Q&A Infectious Substance Shipping Webinar
Frequently Asked Questions from the ABSA hosted panel on July 11, 2013

Please note these answers reflect the personal opinions of the panel and are shared from personal experience and knowledge. There may be mistakes. They do not necessarily reflect the opinion of employers, ABSA, the Department of Transportation (DOT), or IATA. The material herein is intended to provide general guidance. Your specific situation may be different or unique. The panel strongly encourages you to work with the DOT (hazmat.dot.gov) or seek legal/expert consultation prior to shipping.

Can I ship multiple samples assigned to different categories in the same package?

Category A samples can be shipped in the same package as Category B or Exempt samples as long the packaging meets the most stringent (among the samples present) shipping requirements.

Other dangerous goods must not be packed in the same packaging as Division 6.2 Infectious Substances unless they are necessary for maintaining the viability, stabilizing or preventing the degradation of infectious substances.

A quantity of 30ml or less of dangerous goods included in Classes 3, 8, or 9 (for example, ethanol or formalin) may be packed in each primary container with infectious substances. When these small quantities of dangerous goods are packed with infectious substances, no other requirements for substances of these classes need to be met.

What do I use for a technical name for an unknown or emerging Category A pathogen?

Diagnostic or clinical specimens collected during an investigation of an outbreak of a serious, life-threatening or fatal disease of unknown cause must be handled as Category A infectious substances.

When the infectious substances to be transported are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN 2814 or UN 2900, the words "suspected category A infectious substance" shall be shown, in parentheses, following the proper shipping name on the transport document but not on the outer packaging.

What are some of the limitations for shipping infectious substances?

Every infectious substance can be shipped. Not all carriers will accept all infectious substances for transport.

All human and animal specimens should be considered potentially infectious and shipped as either a Category A or Category B infectious substance unless determined to have a minimal likelihood of pathogens by a competent and knowledgeable medical professional.

Intentionally infected live animals cannot be shipped.

Infectious substances must not be hand carried or carried in checked-in baggage during air travel.

Infectious substances must not be placed in diplomatic pouches.

Can infectious substances be sent through the mail?

Not all countries allow shipments of infectious substances by mail.

Contact local postal authorities to determine if the countries you are shipping from, through, and to, allow infectious substances to be shipped by mail.

Shippers must follow postal requirements when shipping infectious substances.
State variations will often list if a country will accept infectious substances in the mail. ICAO recently published a website listing all of the State variations published in the Technical Instructions. [http://www.icao.int/safety/DangerousGoods/Pages/StateVariationPage.aspx](http://www.icao.int/safety/DangerousGoods/Pages/StateVariationPage.aspx) The website will be updated frequently with any changes.

**Can packaging supplies be reused?**

Shipping packages can be reused.

If the shipper plans on reusing the package – it must be in good condition and appropriately disinfected so as to present no hazard to persons or animals.

Before reusing the package, the shipper must make sure all markings and labels reflect the substance actually being shipped.

The shipper must ensure that all of the required components are used. This is particularly important for shipments of Category A infectious substances which require UN Specified packaging. UN specification indicates that a package has been tested and certified to meet international UN test standards. Modifying the package design, such as replacing one type of secondary for another invalidates testing certification. Note: many UN certified category A packages employ single use secondary bags. Appropriate tested/certified replacement components such as secondary bags must be obtained from the package manufacturer.

For Category B packages, the U.S. DOT requires a package manufacturer to provide similar instructions for use for Category B packages. Therefore, to reuse a Category B package the shipper must refer to the original instructions for use. It might not be a bad idea to include a copy of the instructions with the shipment so the receiver will have them at their disposal.

If the shipper plans on shipping an empty package, all non applicable markings and labels must be removed or covered.

**How do you classify environmental samples such as soil, water, or food samples that may contain pathogens?**

IATA/ICAO regulations provide a specific exception for environmental samples (e.g., food and water samples) that are not considered to pose a significant risk of infection.

If there is no significant risk of infection and they do not meet any of the definitions for other classes of dangerous good (e.g. flammable) then environmental samples are not regulated.

