacle with a maximum 500ml capacity and a watertight secondary packaging with a maximum four litre capacity. An absorbent material must be placed between the primary receptacle and the secondary packaging and multiple primary receptacles must be wrapped individually.

The outer packaging must also be of adequate strength for its capacity, weight and intended use. Each complete package must pass a drop test in 6.5.1 at a height of 1.2 metres. Both primary receptacle and secondary packaging must withstand, without leakage, an internal pressure of 95kPa (0.95 bar, 13.8lb/sq in) in a range of -40°C to +55°C. Also packages must be at least 100mm or four inches in the smallest external dimension. Most importantly an itemised list of contents must be between the secondary packaging and the outer packaging

and, as a whole, the package must be capable of passing a pretty severe drop test. This involves subjecting samples to a free fall (again from 1.2 metres) onto a rigid, non-resilient, horizontal surface on to the base, top, longest side, shortest side and, lastly, on to a corner.

Despite the variety of shippers available and the attendant publicity and educational material that goes with them, there is still widespread ignorance surrounding their use, and about the regulatory requirements that led to their creation in the first place.

For example if your organisation was asked to make an air shipment of Class 6.2 infectious substances in the most practical way, would you know how to go about it? It should be remembered that for regulated tasks such as shipping hazardous materials, training is essential. All national and international regulations require that anybody who handles dangerous substances or is responsible for transporting them is obliged to receive the appropriate certified training.

These courses do not involve rocket science, rather common sense applied to some basic regulatory knowledge. It is necessary for instance to know what defines infectious substances. The IATA DGR (dangerous goods regulations) defines them as “substances known to contain or reasonably expected to contain pathogens”.

This may all seem a bit daunting but the answer is quite easy. That is to make certain that you buy user-friendly packaging from a specialist manufacturer. Do this and you will be able to source not only the right package but also training, recognised certification of staff and a regular, reliable and informed update on what is happening in this rapidly growing and fast moving area of activity.

Helapet Limited are the UK healthcare distributors of the Saf-T-Pak™ Inc. range of shipping systems for diagnostic and infectious goods. This article is an abbreviated version of an article written by Katrina Bray, Marketing Manager of Laminar Medica, titled “It’s in the bag: Shipping Infectious and Diagnostic Specimens by Air Made Easy.” Laminar Medica are the European distributors for Saf-T-Pak™ Inc.