

SENTINEL LEVEL CLINICAL LABORATORY GUIDELINES
FOR
SUSPECTED AGENTS OF BIOTERRORISM
AND
EMERGING INFECTIOUS DISEASES

Packing and Shipping Infectious Substances

American Society for Microbiology

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Packing and Shipping Infectious Substances

Revised April 20, 2021

The information in this procedure is not an all-inclusive guide to packing and shipping regulations. The information is a summary of the authors' interpretations of the current (as of December 2020) requirements and regulations issued by the following:

- International Civil Aviation Organization (ICAO; an agency of the United Nations (UN) that issues the Technical Instructions for the Safe Transport of Dangerous Goods by Air)
- International Air Transport Association (IATA; a commercial airline trade association that issues the Dangerous Goods Regulations (DGR))
- United States Department of Transportation (DOT; an agency of the federal government that issues the Hazardous Material Regulations (HMR))

The requirements and regulations governing the transport of infectious substances by commercial carriers change often. Significant changes in IATA DGR are available approximately six months prior to the annual January 1 publication. Shippers (**NOT** recipients or consignees) are responsible for being aware of these changes, being appropriately trained and certified, adhering to current regulations, interpreting applicable regulations for themselves and their facilities, and packing and shipping substances appropriately. Consignees/recipients however must also be trained to properly accept and handle dangerous goods/hazardous materials at their facility and should develop their own policies for accepting or rejecting packages that are improperly packed. The terms, 'dangerous goods' and 'hazardous materials' are somewhat interchangeable in relation to regulated shipping. See Appendix A for definitions of IATA and DOT terms related to packing and shipping used in this procedure.

Significant changes and addendums to the annually published IATA Dangerous Goods Regulations can be found on this website: <https://www.iata.org/en/publications/dgr/>.

Any changes to the DOT Hazardous Material Regulations will be announced before they become effective and will be found at: <https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations>

1 Governing Authorities and Regulations

1.1 Origin of Regulations

Shipping requirements and regulations are developed and published by many authorities, the most notable of which are shown in Table 1. Most regulations for the safe air transport of dangerous goods throughout the world originate as decisions (called Model Regulations) made by the ICAO United Nations Committee of Experts (15). ICAO uses these decisions to develop formal and standardized *Technical Instructions for the Safe Transportation of Dangerous Goods by Air* for use in international aviation (8, 15). These *Technical Instructions* are the standards for the international shipment of dangerous goods regulations by air. IATA uses the *Technical Instructions* to develop the >1,000-page *DGR* which is the routine "go-to" published book of

requirements used by virtually all commercial airlines, other carriers involved in the transport of dangerous goods, and shippers of infectious substances (7). The IATA DGR requirements have become the most widely recognized, copied, and used packing and shipping guidelines in the world. Most national (e.g., U.S. DOT HMR) and international regulations are based on, or are at least in substantial agreement (harmonization) with the IATA requirements (13).

In the United States, the DOT regulates the commercial transportation of hazardous materials by both air and ground carriers [within the HMR, 49 CFR Parts 171-180](#). Just as IATA derives its requirements from ICAO, the DOT also derives its regulations from ICAO (6, 11). For all practical purposes, shippers of infectious substances can consider compliance with IATA requirements to be compliant with DOT regulations (6, 11).

1.2 Importance of Regulations

Laboratory workers who ship or transport dangerous goods/hazardous materials, in general, and infectious substances, in particular, by a commercial land/ground or air carrier/courier are required to follow a complex and often confusing set of national and international requirements and regulations. The purpose of these requirements and regulations is to protect the public, emergency responders, laboratory workers, and personnel in the transportation industry from accidental exposure to the contents of the packages (6, 8). An important non-safety-related benefit of adherence to these regulations and requirements is to reduce the exposure of the shipper to the risks of criminal and civil liability associated with the improper shipment of dangerous goods (6, 8).

1.3 Effectiveness of Regulations

Statistical data from the U.S. Office of Hazardous Material Safety shows that these regulations are extremely effective in protecting both the contents of packages and the persons who handle the packages. To date, the authors are not aware of reported cases of illness due to the release of an infectious substance during transport, [even though incidents of spills, leaks, and improperly packaged shipments have been reported \(20\)](#).

1.4 Exceptions

The transportation of small quantities of some infectious substances (usually patient specimens being transported for clinical, diagnostic, or other patient care purposes, and that do not meet the definition of Category A) may be exempt from most DOT regulations if the specimens are transported by private or contract carrier in a motor vehicle used exclusively to transport such substances (6, 11). Such substances must be packed and secured inside the vehicle according to DOT regulations; however, these regulations are [less stringent than Category A](#) and state that the substances need only be in [triple packaged](#) containers, sealed securely, and secured within the vehicle during transport. Readers should be aware that the usual strict OSHA regulations still apply during this type of transportation of infectious substances. [Biological products, such as blood or blood plasma for transfusion purposes, dried blood spots for newborn screening, or fecal occult samples, may be considered excepted from the regulations \(and thus considered non-regulated\) if infectious material is believed to not be present within.](#)

1.5 Specific Regulations

IATA requirements and DOT regulations mandate the minimum standards for packing infectious substances that can pose a threat to humans, animals, or the environment (7). The safe and legal transport of these substances is based on the following mandated activities:

- classification and naming of the material to be shipped;
- [evaluation of best options for courier \(e.g., investigate credentials, training, acceptance of Category A infectious substances prior to signing of initial contract\)](#);
- training of individuals [who will transport or ship infectious substances](#) on the requirements for appropriate packaging and shipping of [these](#) substances, documentation of the training, and subsequent certification (by the employer) of the trainee;
- selection of appropriate packaging material that will contain the infectious contents and provide adequate protection to the carrier personnel and environment if the package is damaged;
- packing the shipment correctly;
- placing appropriate information (markings and labels) onto the outer package to alert carrier personnel to the hazardous contents of the package and to identify contacts if an accident occurs; and
- documenting relevant aspects of each package and its contents.

Each of the aforementioned activities is presented in detail in the following sections of this procedure.

The current DOT Hazardous Material Regulations (Title 49 CFR Parts 100-185), may be accessed electronically and for free, here:

https://www.ecfr.gov/cgi-bin/text-idx?SID=1d49a3b137cb1b6fc45251074e634b44&tpl=/ecfrbrowse/Title49/49tab_02.tpl

The current edition of the annually published IATA Dangerous Goods Regulations may be obtained for purchase here: <https://www.iata.org/en/publications/dgr/>

1.6 United States Postal Service

The United States Postal Service (USPS) publishes its own regulations in the USPS *Domestic Mail Manual* (DMM), Publication 52, the *Hazardous, Restricted, and Perishable Mail* (14). The USPS regulations for mailing hazardous materials generally align with the DOT regulations, with some exceptions (e.g., USPS does not permit the shipment of Category A infectious substances, but will transport Category B and exempt specimens).

