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Training Requirements for Shipping Human Specimens by Air

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Introduction

Human specimens of blood, urine, tissue, etc., are often transported by air due to their importance and delicate nature. These shipments are subject to various national and international regulations for the transportation of dangerous goods. This article discusses training requirements for shippers of human specimens according to air regulations. However, it does not give detailed classification and packing instructions for shipping specimens and does not constitute comprehensive training.

Regulations

The transportation of dangerous goods by air is regulated by the International Civil Aviation Organization (ICAO), which publishes "Technical Instructions for the Safe Transport of Dangerous Goods by Air" (ICAO TI).[1] The ICAO TI is updated every two years to incorporate changes in the regulations, such as, upcoming changes to packing instructions. These regulations are then adopted by the International Air Transport Association (IATA), comprised of most of the world's major airlines and couriers. Some of IATA's members include United Airlines, Air France, Lufthansa, FedEx and United Parcel Service (UPS). IATA works with the airlines to encourage efficiency and safety in many areas of the industry, including the transport of dangerous goods by air. Using the ICAO TI as a guide, IATA publishes the "Dangerous Goods Regulations" (IATA DGR), a document that incorporates all the regulations found in the ICAO TI, as well as additional restrictions designed to further increase the safety of a shipment of dangerous goods by airplane.[2]

Both the ICAO TI and the IATA DGR assign human specimens to Class 6 Division 6.2 Dangerous Goods, or Infectious Substances. The regulations define infectious substances (pathogens) as those capable of causing disease in otherwise healthy humans or animals. These substances include bacteria, viruses, rickettsiae, parasites, fungi and other agents like prions. The term "infectious substance" includes substances regardless of the risk and severity of the diseases they can cause; all pathogens are included in the definition.

The regulations classify human specimens into two different groups: those containing or suspected of containing infectious substances and those that have a minimal likelihood of containing infectious substances. Human specimens containing infectious substances or suspected of containing infectious substances must be packaged for shipping based on the risks of the pathogen(s) contained in the sample, for example, Ebola virus versus influenza virus. Such specimens require specialized packaging and proper marking, labeling and documentation. Human specimens that are highly unlikely to contain an infectious substance require less robust packaging and less comprehensive documentation than for shipments of infectious human specimens.

Mandatory Training

The ICAO TI regulations require training for all persons involved in shipping human specimens of any kind:

> "The successful application of regulations concerning the transport of dangerous goods and the achievement of their objectives are greatly dependent on the

appreciation by all individuals concerned of the risks involved and on a detailed understanding of the regulations. This can only be achieved by properly planned and maintained initial and recurrent training programmes in the transport of dangerous goods for all persons concerned." (ICAO TI 1:4 introductory note)

Both ICAO and IATA mandate that shippers receive training in the following areas:

- General familiarization training provides familiarity with the general provisions.
- Function-specific training provides detailed training in the regulatory requirements applicable to the function for which that person is responsible.
- Safety training covers the hazards presented by dangerous goods, safe handling, and emergency response procedures. (ICAO 1;4.2.1/IATA 1.5.2.2)

General familiarization training introduces the basics of shipping dangerous goods:

- Shipper's and operator's (carrier's) responsibilities
- Interpreting the dangerous goods list
- Selecting the proper packaging
- Correct marking and labeling
- Proper documentation
- Recognition of undeclared or hidden dangerous goods
- State (country) and operator (carrier) variations
- Emergency response procedures
- Special provisions

Retraining for everyone involved in the transport of dangerous goods by air is required every two years. Courses are available through training providers or may be conducted by an organization's qualified personnel. Either way, training must be fully documented according to the regulations. Training courses normally take from three to eight hours to complete, depending on the level of certification required. In some clinical studies, clinical research associates train site personnel on shipping. Any training must meet the standards set forth in the regulations.

Shipments of human specimens can create risks other than the obvious ones. For example, they may include other hazardous materials. Many incidents on airplanes, some with devastating consequences, have been attributed to hidden or undeclared dangerous goods. For example, in 1996, a ValueJet flight crashed because a shipment of expired airplane safety equipment (chemical oxygen generators) caused a fire to burn out of control. Examples of flammable liquids commonly used in the transport of human specimens are formalin and ethanol. Without proper training, a shipper could include these dangerous goods without the correct packing, marking, labeling and documentation. Because the airline would not be aware of their presence, they could more likely contribute to a catastrophic fire. In the United States, shipping a package containing dangerous goods that is not correctly marked and labeled may result in a fine up to $11,000.

One of the most common dangerous goods shipped with human specimens is dry ice (frozen carbon dioxide). As dry ice sublimates, carbon dioxide gas is released and can build up significant pressure in a sealed container. If enough pressure builds up, the container may rupture in a violent explosion. Even if dry ice is not in a sealed container, the release of carbon dioxide into the cargo hold could cause asphyxiation to loading staff or animals in the hold. To ensure such accidents do not happen, there are strict limits on how much dry ice is allowed on an airplane. Hidden dry ice shipments may result in exceeding these limits.

Some states (countries) and operators (air carriers/couriers) impose more stringent restrictions for the transport of dangerous goods within their borders or aboard their

aircraft. Violations of these state and operator variations may cause shipments to be rejected, which can be problematic when the specimen is sensitive to time or temperature. Some of these rules apply specifically to human specimens. For example, Air France's Variation 02 states that the carrier will only accept shipments of infectious substances, patient specimens, diagnostic specimens, clinical specimens, and biological specimens (human or animal) if they are prepared according to the most stringent packing requirements for infectious substances. Not all Air France flights depart or arrive from airports in France. For example, Air France flies between the U.S. and the U.K.

If an improperly marked or labeled package leaks, there will be consequences. The consequences escalate if the package leaks blood. If it is not known whether the leaked blood contains infectious agents, first responders in the U.S. and many other countries must treat the blood as infectious and respond according to the U.S. Department of Transportation Emergency Response Guidebook.[3] The area surrounding the leak will be evacuated for up to 25 meters (75 feet) in all directions. The leak will then be cleaned up under the supervision of a specialist. Clean-up personnel must wear a positive-pressure self-contained breathing apparatus (SCBA). Costs, fines and other penalties to the shipper will be substantial.

Conclusion

Shippers must properly prepare all shipments of human specimens sent on IATA member airlines, regardless of pathogenicity, according to ICAO and IATA transport regulations. These regulations require that anyone involved in shipping these specimens be trained to perform the duties required by the regulations. Proper training helps ensure correct packaging, marking, labeling and documentation; avoids package rejections and penalties; and, most importantly, increases safety for everyone who handles or may come in contact with these packages.

References

1. Technical Instructions for the Safe Transport of Dangerous Goods by Air, published by the International Civil Aviation Organization, 2009-2010
2. Dangerous Goods Regulations, published by the International Air Transportation Association, 51st edition
3. Emergency Response Guidebook, published by the United States of America Department of Transportation, Pipeline and Hazardous Materials Safety Administration, Office of Hazardous Materials Initiatives and Training, 2008

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