The regulations do not define what is meant by a “significant risk” but if the shipper determines that a significant risk of infection remains then the samples should be considered for classification as either Category A or B infectious substance.

**How are biological materials that contain portions of a lentiviral vector identified for foreign shipment?**

If the vector is replication competent, it will likely meet the definition of a pathogen: able to cause disease in humans or animals. If this is the case, then it would be necessary for the shipper to classify it as either Category A or Category B. Since most lentiviral vector preps are not replication competent and are not capable of causing disease they are not classified as infectious substances. A shipper using the IATA regulations may consider classification under Class 9 Genetically modified micro-organisms (note: such a classification does not exist under 49 CFR regulations). There are two possible exceptions in that a shipper may consider

IATA 3.6.2.2.3.2 – Substances containing micro-organisms, which are non—pathogenic to humans or animals are not subject to these Regulations unless they meet criteria for inclusion in another class

IATA 3.6.2.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet criteria for inclusion in another class.

I always considered 3.6.2.2.3.2 applying to shipments of RG1 micro-organisms and since we do not handle lentiviral vectors as such this exception does not apply. One could argue that since the vectors are not replication competent,
they have been neutralized or inactivated in a way that removes their pathogenicity. However, the second part of 3.6.2.2.3.3 indicates that they no longer pose a health risk and I do not believe this is the case with rep-lentiviral vector preps. They still pose a health risk. Otherwise, we would handle them at BSL1.

Similar exceptions are found in 49 CFR 173.134(b) *Exceptions*. The following are not subject to the requirements of this subchapter as Division 6.2 materials:

(3) A material containing micro-organisms that are non-pathogenic to humans or animals.

(4) A material containing pathogens that have been neutralized or inactivated such that they no longer pose a health risk.

After all of these considerations, as a shipper, I usually classified my shipments of lentiviral vector preps as Category B infectious substances.

**How are non-infectious viral particles classified and shipped?**

IATA 3.6.2.2.3.2 – Substances containing micro-organisms, which are non—pathogenic to humans or animals are not subject to these Regulations unless they meet criteria for inclusion in another class

49CFR173.134(b)(3) A material containing micro-organisms that are non-pathogenic to humans or animals

If the viral particles are non-infectious or non-pathogenic to humans or animals, then they are excepted from the regulations.

**Please describe all instances when a CITES permit is required with respect to shipping non-human primate (NHP) materials.**


Such permits are not required for dangerous goods transport but may be required by country of origin or destination. In the United States CITES enforcement is managed by the US Fish and Wildlife Service. I’m not familiar with CITES requirements, please contact them for more information. [http://www.fws.gov/international/](http://www.fws.gov/international/)

**Is it required for NHP primary cell lines and NHP established cell lines?**

See above

**What labeling is required on packaging when shipping plasmids containing inserts of human genes, animal genes, toxin genes, etc?**

Naked plasmids would be considered exempt from shipping regulations and therefore do not require any specific packaging, marking or labeling.

IATA 3.6.2.2.3.1 Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to these Regulations unless they meet the criteria for inclusion in another class

49 CFR173.134(b)(2) Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic elements.

**Does exempt human specimen or exempt animal specimen need to be listed on the packaging?**

In the case above, no marking or labeling is required. Exempt human (animal) specimens apply only to those specimens collected directly from humans or animals (such as swabs, blood, body fluids, tissues, body parts, etc.)
which have minimal likelihood that pathogens are present. Such a package would need to be triple packaged and
marked “Exempt human specimen” or “Exempt animal specimen” as appropriate. Purified human genes or
processed genetic material would not qualify as patient specimens since they are not “collected directly from . . . ”

I don’t have to do dangerous goods shipping all the time, is there anywhere online that there is
a review on the marking and shipping and what rules to look at?

Not that I know of. However, I have created a checklist for packaging, marking and labeling that one could use to verify
compliance. I plan to provide these checklists to ABSA for them to post on their training tools website. So hopefully
something will be available online to use in the future.

As long as the biological material is packaged correctly, is it OK to use your personal vehicle or
public transportation to transport the material?

Short answer, yes for Category B patient specimens, no for Category A.