<https://pe.usps.com/text/pub52/welcome.htm>

1.7 Penalties and Fines

Incidents with hazardous material or hazmat inspections may result in imposing fines and be subject to civil and/or criminal penalties for violations to comply with the HMR.

| | | |
|-----------|-------------|------------|
| Civil | Maximum | \$79,976** |
| Criminal* | Individual | \$250,000 |
| | Corporation | \$500,000 |

- *\$481 = minimum penalty per day, per violation if related to training
- ** = Fines are per violation, per day
- **\$186,610 if violation resulted in death, serious illness or severe injury to any person or substantial property damage

See 49 CFR §107.329-333 for maximum penalty information and further details.

2 Training and Certification

DOT and IATA provide an outline for who is required to receive hazardous material / dangerous goods shipping training based on job functions, and both provide general information for what the training must encompass. However, both organizations have historically provided little direction and details for conducting training of shippers, including who should or can be a trainer, how training should be performed, detailed contents of training, how testing is to be performed, the definition of a passing grade, and how to determine if a person is adequately trained.

In the January 2020, 60th edition, Appendix H of the IATA DGR, an announcement was made that outlines new competency-based training assessment (CBTA) requirements for dangerous goods training that will become effective beginning January 1, 2023. Appendix H of the annually published IATA DGR provides details for training programs and training requirements and should be consulted annually. The 60th edition DGR Appendix H CBTA announcement can be found here: <http://dl.icdst.org/pdfs/files3/b94e8e5f4704b74b726a557a472c47e7.pdf>

DOT and the Pipeline and Hazardous Material Safety Administration (PHMSA) have also created guides for developing an effective hazmat training program to provide assistance to employers to meet the DOT HMR requirements which can be found here:

- <https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/training/hazmat/6586/guide-developing-hazmat-training-program.pdf>
- [https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/Hazmat Transportation Training Requirements.pdf](https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/Hazmat_Transportation_Training_Requirements.pdf)

Further information about training and certification is listed below.

2.1 Applicability

Anyone involved in the shipping or transportation of dangerous goods (including infectious substances) must be trained and certified by their employer in the shipment of dangerous goods (6, 7, 11). Training must be function-specific, (i.e., directly relevant to the role the person plays in the packing and shipping process). Persons who pack and ship Category B infectious substances and exempt human and animal specimens (for air transport) must receive clear instructions, guidance, and specific training for all functions involved in packing and shipping these substances, and be certified by their employer to do so. However, persons who pack and ship Category A infectious substances must receive the aforementioned training plus specific training for all functions involved in packing and shipping more hazardous Category A substances and be certified to do so. [Training will be required if an employee performs any of the following functions \(16\):](#)

- [Preparation of a shipping paper \(e.g., a dangerous goods shipper's declaration form, airway bill\)](#)
- [Signing a shipper's declaration form](#)
- [Classifying Division 6.2 materials](#)
- [Selection of packaging for Division 6.2 materials](#)
- [Packing hazardous material for transport](#)
- [Labeling or marking a package that contains hazardous materials](#)
- [Transportation of hazardous materials in commerce](#)

2.2 Essential Components of Training

The essential components of a [shipping](#) training program [should](#) include the following:

- General awareness and familiarity with the many aspects of shipping dangerous goods
- Importance, nature, and contents of IATA and DOT regulations
- Function-specific training (hands-on or demonstrations of and packing techniques) for the specific duties expected of the employee
- [Modality of shipment \(e.g., air vs. ground\)](#)
- Marking and labeling
- Documentation of shipments of dangerous goods
- Safety training (e.g., [OSHA bloodborne pathogen](#))
- Security awareness training (if applicable to a trainee's job responsibilities)
- Testing
- Issuance of a certificate after successful completion of the training (6,7)

2.3 Training Materials

Acceptable training materials and methods include manuals, training courses, and workshops, all of which are commercially available from professional organizations and commercial suppliers of packaging materials for dangerous goods. Alternatively, a training program or workshop which includes hands-on training and demonstrations can be developed by any hospital, laboratory, school, institution, or other facility through the direction of a certified trainer. All training programs should be designed to provide initial and regular follow-up training to each employee responsible for shipping and packing infectious substances. Training and training

material for the transportation of dangerous goods and infectious substances is available at the following [example](#) sources (all websites accessed April 8, 2021):

- American Society for Microbiology (www.asm.org)
- International Air Transport Association (training manuals) (<https://www.iata.org/en/training/>)
- Regional and national clinical microbiology meetings (workshops and presentations)
- Many major universities and medical centers
- Many state departments of health and public health laboratories
- Association of Public Health Laboratories (<https://www.aphl.org/training/Pages/default.aspx>)
- Many professional scientific organizations
- Saf-T-Pak/InMark (<https://inmarkinc.com/>)
- CARGOpak (www.cargopak.com)
- Dangerous Goods International (www.dgitraining.com)
- World Courier Training Course (www.worldcourier.com)
- MediaLab, Inc. (<https://www.medialab.com/>)
- Centers for Disease Control and Prevention (www.cdc.gov/labtraining/)
- World Health Organization (https://www.who.int/ihr/i_s_shipping_training/en/)

2.4 Documentation and Certification of Training

IATA and DOT require all aspects of training to be documented. Employers **must** keep a detailed record for each employee who is trained. The record should include employees' names, location and date of training, name of the trainer, course content, and evidence of successful completion of a test of the presented materials. A convenient and useful form of the record is a certificate which states the aforementioned details of the training. All certificates can be placed in a central location or certificates can be placed into individual employees' employment records. **If an employee receives training from an external source, the trainer or training agency will provide a record of the training to the training participant.** Employers must also keep a record of the additionally required training such as safety and security. IATA and DOT training certification is valid for 2 and 3 years, respectively. **Clinical laboratories must also take into consideration what their accrediting body (e.g., Joint Commission, College of American Pathologists) requires for training frequency, as well as any internal policies for recurrent training, which may be stricter and more frequent than the IATA and DOT requirements.** Employers certify their employees to be fully trained. Training programs will provide a certificate of attendance and a pass/fail rating for those attending a training on packaging and shipping regulations and requirements. Employers of hazmat personnel will certify their staff have successfully received other applicable and required training at their place of employment such as safety, security awareness, and additional function-specific procedures, and any retraining that may be needed.

2.5 Enforcement of Compliance

The DOT and the Federal Aviation Administration (FAA) have authority to perform unannounced inspections of facilities (e.g., clinical laboratories) that ship dangerous goods, and to inspect these facilities for compliance with the training regulations and to inspect training records. Facilities which do not comply with prescribed regulations are subject to substantial fines. Therefore, it is extremely important to (a) keep employees' training current, (b) retain training records, and (c) keep training records accessible!

3 Classification of Substances

3.1 Classification

Shipping of all dangerous goods begins with classification of the substances. Classification is a mandatory three-step process to define dangerous goods that are shipped by commercial carriers (4, 6, 7, 9, 11). Classification serves two purposes: (a) it allows the shipper to select the proper IATA packing instructions (PI) and directions to use, and (b) if the substance is a Category A infectious substance, it provides important information necessary to complete documentation (a Shipper's Declaration) which must accompany shipments of Category A substances.

3.2 Classification Steps

All infectious substances fall under Class 6, Division 6.2 of the hazardous material regulations. Decisions regarding classification within Division 6.2 are extremely important because they will determine exactly how a substance must be packed and shipped. Training and professional judgement should lead shippers to properly classify substances and avoid making discriminatory shipping decisions. Willful misclassification of package contents not only leads to excessive shipping-associated expenses, but also violates federal and international law.

Caution should be taken with assigning the task of sample classifications. Commonly, the microbiologist or medical laboratory scientist in a clinical laboratory will determine what pathogens are to be shipped. Therefore, the same laboratorian is in the best position to classify the pathogen for shipment because of their knowledge of the source of the specimen, any testing results, as well as the history and symptomatology of the patient (if possible). If it is not the laboratorians themselves who are packaging and labeling, this person is then responsible to share the classification decision in writing with the shipping department to ensure proper labeling and marking is performed. The shipping department must not assume the classification when shipping a package without obtaining knowledge of the contents. In some laboratory settings, one person may perform several or all of the shipping functions (classification, packing, labeling, etc.)

3.2.1 First Step

The first step of classification is to determine whether the substance being classified is a patient specimen or culture. A "Patient Specimen" is defined as material collected directly from humans or animals for diagnostic, treatment, prevention, investigational, or research purposes. According to DOT, patient specimens can include secreta, excreta, blood and its components, tissue and tissue swabs, body parts, and specimens in transport media such as transport swabs, culture media, blood culture bottles, etc. However, transport media which is incubated prior to transport and demonstrates propagated growth or turbidity, is no longer considered a patient specimen and would need to be classified as being a culture. "Culture" is defined as an infectious substance containing a pathogen that is intentionally propagated.

The material will fit into one of the nine DOT and IATA-specified classes (Class 1 through Class 9) of hazardous materials (Table 2). Infectious and toxic substances are Class 6 hazardous

materials, or dangerous goods. Infectious substances are further classified into Division 6.2 of the Class 6 hazardous material, and toxic substances are further classified into Division 6.1. If a laboratory were to ship a purified toxin, it would need to conform to the requirements of shipping Division 6.1 material (not covered in detail in this document). When a laboratory ships a substance such as bacteria that may produce a toxin (e.g., botulinum toxin producing *Clostridium botulinum*, or shiga toxin-producing *Escherichia coli*) the material (bacterial specimen) would still be classified as Division 6.2, not 6.1, since it would fall under the definition of containing a pathogen which can cause harm to a human or animal when exposure to it occurs. Occasionally, a shipment may fall into more than one hazardous material category. When dry ice is used to keep specimens frozen, the additional category of Class 9, miscellaneous dangerous goods is used when shipping by air. Class 6 and Class 9 substances usually are the most common regulated dangerous goods shipped by clinical laboratories for diagnostic testing.

3.2.2 Second Step

The second step of classification is determining whether the substance meets the definition of Category A, Category B, Exempt Specimen, non-regulated, or another group as listed in Table 3. Description details of each can be found in the specific sections on each topic below.

DOT and IATA have published an Indicative List (Table 4) to catalog current known Category A pathogens. This list can assist shippers to correctly classify their specimens and help differentiate between classifications of a patient specimen versus propagated isolates (e.g., cultures). The list itemizes each Category A pathogen in the form(s) known to fit the definition. Meaning, if a Category A pathogen is listed as “culture only” on the list, the isolate (culture) must be classified and shipped as Category A, and if in a form other than culture (e.g., a patient specimen), it may be permitted to be classified as Category B. For example, *Mycobacterium tuberculosis* is listed on the Category A list as “cultures only”. Therefore, if a lab is shipping a culture it would need to be classified as Category A, but if the lab is shipping a patient specimen (e.g., sputum), it would be acceptable to classify it as Category B since sputum is not in culture form. If the Category A pathogen on the Indicative List is not followed by the words “cultures only”, any form of the specimen must be classified and shipped as Category A, whether in culture form or patient specimen. For example, Ebola virus on the Category A Indicative List is not followed by the words “cultures only”, therefore any form of a specimen (e.g., tube of blood) suspected to contain Ebola virus would need to be classified as either Category A, or Suspected Category A Infectious Substance. Specimens that are confirmed to contain Ebola virus, must be classified only as Category A, Infectious Substance.

If the patient specimen is not obviously a Category A or Category B substance but it *meets the criteria* of or *has characteristics* of either type, the shipper must classify it **accordingly** as either Category A or Category B. Otherwise, the substance **may** be classified as an exempt human or animal specimen (Table 3) (6, 7, 11).

Potentially infectious substances must be classified into one of the following categories (Fig. 1) (Table 3):

- Category A Infectious Substance
- **Biological Substance**, Category B

- Patient Specimen
- Exempt Human or Animal Specimen
- Genetically Modified Organism (GMO) / Genetically Modified Microorganism (GMMO)
- Exempt Substances
- Biological Products
- Infected Animal
- Medical or Clinical Waste

3.2.3 Third Step

The third step of classification is determining the mode of transport and who is transporting the material, whether it is an air or ground carrier, or if the DOT packaging exception known as Materials of Trade (MOT) may be utilized. Each will be described further below (see Figure 1 for classification determinations). Individual carriers, such as FedEx, may have their own requirements in addition to the DOT and IATA regulations. Therefore, those shipping hazardous materials must be familiar with any carrier/courier requirements. The shipper must also be aware of the regulatory differences between transporting hazardous material by ground versus by air. Air transport will have more restrictions than ground, such as quantity limitations and the requirement for pressure rated primary or secondary containers (e.g., 95 kPa packaging).

3.3 Category A Infectious Substances

A Category A substance (pathogen or agent) is “an infectious substance which is transported *in a form* that, when exposure to it occurs, is capable of causing permanent disability, or life-threatening or fatal disease to otherwise healthy humans or animals” (7).

3.3.1 List of Category A Substances

Category A substances are specifically designated and listed by IATA and DOT (Table 4). The [indicative](#) list of Category A substances is not all-inclusive, and a [shipper should perform a thorough risk assessment](#) before assigning a substance [currently not on the indicative list](#) to the Category A [designation](#). Sentinel laboratories should seek guidance from their state [or local public health laboratory](#) for accurate classification of novel and emerging pathogens.

3.3.2 Decisions to Classify a Substance as Category A

IATA requirements allow shippers to use their discretion and professional judgment when deciding if a substance meets Category A criteria (Fig. 1) (7). IATA *Dangerous Goods Regulations* state the following:

- regarding judgment: “Assignment to UN2814 or UN2900 [i.e., Category A] must be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgment concerning individual circumstances of the source human or animal.”