During any transport operation, there are two parties who have specific responsibilities defined in the regulations: the
shipper and the carrier (consignor and operator). If you elect to transport dangerous goods, in addition to the
responsibilities of the shipper, you must meet all the additional requirements and responsibilities of a transporter.
These responsibilities will vary depending on the mode, the amount and the type of dangerous goods you are
transporting.

There are additional restrictions if you elect to use public transportation such as a bus, train or taxi. In which case the
driver of the train, bus or taxi also must meet certain dangerous goods regulatory requirements. For example, there
may be specific requirements for how and where the material is segregated, stored and secured during transport. The
operator of the vehicle may or may not need a hazmat endorsement on their driver’s license. There are additional
training requirements for the driver. There may also be a need for security awareness and security plans, etc. Therefore
it is not advisable to use public transportation to move dangerous goods without express consent of the operator.

There are exceptions for Category B infectious substance packages and human/animal material with low probability the
sample is infectious as stated below:

49CFR 173.134(b)(10) A Division 6.2 material, other than a Category A infectious substance, contained in a patient
sample being transported for research, diagnosis, investigational activities, or disease treatment or prevention, or a
biological product, when such materials are transported by a private or contract carrier in a motor vehicle used
exclusively to transport such materials. Medical or clinical equipment and laboratory products may be transported
aboard the same vehicle provided they are properly packaged and secured against exposure or contamination.

Note that the exception above only applies to Category B patient specimens and not Category B cultures. And only
applies when transported in a private or contract vehicle used exclusively to transport such specimens (i.e. it is not a
general delivery vehicle used for the delivery of various materials)

49CFR 173.134(b)(11) A human or animal sample (including, but not limited to, secreta, excreta, blood and its
components, tissue and tissue fluids, and body parts) being transported for routine testing not related to the diagnosis
of an infectious disease, such as for drug/alcohol testing, cholesterol testing, blood glucose level testing, prostate
specific antibody testing, testing to monitor kidney or liver function, or pregnancy testing, or for tests for diagnosis of
non-infectious diseases, such as cancer biopsies, and for which there is a low probability the sample is infectious.

Such material (10 and 11) does not require any packaging, marking or labelling and can be transported in private
vehicles with no further dangerous goods considerations. Those that fall under paragraph (11) can also be carried on
public transportation without dangerous goods consideration.

I will provide three examples:

1. A private company shuttle used to transport employees from one worksite to another. Occasionally, category B
   patient specimens are collected at one worksite and transported to another using this vehicle.
This example does not qualify for the 173.134(b)(10) exception since the vehicle is not used “exclusively” to transport such material. It could qualify for this exception if no passengers were transported at the same time. Such material must be properly packaged, marked and labelled and transported according to the requirements found in 49CFR 173.199. Provided all the requirements in 199 are followed, this can be transported in a private vehicle. One precaution though:

173.199(e) Training. Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section.

A taxi driver, bus driver or subway operator would need to be trained in order to legally "transport" a Category B infectious substance.

2. A worker takes a test tube of blood on the subway (or bus) to deliver the material to a local clinical laboratory. If this material does not meet the criteria for exceptions found in 134(b) and it is not a Category A then it must be properly packaged, marked and labelled as a Category B infectious substance according to 173.199. All the requirements (including training for the driver) must be met. Since the bus driver or subway operator is not trained, even if the tube was properly packaged, marked and labelled it would not meet the requirements of 173.199

3. Same worker, same tube in their own private car. Since this meets the requirements of 173.134(b)(10) transported in a vehicle used exclusively to transport patient specimens (at least during the transport operation), then it is excepted from the hazmat regulations.

4. Same worker in a private car but this time transporting a culture of Salmonella (Category B infectious substance). In this case, the exception found in 173.134(b)(10) does not apply because this is not a patient specimen. However, if the sample were properly packaged and marked according to the requirements in 173.199 and the driver was trained according to 173.199(e) then it could be done.

What are the excepted quantities of formalin (amount & concentration) for a package?