- regarding assigning infectious agents which, in the shipper’s opinion, meet Category A criteria, but which are not specifically listed as a Category A agent: “...infectious substances...which do not appear in the table but which meet the same criteria must be assigned to Category A.”
- regarding uncertainty of Category A criteria: “...if there is doubt as to whether or not a substance meets the criteria [of Category A] it must be included in Category A.”

3.3.3 UN Numbers of Category A Pathogens

Substances likely to contain Category A pathogens must be assigned to either the UN number UN2814 (proper shipping name: Infectious Substance, Affecting Humans) or to UN2900 (proper shipping name: Infectious Substance, Affecting Animals **Only**) (7). If a Category A pathogen/substance is capable of causing disease in both humans and animals, the pathogen/substance must be classified and shipped as a Category A Infectious Substance Affecting Humans (UN2814).

3.3.4 Agents of Bioterrorism

Some Category A pathogens have been designated as agents of bioterrorism and are known as select agents (Appendix B). NOTE: United States federal regulations require shippers to have special permits to possess, use, transfer, and receive these agents (1, 2a, 2b, 3, 5).

Clinical laboratories that are sending suspected select agent samples to a Laboratory Response Network (LRN) reference laboratory for either rule-out or confirmatory testing should provide an advanced notification of the shipment. The receiving LRN reference laboratory is required to have a permit for the receipt of the agent (see section 12 on permits).

3.4 Biological Substance, Category B

A Category B substance is defined by IATA as “an infectious substance which does not meet the criteria for inclusion in Category A” (Fig. 1) (Table 3) (7). Category B substances are *not* in a form generally capable of causing disability, life-threatening illness, or fatal disease (10). In the authors’ opinion, examples of possible Category B substances are the following:

- typical clinical, diagnostic, or patient specimens, e.g., blood, biopsies, swab specimens, excreta, secretions, body fluids, tissues, etc., (a) being shipped for routine culturing or other testing for non-Category A infectious microorganism(s) or (b) suspected of containing a non-Category A microorganism(s),
- typical clinical laboratory cultures (usually on solid or in liquid media) of routinely encountered non-Category A microorganisms grown and used in clinical microbiology laboratories.

A patient specimen suspected of containing a “culture only” Category A pathogen may be shipped as a Biological Substance, Category B because the suspected Category A substance is

not in culture form, such as sputa being tested for *M. tuberculosis* or serum to be quantitated or cultured for HIV. If there is doubt as to whether a substance meets Category A criteria, it must be shipped as Category A. A shipper may ship any substance or specimen as Category A if, in their professional opinion, the specimen poses health risks equivalent to that of a Category A substance.

Category B substances must be assigned UN number UN3373 (proper shipping name: Biological Substance, Category B) (7, 11).

3.5 Exempt Human or Animal Specimens

Exempt Human or Animal Specimens are those for which there is “minimal likelihood there are pathogens present” (Fig. 1) (Table 3) (7). Examples of such specimens include urine or serum to be tested for glucose, cholesterol, hormone levels, prostate-specific antigen, and analytes used to evaluate heart and kidney function. Professional judgment and knowledge of patient medical history may be used to determine if the specimen is an infectious risk or contains pathogens. Exempt Human or Animal Specimens have less stringent packaging requirements than do Category A and Category B substances. IATA requires outer packages which contain Exempt Human or Animal Specimens to be clearly labeled as “Exempt Human Specimen” or “Exempt Animal Specimen” (7). DOT does not require this label on outer packages (11). Exempt human and animal specimens are not assigned a UN number or proper shipping name.

3.6 Exempt Substances

Many substances commonly encountered in clinical laboratories are entirely exempt from the strict dangerous goods shipping requirements and regulations which apply to Category A and Category B substances and to Exempt Human or Animal Specimens (when shipped by air) (Fig. 1) (Table 3) (7). The following are examples of such exempt substances:

- substances which do not contain infectious substances or are unlikely to cause disease in humans and animals;
- substances which contain non-pathogenic microorganisms;
- most environmental samples (food, soil, etc.) which do not pose a health risk to humans or animals;
- substances which contain neutralized or inactivated microorganisms that do not pose a health risk to humans or animals (e.g., formalin fixed paraffin embedded (FFPE) samples);
- dried blood spots and fecal occult blood screen specimens;
- blood and blood components collected for the purpose of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissue or organs intended for use in transplantation;
- U.S. Food and Drug Administration (FDA)-approved and FDA-licensed biological products; and
- ≤30 mL of formalin per primary container if the formalin is used as a preservative of an infectious substance, e.g., tissue and worms in 10% formalin.

“Exempt Human Specimen” and “Exempt Animal Specimen” are IATA classification terms, and will not be found within the DOT HMR. The DOT HMR will consider biological product

samples that are not infectious as non-regulated, or ‘excepted’ from the HMR. Exempt human or animal classifications will apply to samples transported by air, and non-regulated / excepted samples will apply to non-infectious samples transported by ground.

3.7 Patient Specimens

IATA and DOT have defined a “patient specimen” as material collected directly from humans or animals for diagnostic, treatment, prevention, investigational, or research purposes (Fig. 1) (Table 3) (7, 12). Patient specimens which have Category A or Category B criteria should be classified, packed, and shipped as Category A or Category B substances (Fig. 1) (Table 3) (7, 12). Patient specimens which do not meet either Category A or Category B criteria can be packed and shipped as “Exempt human specimen” or “Exempt animal specimen” when transported by air.

3.8 Genetically Modified Organisms and Microorganisms

A genetically modified (micro) organism (GMO/GMMO) is an organism in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. GMOs and GMMOs which meet the criteria for containing a Category A or Category B substance must be classified as either Category A and assigned to either UN2814 or UN2900, or classified as Category B respectively. If a GMO or GMMO is determined not to meet the Category A or Category B criteria and is not likely to cause disease in humans or animals, the organism must be classified as a GMO/GMMO and must be assigned to Class 9, miscellaneous dangerous goods; UN3245; proper shipping name: Genetically Modified Organism, and packed and shipped as GMO/GMMO (Tables 3 and 6) (7).

3.9 Biological Products

Virtually all commercially available biological products as defined by IATA are exempt from the packing and shipping regulations presented in this procedure. However, if a biological product is determined to meet the criteria of one of the aforementioned infectious substances (Category A, Category B, Exempt Human Specimen or Exempt Animal Specimen, etc.) it must be packed and shipped as such (7). Examples of biological products include bacterial typing sera, vaccines, bacterial antigens, antimicrobial agents, reagents for identifying bacteria, and reagents used in antimicrobial susceptibility testing. Biological products are not assigned a UN number or a proper shipping name.

3.10 Medical or Clinical Waste

Medical or clinical waste which contains Category A infectious substances must be packed and shipped as such and assigned UN2814 or UN2900. Medical or clinical waste which contains Category B materials, or is reasonably believed to have a low probability of containing infectious substances must be packed and shipped as Medical Waste, n.o.s. (not otherwise specified) (UN3291; proper shipping name: Medical Waste, n.o.s.) (7). See Tables 3 and 7.

3.11 Infected Animals

A living, intentionally infected animal that is known to contain or reasonably expected to contain an infectious substance cannot be transported by air unless the substance cannot be transported by any other means (7). Consultation with individual carriers is advised if either live or dead infected animals need to be shipped. Infected animals are not covered in detail in this document. [See the DOT requirements within 173.196 for additional information.](#)

4 Proper Shipping Names

[According to Section 4 of the IATA DGR, dangerous goods are assigned to UN numbers and proper shipping names according to their hazard classification and their composition.](#) If the substance is classified as Category A, Category B, GMO/GMMO, dry ice, or medical waste, the shipper must identify (officially name) the substance by assigning the substance to one of the [approximately 3,000 IATA-specified and internationally recognized UN numbers and proper shipping names most likely to be shipped by air listed in the IATA requirements in the List of Dangerous Goods, Subsection 4.2 \(7\).](#) A “proper shipping name” is a unique designation that describes the regulated material being shipped.

Proper shipping names and their associated UN numbers are specifically listed and published internationally by IATA so that most carriers around the world will recognize *the general group or kind* of infectious agent or dangerous good they are handling. [The list provides 14 informational items \(A through N\) for each of the proper shipping names and UN numbers \(Table 5\).](#)The 14 items correspond conveniently to the information needed to complete the [Dangerous Goods Shipper’s Declaration](#), and can be used to populate required information from DOT on Shipping Papers. [For most common clinical laboratory shipments, only a handful of the 3,000 proper shipping names are routinely used and are listed below.](#) [Additional details about this list, including other packaging restrictions and requirements are found in Table 6.](#) Table 6 shows the IATA- and DOT-designated infectious substances commonly shipped by clinical laboratories. The table provides proper shipping names, UN numbers, [hazard class or division, hazard label](#), packing instructions, quantity limits, restrictions for “cargo aircraft only” and other information related to packing and shipping these substances.

- [UN2814, Infectious Substance, Affecting Humans](#)
- [UN2900, Infectious Substance, Affecting Animals Only](#)
- [UN3245, Genetically Modified Microorganisms](#)
- [UN3245, Genetically Modified Organisms](#)
- [UN3291, Biomedical Waste, n.o.s.](#)
- [UN3291, Clinical Waste, unspecified, n.o.s.](#)
- [UN3291, Medical Waste, n.o.s.](#)
- [UN3291, Regulated Medical Waste, n.o.s.](#)
- [UN3373, Biological Substance, Category B](#)
- [UN1845, Dry ice](#)

5 Packing Instructions and Packing Substances

5.1 Packing Instructions

DOT regulations, IATA requirements, and IATA Packing Instructions (PI) describe the minimum standards for the correct way to pack, label, and prepare infectious substances for safe transport. Shippers are legally responsible for complying with these regulations, for following prescribed PI, and for packing substances correctly to ensure the safety of all personnel who handle the package before, during, and even after shipment to the point of acceptance of the package by the consignee/recipient. After determining the exact nature and category of the substance to be shipped, the shipper must select the most appropriate PI and packing directions to use (Fig. 1) (Table 6). Shippers must also follow the instructions provided by a manufacturer for how to use their shipping materials as intended. Generally, the PI used by clinical laboratories are those that relate to shipping Category A infectious substances (PI 620 [previously, PI 602]); Category B infectious substances (PI 650); and dry ice (PI 954 [previously 904]). There are no specifically numbered PI for specimens classified as Exempt Human or Animal Specimens; however, IATA provides directions which must be followed (7). See Table 7 for a comparison of the details of packing instructions and directions.

5.2 Comparison of Packing Instructions and Directions

The three more common infectious substances shipped by clinical microbiologists are Category A, Category B, and Exempt Human Substance. Details of the similarities of and differences between PI of these substances are shown in Table 7. The major similarity these three instructions have is commonly known as triple packaging. In its simplest form, triple packaging consists of a primary container, a secondary container, absorbent material between the containers, and an outer shipping container (Figure 16). The major differences between these instructions are those associated with documentation and with marking and labeling outer containers. The following are the main components of PI 620 (packing instruction for Category A shipments) and PI 650 (packing instruction for Category B shipments):

- A leak proof primary container made of glass, metal, or plastic and, if it contains a Category A infectious substance, sealed by a positive method (e.g., heat seal, metal crimp, or taped screw-cap lid). For Category A and Category B substances to be shipped in either passenger or cargo aircraft, the maximum allowable volume per primary container is 50 mL (50 g) and 1 L (4 kg) for Category A and Category B substances, respectively.
- Absorbent material sufficient to absorb all **hazardous material** (liquid) contained within the primary container(s) in case of breakage **must be** placed between the primary and secondary containers. Absorbent material is not required if the material being shipped is a solid. Solids need to be in sift proof containers. Absorbent material must be used with liquids shipped in a frozen state.
- A leak proof secondary container which contains the primary container(s) **and absorbent material**.
- **The universal biohazard symbol must be displayed on either the primary or secondary container.**
- Either the primary or secondary container must be able to withstand an internal pressure of at least 95 kPa (13.8 lbs/in²) **when shipped by air** because shipments may be placed into

unpressurized cargo sections of aircraft which fly at high altitudes. The containers must also be able to withstand -40°C to 55°C conditions for both Category A and B.

- An itemized list of contents describing the quantities of hazardous material within the primary container(s) must be attached to the outside of the secondary container or available outside of the secondary container, such as in the outer ‘pouch’ of a specimen collection bag. A description of the hazardous material contents and quantities must be listed on a required Dangerous Goods Shippers Declaration if shipping a Category A substance.
- A rigid and durable outer package of adequate strength for its intended use and constructed of cardboard, wood, or material of equivalent strength and which measures no less than 100 mm (4 inches) at its smallest overall external dimension. For shipping Category A infectious substances, these outer containers must meet strict United Nations manufacturing and testing specifications (UN certified).

5.3 Packing Directions for Exempt Human or Animal Specimens

Packaging used with Exempt Human or Animal Specimens is less strict than the aforementioned requirements in packing instructions 650 and 620. However, such packaging must be composed of four important elements: (a) a leak proof primary container, (b) a leak proof secondary container, (c) for liquid substances, absorbent material of sufficient quantity to absorb the entire liquid must be placed between the primary and secondary containers, and (d) outer packaging “of adequate strength for its intended capacity, mass, and intended use” (Table 7) (7).