This depends on the exact mixture of formalin (check the SDS for the proper shipping name, cross reference that with the “E” number in column F of the IATA Dangerous Goods table). Generally, formalin will qualify for E1 level of excepted quantities: 30 ml per primary and up to 1 L in a package. There is still packaging requirements (IATA 2.6.5) and the package must bear the excepted quantities mark (IATA 2.6.7)

A similar 30 ml exception per primary also applies when transported on road or rail in accordance with 49CFR173.4

What are some examples of non-infectious GMO’s?

Domestically in the US, the DOT has not elected to regulate non-infectious GMOs. These are not subject to hazmat regulations when transported in the US. Internationally, IATA regulated the transport of GMOs as Class 9 dangerous goods if they meet the following criteria:

IATA 3.9.2.5 GMOs are micro-organisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally.

Some examples: live mice that have been engineered to express a human gene; a culture of K12 E. coli that express GFP; live tissue culture of virally transduced cells.

Note that to qualify; they must be living organisms, bacteria, cell line (or virus) that have been engineered in a way that does not occur naturally. Purified plasmids, DNA, RNA would not meet this definition.

What about infectious GMOs, would they then be UN 2814?

Infectious GMOs must be classified as either UN2184, UN2900 or UN3373 as appropriate.
What about plant pathogens that are not genetically modified? If you have the proper USDA APHIS permit then what category is this shipped as?

Plant pathogens do not meet the definition of Class 6.2 according to the dangerous goods regulations and therefore are not regulated as hazardous materials. However, such materials still require packaging and appropriate marking. Packing and marking requirements should be explained in detail on the permit or the paperwork that comes with the permit. If you are still not sure, send a request to APHIS and I’m sure they will explain what needs to be done.

When should the exempt quantities label be used?
I assume that this question is in reference to the exempt human specimen or exempt animal specimen shipment. There is also an IATA “excepted quantities” mark shown below that is used when shipping small quantities of certain dangerous goods in accordance with IATA 2.6. For example small amounts of alcohol or formalin.

The definition of, packaging and marking requirements for Exempt human/animal specimens are found in the IATA regulations 3.6.22.3.6.

These are patient specimen in which there is minimal likelihood of pathogens being present. Such material is considered excepted from DOT hazmat regulations (see 49 CFR173.134(b)(2) and (11)). Therefore according to DOT there are no packaging marking or labeling requirements. IATA requires triple packaging and package must be marked “Exempt human specimen” or “Exempt animal specimen” as appropriate.

Were there any changes made to drivers license requirements that will affect an individual’s ability to transport infectious substances?

Short answer: yes but only if you are transporting select agents or toxins.

Driver training and other requirements for road transport of hazardous materials can be found in Part 177 of 49 CFR and are too numerous to mention here. In addition drivers must comply with Federal Motor Carrier Safety Regulations found in 49 CFR part 383 and part 390 through 397. If you are transporting a select agent, then you may not engage in or allow texting or hand held mobile phone use while driving. As far as the requirements for a commercial driver’s license, according to 49 CFR 383, if you transport any hazardous material that requires placarding or if you transport a select agent or toxin, then you must have a valid CDL with a hazmat endorsement.

Can the 24 hour Emergency Contact for Category A shipments be the Campus Police Department if Campus Police knows who to contact regarding biological shipments?

Short answer: Yes, if the campus police can reach someone immediately (within two minutes) who is able to provide emergency response mitigation information.

The three basic requirements for the emergency number can be found in 49 CFR 172.604

1. Must be monitored at all times the hazmat is in transportation including storage incidental to transport
2. The number of a person who is either knowledgeable of the hazmat and has comprehensive emergency response and incident mitigation information for that material or has immediate access to such a person
3. The number must be of the “person” offering the hazmat or the number of an agency or organization capable of and accepting responsibility for providing the detailed information required above.

When permits are required for shipping infectious materials, how long does it generally take to obtain these permits (what kind of lead time should I recommend to researchers wanting to ship items requiring a permit)?

It depends on the type of permit. In my experience, it generally takes two weeks to get an import permit from the CDC for human pathogenic material, this is assuming that you have filled everything out correctly on the form and there is
not a lot of back force for clarification or resubmission. On the animal side for an APHIS permit, it has taken me slightly less time. However, I have not filed for permits for several years and the wait times may have changed.