5.4 Packing Instructions for GMO

GMO/GMMO which meet the criteria of Category A or Category B substances, must be packed and shipped according to PI 620 or 650, respectively. Otherwise, they must be packed according to PI 959 (GMO) (previously 913). PI 959 mandates use of packaging which is virtually the same as that described in PI 650 except a diamond-shaped label “UN3245” and “Genetically Modified Organism” (Fig. 5) are required on the outer package (instead of “UN3373” and “Biological Substance, Category B”).

6 Marking and Labeling Outer Packages

Marking is the act of writing or typing information onto the outer surface of an outer package, and labeling is the act of placing informational labels or stickers onto the surface of an outer package. The two terms frequently are used interchangeably. The shipper is responsible for the proper marking and labeling of the outer shipping container. The markings and labels on the outer container communicate essential information regarding the shipper and consignee (recipient) of the package, nature and weight of the contents of the package, the potential hazard of the substance, how the substance is packed, and information to be used in case of an emergency. Some of these markings and labels can be seen in the IATA *Dangerous Goods Regulations* and other publications (6, 7, 11).

6.1 Specific Markings and Labels

- **Shipper and Consignee (Recipient)** -- The shipper and consignee's name and address. The name and address of the shipper and consignee must be on the same package surface as the UN number and proper shipping name when the package size is adequate.
- **Responsible Person** -- The name and telephone number of a "person responsible" (IATA quote) for the contents of the shipment (7). The authors' interpretation of "responsible person" is someone familiar with the shipment and can answer general questions about the shipment (not necessarily questions regarding emergency or accident mitigation response information). If the substance being shipped is a Category B substance, this information must be provided either on the outer package or on the air waybill (7). *If shipping a Category A package by air, the name and phone number of the person responsible must appear on the Dangerous Goods Shippers Declaration in the "Additional Handling" space provided. (IATA DGR 7.1.4.1 (e); 8.1.6.11.4) and on the outer package.*
- **Category A Substances** -- (a) The Class 6 diamond-shaped hazard label "Infectious Substance. In Case of Leakage, immediately notify public health authority" label, and (b) a label which shows the applicable UN number and quantity of the substance (Fig. 2).
- **Category B Substances** -- (a) The hazard label "Biological Substance, Category B" and (b) the marking or label "UN3373" (Fig. 3). *"Diagnostic Specimen" is no longer a legitimate classification term and should not be used.*
- **Exempt Specimens** -- Patient specimens not classified as Category A or Category B, may then be classified as "Exempt Human Specimen", "Exempt Animal Specimen" or "Not Regulated" if transported by an IATA member carrier or US Post Office. Assignment to the category of exempt patient specimens applies when only a minimal or no likelihood which a pathogen may present when shipped such as specimens tested for routine, non-infectious disease testing (e.g. cholesterol, blood glucose, hormone, cancer biopsies). IATA requires that "Exempt Human" or "Exempt Animal" specimens be labeled as such with that terminology, and triple packaged.
- **Non-Regulated Substance** -- The term "Exempt Human or Animal Specimen" is an IATA / ICAO related term and does not exist within the DOT regulations. DOT refers to samples that are not considered infectious as 'excepted' from the regulations, or also known as 'non-regulated' material, or material that does not fall under the HMR. DOT does not have packaging requirements for non-regulated material.
- **Emergency Contact** -- Must be listed on the Shipper's Declaration form in the designated space, or in the 'additional handling' space if transported by air and as required by IATA, or listed on a Shipping Paper if transported by ground and as required by DOT. The emergency contact must be a live person who is available the entire time the material is in transit, is knowledgeable of the material and has comprehensive emergency response mitigation information for the material. (49 CFR 172.604). According to DOT, emergency contact info is not required if a shipping declaration is not required. Therefore, Category B shipments

going by ground would not be required by DOT to provide emergency response information, but would still be required to list a Responsible Person. (22) When emergency contact is required for Category A shipments, the information must be available away from the package (e.g., accessible from the outside of the box, such as within a pouch attached to the outer box).

- **GMO/GMMO -- GMO/GMMO which does not meet the criteria for Category A or B must be labeled with a diamond-shaped hazard label containing “UN3245” and “Genetically Modified Organism” and the “Class 9 Miscellaneous Dangerous Goods” label (Fig 5).**
- **Dry Ice** -- Class 9 “Miscellaneous Dangerous Goods” label and the weight of dry ice in kilograms (kg) (Fig. 6).
- **Package Orientation** -- Package orientation label (Fig. 7). Orientation labels (arrows) must be placed on opposite sides of all packages which contain >50 mL of a liquid or frozen liquid infectious substance to indicate the correct orientation of the package.
- **Cargo Only** -- “Cargo Aircraft Only” label if the substance (because of its quantity) must be transported only by cargo aircraft (Fig. 8). This label must be used if an infectious substance in a primary container amounts to over 50 mL (for liquids) and 50 g (for solids) but still less than 4 L (4 kg) **maximum allowable** total per outer package.
- **Overpack** -- “Overpack” markings if overpacks are used (Fig. 9). **Overpack will include a fully complete and labeled inner package or packages. Overpack is commonly used with shipments containing dry ice, and can also be used to consolidate multiple completed packages into one larger container in order to: (1) reduce shipping costs by consolidation, (2) ship more than one class of hazardous material together, and/or (3) ship different temperature packages together.**
- **Outer Package** -- All outer packaging used to ship Category A infectious substances and substances considered by the shipper to be an infectious risk to the health of carrier personnel must meet manufacturing and performance specifications established by the United Nations, and must be marked as such by the manufacturer. Packaging that meets the UN specifications are marked by a “UN” inside of a circle, and a series of letters and numbers which indicate the type of package, class of goods the package is designed to carry, manufacturing date, authorizing agency, and the manufacturer (Fig. 10). The designation “Class 6.2” in the marked UN code indicates that the container is approved for shipping infectious substances. These containers are commercially available and are preprinted with the appropriate UN marking. The strict UN specifications for **Category A** outer packaging does not apply when shipping Category B substances. Outer boxes used to ship Category B substances need only to be rigid and strong enough for their intended purpose and be able to pass a 3.9-foot drop test (7).

6.2 Examples of Labeled and Marked Outer Packages

Figures 11, 12, and 13 show simplified examples of completely labeled and marked outer shipping containers which contain an Exempt Human Specimen, a Category B infectious substance, and a Category A infectious substance, respectively. Packages in Figures 12 and 13 also contain dry ice. For convenience and lower costs, one or more triple packages packed in full compliance with IATA regulations may be shipped within a single overpack. However, the overpack must be labeled “Overpack”, and all inner packages must be completely labeled according to applicable IATA regulations (Fig. 9).

Up arrows on the outside of a package are only required to be on opposing sides when shipping liquids over 50 mL within a primary container. However, most commercially purchased shipping boxes will have the up arrows already pre-printed on the outer box.