When are permits not required and what specific wording should be used to make sure the package does not get stopped in customs or during shipping?

Most animal source material (including components commonly found in cell culture media such as FBS) will require an APHIS permit.

On the human side, only those human materials that you suspect contain a pathogen will require a CDC permit. Thus any Category A or B shipment will require a permit but most exempt and excepted materials (of human origin) will not require a permit.

The language that I use for such exempt packages goes on the air waybill: "Non-hazardous, non-infectious protein (human blood sample, DNA, plasmid, list it specifically by name, etc.) for research purposes only as per 49CFR173.134(b)(and then I list the specific exception # here which is usually 1, 2 or 11)."

What are the most common mistakes that shippers make when shipping infectious materials that may result in the package being shipped back to the originator?

In my experience the most common mistakes that result in a rejected package are found on the shipper's declaration for dangerous goods usually associated with extra or incorrect information on the paperwork. Forgetting to put the date or place. Forgetting to mark 1 of 1 pages. Using a handwritten form (FedEx requires a computer generated form). Misspelling the proper shipping name.

Another common mistake is mis-use or misunderstanding of an Overpack. Often shippers assume that since it has the proper labels, it will be accepted, but without a UN specification mark on packages on the inside it will not be accepted for transport. They often open overpacks to check.

If mixed category A and B are shipped as an overpack, please describe the labeling and paperwork requirements.

Each package must be individually marked and labelled as required. All marks and labels that are not visible through the overpack must be reproduced on the outside of the overpack. The word “Overpack” is written on the outside of the overpack. The shipper's declaration for dangerous goods should be written to list both the Category A and the Category B proper shipping names (as shown below). Alternatively, the Shipper's declaration can be written to only list the Category A information if the Category B information (UN ID Numbers and Proper Shipping Name) is included on the waybill. Here is an example picture of the marking and labeling and following is an example shipper's declaration.
Does the condition of a pathogen affect status? For example, if shipping something that has a period in its life cycle that is not infectious (that is in that part of its life cycle during shipment) could that change something from Category A to B?

All possible life cycles that the organism could go through during the shipment process should be considered and the sample should be classified according to the most hazardous. If you ship a sample that meets the definition for category B at the outset but it is possible for it to change to a life stage that would qualify it for category A during the shipment then it should be shipped as Category A. If you are shipping a parasite that is in a life stage that is non-infectious to humans or animals in that particular life stage and it cannot undergo change during the shipment then it does not meet the definition of an infectious substance and therefore is excepted from the regulations for Class 6.2.

In the past we have used several companies for shipping Category A infectious substances (both risk group 3 and risk group 4 agents). However, many of these companies will no longer accept risk group 4 agents (note: Category A shipments that are risk group 3 agents are still being accepted by several companies). For example, in the past we routinely used World Courier for domestic shipments of risk group 4 agents, but were recently told by World Courier that they can no longer provide this service due to a lack of "licensed couriers in our area". Fed Ex, DHL, and other major companies will not accept risk group 4 shipments. As a result, we have been reduced to a single option which is Fed Ex's Custom Critical (White Glove) service which comes only at a premium price. In fact, the price for their service is so exorbitant that it is cost prohibitive and we will be forced to cease all future shipments unless we find another viable option. Have others experienced this same issue? Can you explain the reasons why our options have become so limited for risk group 4 shipments?

FedEx is one of the few big name commercial carriers that will transport dangerous goods. Carriers are allowed to make variations to the regulations that are more restrictive. One variation that FedEx has listed is FX-09: Division 6.2 items.
classed as Risk Group 4 by the WHO will not be accepted for carriage. Therefore FedEx will not accept these shipments. However, there is nothing in the regulations that require you to tell them it is Risk Group 4. You must list the technical name of the organism on the shipper’s declaration and if FedEx chooses to look it up then they may see that it is a listed agent and not accept it. One big challenge now is the select agent rules in the US and the need for special security during transport. Such additional security requirements are necessary and cost much more. It could be that FedEx wants to direct these type of shipments to the custom critical service since most select agents are risk group 4. That could be why they have become so limited. The risks for shipping RG 4 are much greater and therefore require additional security mitigation that many carriers are not equipped to handle.

It is my understanding that UPS is in the process of obtaining the necessary permits, training, and security protocols that will enable them to ship Category A infectious substances. However, I have not heard whether that will include RG 4 or not.

**When do the DOT rules stop? For example, would a person at a loading dock who is receiving a hazmat package from a FedEx driver be required to have DOT training?**

A hazmat employee is defined as employed on a full-time, part time, or temporary basis by a hazmat employer and who in the course of such full time, part time or temporary employment directly affects hazardous materials transportation safety. This term includes an individual who during the course of employment:

(i) Loads, unloads, or handles hazardous materials;

(ii) Designs, manufactures, fabricates, inspects, marks, maintains, reconditions, repairs, or tests a package, container or packaging component that is represented, marked, certified, or sold as qualified for use in transporting hazardous material in commerce.

(iii) Prepares hazardous materials for transportation;

(iv) Is responsible for safety of transporting hazardous materials;

(v) Operates a vehicle used to transport hazardous materials.

Once a package is unloaded and received, it is no longer considered in transport. Note, the “handles hazardous material” above only applies to the transport operation (from the moment you begin to package it to the moment it arrives at its destination safe and intact, unloaded from the transport vehicle.) So as long as the employee is not helping to unload the FedEx truck then they are not hazmat employees and they are not directly affecting safety of hazardous materials in transport.

**What is the recommended training to be offered for couriers only shipping Category B, not A?**

The training requirement is the same for both shippers and couriers of Category B materials. The training requirements are summed up in 173.199(e):

(e) *Training.* Each person who offers or transports a Category B infectious substance under the provisions of this section must know about the requirements of this section.

Simply, the person, carrier or shipper, must be knowledgeable about section 173.199. I have developed a short, two hour presentation that focuses on these requirements. These training requirements are not as detailed nor onerous as those required for other types of dangerous goods. While there is no record keeping requirement or testing requirement or refresher training requirement, I still keep a record, administer a test and ask them to participate in refresher training every two years.

What constitutes "general awareness" level training?

Knowledge of the following: what are dangerous goods? General information about DOT and IATA and applicability of the regulations, general knowledge about the 9 classes of dangerous goods and what qualifies as a dangerous good.
Familiarization of the general provisions (applicability, limitations, classification, identification, packaging, marking, labeling and documentation).

**Is a DOT certified training, or certificate, required for shipping Category A’s?**

Yes. DOT requires all shippers of hazardous materials to have training.

The DOT does not certify any training organizations nor do they certify, test, license or otherwise acknowledge individual trainers. Therefore, DOT-certified training does not exist. The individuals must be trained according to the DOT training requirements found in Subpart H of Part 172 of 49 CFR. (See further details below)

**Is an IATA certified training, or certificate, required for shipping Category A’s?**

Yes if one wishes to use an IATA carrier.

IATA is similar to DOT in their requirements for training. However, they do certify a few training programs that meet certain IATA standards and a trainer can attend an IATA train the trainer certificate program. However, in order to ship with an IATA carrier you only need to be trained according to the IATA requirements found in section 1.5 of the IATA DGR, not by an IATA-certified training school or IATA certified instructor. (See further details below)

**Other FREQUENTLY ASKED QUESTIONS About Training**

**May hazmat employers/employees train and test themselves (an owner-operator)?**

Yes. Self-training is acceptable provided that all training requirements of § 172.704 are met.

**Who certifies that an instructor is qualified to train, test, and certify in accordance with § 172.704?**

Except for certain FAA required 14 CFR training, the U.S. DOT does not review or certify training programs for pre-approval purposes. The employer must determine a trainer’s qualifications based on the employer’s need.

IATA requires the trainer to have offered training or been trained in the past 24 months. They are also requiring the training to have adequate instructional skills, although adequate instructional skills is subject to interpretation. The trainer must be aware of any regulatory changes on a yearly basis. ICAO will be adopting similar requirements in 2015.

**Does the trainer who teaches and tests the hazmat employee certify that the hazmat employee is trained and tested?**

It is the hazmat employer’s responsibility to ensure that a hazmat employee is properly trained and tested; however, the hazmat employer may designate an outside source to train, test, and certify on his/her behalf that the employee has been trained and tested.