7 Documentation

A Shipper’s Declaration of Dangerous Goods is a legal contract between the shipper and carrier, is required to document the shipment of Category A infectious substances by air, must be accurate, [requires a signature](#), and must be legible. If any of these conditions are not met, even to the slightest degree, the carrier may reject and return the package for transport. Most carriers and some packing material suppliers provide blank Shipper’s Declaration forms, all of which require virtually the same information be provided to the carrier. However, some carriers (e.g., FedEx) require the Shipper’s Declaration to be prepared by using proprietary [online edit-checked software to help further reduce entry errors](#); some require the information to be completed online; and some require multiple copies to be included with the shipment. The original Shipper’s Declarations used by IATA member carriers must have slanted red candy stripes along the left and right edges of the document. Shippers must retain copies of Shipper’s Declarations for two years (10).

A Shipper’s Declaration of Dangerous Goods form must list dry ice (a dangerous good) if it is used as a refrigerant with a Category A shipment, but [not required if dry ice is included with a Category B shipment](#).

Regardless of the carrier-specified format of the Shipper’s Declaration, the “Nature and Quantity of Dangerous Goods” section must contain the following information (Fig.14):

- UN number (e.g., UN2814)
- proper shipping name followed by the technical name (e.g., Infectious Substance, Affecting Humans [*Mycobacterium tuberculosis*]). [If the pathogen has not yet been confirmed, “UN2814 Infectious Substance, affecting humans \(suspected Category A Infectious Substance\)” should be stated.](#)
- class [or division](#) (e.g., 6.2)
- quantity of substance and type of outer container (e.g., 2 mL - Packed in a Single [Fibreboard Box](#))
- packing instructions used (e.g., PI 620 for Category A)

- authorization code, if applicable (e.g., A140 to be permitted to omit the technical name of organism from outer box, or A81 to allow quantity limits to not apply to body parts, organs or whole bodies)

There are numerous instances in which IATA/DOT requirements are so restrictive that they (a) preclude shipping important substances and goods or (b) do not address unusual or unforeseen circumstances and substances encountered by shippers. IATA special provisions address and facilitate these situations. Special provisions are authorizations, allowances, permissions, exceptions, and exemptions which allow shippers to bypass some regulations. Special provisions are numbered and are preceded by an “A” (for *authorization*). If a special provision applies to a particular shipment, the number of the special provision must be provided on the Shipper’s Declaration. Two special provisions apply particularly to clinical microbiologists and shippers of infectious substances: A81 and A140.

- A81 allows shipment of organs, body parts, and whole bodies because quantity limits (obviously) would otherwise prevent shipment of these important items.
- A140 eliminates the requirement for Category A technical names to follow the proper shipping name on outer packages. (Technical names are required on Shipper’s Declarations and Shipping Papers and are seen only by shippers and carriers, but technical names written on an outer package can be seen in public. Therefore, boldly advertising the technical name, e.g., *Mycobacterium tuberculosis*, of the contents of Category A packages is not advisable.)

It is a carrier’s prerogative to reject a shipment if each field on the Shipper’s Declaration is not completed exactly to the carrier’s satisfaction, and if the information and phrasing on the Shipper’s Declaration do not match exactly the corresponding information on the outer package. Commercial carriers and the Federal Aviation Administration (FAA) often exercise their authority at airports to examine Shipper’s Declarations for compliance with applicable regulations and to open and inspect any package (whether or not the package is leaking) which contains or is suspected of containing an infectious substance. In addition, these agencies can and do examine documentation of perfectly packaged shipments, go to the facilities from which the packages originated to inspect, and request documentation of adequate training of employees.

Figure 14 shows an example of a blank ([manually fillable version](#)) Shipper’s Declaration and the sections which shippers must complete. Virtually all of the IATA-specified technical information required in the “Nature and Quantity of Dangerous Goods” section can be found in Table 6 and reference 7. Figure 15 shows an example of a completed Shipper’s Declaration, [if shipped by a common commercial carrier such as FedEx](#). In this [example form](#) the FedEx proprietary software prints both (a) a Shipper’s Declaration with all the information required in Section 7 (Fig. 14) in non-column linear running text rather than in column format and, automatically, (b) an air waybill (not shown). The differences in the “Nature and Quantity of Dangerous Goods” section (section 7) of the manually fillable and online edit-checked software version forms can be seen in Figures 14 and 15, respectively. If a software program for printing Shipper’s Declarations does not allow the shipper to delete one of the aircraft types (passenger or cargo aircraft; cargo aircraft only) as required, the shipper should print the appropriate aircraft type (passenger or cargo

aircraft; cargo aircraft only) on the Shipper's Declaration. Shippers are advised to contact their carriers regarding these other carrier-specific requirements for completing a Shipper's Declaration.

DOT requires that Shipping Papers be included for Category A shipments sent by ground transport. DOT provides an outline of the information that must be present on a shipping paper but does not provide a template for shippers to use. Therefore, a shipper may either develop their own paperwork with the required information or use a manually fillable dangerous goods shipper's declaration form to meet the DOT shipping paper requirement.

DOT and IATA regulations state an "emergency response telephone number" must be provided on Shipper's Declarations or shipping papers which accompany shipments of Category A infectious substances (12). The number must be monitored all times **for the duration of the transport** by a person (*not* an answering machine, message service, pager, etc.) who has knowledge of the following: (a) the hazards of the material being shipped and (b) emergency response and accident mitigation information in case a handler contacts the released contents of the package. Alternatively, the number can be that of a person who has immediate access to a person who has such knowledge and information. The name and phone number of an agency of a **third party organization** or commercial company may be used instead of the aforementioned persons if the shipper can ensure the agency, organization, or company can supply the required aforementioned emergency information in a timely manner.

An air waybill will also be required for air transport and serves the function of providing tracking information, payment information, and has spaces for information about the contents (e.g., asking about presence of hazardous material). Responsible person information may be listed on an air waybill for either Category A or B shipments when an air waybill is required by the carrier.

8 Couriers

Safe ground transportation of specimens to and from laboratories is governed by regulation issued by the Department of Transportation (DOT) and the U.S. Postal Service (USPS). Shippers **MUST** be aware of what types of packages the carrier or courier accepts or what is restricted (variations), what liability the courier company possesses and have written agreement before utilizing their services. Courier credentials can be found at: <http://safer.fmcsa.dot.gov/CompanySnapshot.aspx>.

Couriers need to have a driver's license appropriate for their job (commercial driver's license for commercial couriers) and have a clean driving record. Knowledge of medical terminology and basic medical procedures is helpful. Couriers must be trained in function-specific tasks, safety and security awareness, and be familiar with regulations. Finally, couriers are responsible for knowing what their emergency response obligation is if there is an incident involving packages being transported (17).