**If a designated outside source trains but does not test the employee, must the employee be tested to complete this training?**

Yes. The employee must be tested in order for the training to meet the requirements of the HMR. The hazmat employer is responsible for ensuring each hazmat employee is trained and tested.

**Must the test be in a written format or may a skill demonstration be used?**

Any test that ensures that the employee can perform the assigned duties in compliance with the HMR is acceptable. Training and testing may be accomplished in a variety of ways: performance, written, verbal, or a combination of these.
**Must the employee “pass” a test?**

The requirements do not state that the employee must “pass” a test; however, an employee may only be certified in areas in which he/she can successfully perform his/her hazmat duties.

**Does IMDG Code, ICAO Technical Instructions, OSHA or EPA training fulfill the HMR requirements?**

This training may be used to the extent that the general awareness, function-specific, safety, and security training and testing requirements of the HMR are met. Areas not covered will require additional training.

**Who will enforce the training requirements in § 172.704?**

Enforcement is the responsibility of each U.S. DOT modal administration. Compliance or noncompliance with the training rule will be determined during safety and compliance reviews of shippers, carriers and package manufacturers. Since the majority of biological shipments use air transport the most common enforcement agency will be the Federal Aviation Administration (FAA), a branch of the DOT.

**What type of fines would be involved?**

Violations of any hazardous materials regulations including training may be subject to a civil penalty of up to $75,000 for each violation. If the violation results in death, serious illness or severe injury to any person or substantial destruction of property, the maximum civil penalty is $175,000. Criminal violations may result in fines, imprisonment or both. (See 49 CFR §107.329 and §107.333.)

The minimum fee for training violations is $450 per violation.

**An office secretary types the required hazardous materials description on a shipping paper at the direction of another, item by item. Is the secretary a hazmat employee requiring training?**

Yes. Each person who performs any function subject to the HMR must be trained, except special circumstances addressed by § 172.704(e).

**How does the classification of a sample change when the testing purpose is for research vs. clinical? For example, what if the specimen is stool and the patient/donor history is completely unknown?**

In a clinical setting often little is known about the specimen but the doctor has ordered some testing. If the testing involves a suspected pathogen then the sample will most likely be classified as a Category B infectious substance. Category A is reserved for the highest risk pathogens, those that cause death or severe consequences in otherwise normal healthy people. Reviewing the indicative list of category A agents (Table 3.6D in IATA) there are two types of entries those for cultures and those for patient specimens. Granted these are just examples of Category A agents, but if you review the list and are familiar with the WHO risk group classification system only RG4 patient samples are considered category A. Cultures of RG3 agents are also Category A. However, patient specimens with suspected RG3 pathogens are considered Category B. Therefore unless it is a suspected outbreak of hemorrhagic fever or some new and deadly disease that people are dying from then most clinical samples should be classified as Category B.

**Would most established cell lines (immortalized, commercially purchased) also be exempt from shipping regs (as long as it wasn’t be used for infectious disease studies)? Or would it be “exempt human/animal specimen”. For the record, I would classify a primary patient cell line as “exempt human specimen” or Cat B depending on medical data, etc.**

The DOT specifically excepts non-infected established cell lines from the regulations. No packaging, marking or labeling. In my opinion, “Exempt human specimen” would not be an acceptable classification for cell lines, since this category is
reserved for samples collected **directly** from humans or animals. Not those collected from humans or animals and then cultured.

49CFR173.134(b) *Exceptions.* The following are not subject to the requirements of this subchapter as Division 6.2 materials:

... 

(2) Non-infectious biological materials from humans, animals, or plants. Examples include non-infectious cells, tissue cultures, blood or plasma from individuals not suspected of having an infectious disease, DNA, RNA or other non-infectious genetic elements.

Also Biological products would also apply especially to commercially produced cell lines as they have been approved for sale.

(6) A biological product, including an experimental or investigational product or component of a product, subject to Federal approval, permit, review, or licensing requirements, such as those required by the Food and Drug Administration of the U.S. Department of Health and Human Services or the U.S. Department of Agriculture.