8.1 Private Couriers

A private motor carrier transports its own cargo, usually as a part of a business. A courier on the other hand may be contracted for the purposes of transporting shipments, either as one-time shipments, or employed and used often for regular transport. Private couriers may not be subject to the requirements of Division 6.2 under DOT MOT exception if the private vehicle is used only to transport patient specimens (not Category A material), and other medically-related items such as diagnostic test kits, other non-infectious biological products, or medical documents or equipment. Each item must still be appropriately packaged and be protected from damage which may result in exposure. Couriers CANNOT transport other patients, other persons including employees or non-medically related items if utilizing the exclusive use vehicle and MOT exception. See sections 1.4 and 8 for additional information (17).

8.2 Commercial Couriers

Motor carriers must have specific insurance and legal process agent documents on file with the Federal Motor Carrier Safety Administration (FMCSA). The required filings vary, based on the product being carried. Most important, the courier who accepts package(s), MUST recognize what is offered to them as UN3373 Category B Biological Substances, UN2814 Infectious Substances or specimens not regulated by DOT (Exempt); and if the courier company has the ability to accept. They must also recognize if the package is correctly marked and has proper documentation offered with the package (17).

8.3 Government Courier Exemption

49 CFR § 171.1 (d) describes functions not subject to the requirements of the HMR when transportation of a hazardous material (e.g., Category A or B specimens) occurs in a motor vehicle, aircraft, or vessel operated by a Federal, state, or local government employee solely for non-commercial purposes. The exemption is limited only to Federal, state or local government employees. It is not necessary for the motor vehicle, aircraft or vessel to be government owned, but in order for the exemption to apply, the operator of the vehicle must be a government employee.

During public health emergencies, such as a bioterrorism-related event, or other special circumstances such as the lack of or extremely limited commercial courier/carrier availabilities during the 2014-2015 Ebola virus outbreak, law enforcement agents or other designated government officials with identification may become involved to assist with or expedite the transport of specimens. Appropriate triple packaging instructions must still be followed to ensure safety, but the government courier exemption may provide assistance specifically for the transportation aspect. Clinical laboratories should contact their state or local public health laboratory for assistance in these rare circumstances.

9 Exclusive Use Motor Vehicle Exception

The exclusive use motor vehicle exception found in 49 CFR § 173.134 (b)(10) may apply to 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. If the human or animal sample or biological product meets the definition of regulated medical waste, it must be offered for transportation and transported in conformance with the appropriate requirements for regulated medical waste. An example of the Exclusive Motor Vehicle Exception in public health practice may be when a suspected outbreak patient drives their own stool sample to a health department (17).

If a shipper intends to utilize the Materials of Trade exception with an appropriate exclusive use vehicle to transport patient specimens, the following key points related to packaging must be met:

- The packaging must be ‘combination’ packaging.
 - This means that triple packaging is not required but would still be considered a best practice to use.
 - Combination packaging means at least two layers (outer and inner packaging).
- Outer package must be ‘strong and tight’.
 - A rigid outer container is not required but would still be considered a best practice to use.
 - Note: Category B shipments require a rigid outer package.
- The universal biohazard symbol must be present on the outer container.
- The outer package must be marked with the ‘common wording’ or proper shipping name of the material within.
 - Such as: “Blood” or “Patient Specimen”
- Multiple primary containers (e.g., specimens) are permitted to be included within the outer container.
- Total quantity of inner packaged material may not exceed 1.1 lbs / 0.5 kg / 500 mL
- Total quantity of outer packaged material (the entire contents) may not exceed 4 kg / 4 L

Additional information about the Materials of Trade exception can be found within 49 CFR 173.6.

10 Emergency Response or Incident Reporting

Emergency Response Information (ERI) must accompany Category A packages when transported by ground or air and must be kept within reach of the courier. A Responsible Person’s contact information and 24-Hour Emergency Contact information must be marked on both the outside of the package and the Shipper’s Declaration form. The Emergency contact must be a live person who is familiar with the contents of the package being shipped, available for the duration of the shipment, and able to provide emergency response information. There are two types of ERI which are available and may be used. DOT provides the Emergency Response Guidebook (ERG) with Guide 158 (18) being related to infectious substances, found on the PHMSA website. And the Public Health Agenda of Canada’s website provides specific pathogen safety data sheets (19) which may also be used as ERI. (22)

DOT requires notification of any release (e.g., breakage, spillage) of an infectious substance (Category A and B material) during transport in such instances of death, injury or public disruption (49 CFR Sections 171.15 and 171.16). Notification should be immediate (within 12 hours) and reported to both DOT at 1-800-424-8802 and the CDC in any cases involving select agents. Incidents that occur with infectious material while in transit with the US Postal Service must be reported to the postal service.

11 Refrigerants

Wet and dry ice are two common refrigerants used to ship biological substances (i.e., patient specimens) and infectious substances. Packaging must be leak proof when wet ice is used. Ice or dry ice must be placed between the secondary and outer packaging. Dry ice is a Class 9 miscellaneous dangerous good, it must be packaged according to PI 954, and its use requires completion of a Shipper's Declaration if it is used to ship a Category A substance. The secondary container must be secured so that it does not become loose as the dry ice sublimates. Outer packages must be labeled "Dry Ice", and the net weight of the dry ice must be indicated on the outside of the outer package and be recorded on the Shipper's Declaration (Figs. 6, 12, and 13). The maximum permitted net weight of dry ice per outer package is 200 kg.

NOTE: Dry ice is an explosion hazard and must never be placed into a tightly sealed container! Dry ice must be placed *outside* the secondary container, and the outer packaging must permit the release of CO₂!

12 Permits

Both the DOT HMR and the IATA DGR do not require a permit to be included as a record within routine shipments of Category A or B material. It is the receiver of the materials that needs to possess the permit. However, laboratories may be requested or required by those who are shipping Category A or B material to verify or include a copy of a permit with a shipment before the material will be sent. It is not a requirement for the shipper to verify the permit, but it is good practice. Typically, clinical laboratories will be required by the U.S. Department of Agriculture (USDA), U.S. Department of Health and Human Services (HHS), or FDA to have a permit when importing or transporting animal products, organisms or vectors. The regulations in 42 CFR § 71.54 require that anyone wishing to import infectious biological agents, infectious substances, or vectors must first obtain a permit issued by CDC. Example laboratory activities that would require a permit or licensing include shipping an experimental or investigational biological product as defined in 49 CFR § 173.134, interstate shipping or receiving of infectious isolates or quality control strains, or shipping of a select biological agent or toxin. When applicable, laboratories must keep a copy of their permits with their shipping records and be able to provide verification or a copy when requested.

Laboratories can obtain permits and additional information here:

- USDA
 - <https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/animal-and-animal-product-import-information/animal-health-permits>

- CDC Import Permit Program
 - <https://www.cdc.gov/cpr/ipp/index.htm>

DOT may issue a special permit on occasion to address a need or situation when the shipper or carrier cannot comply with the hazardous material regulations, such as the special permits that were issued in response to Ebola virus and Category A waste. Additional information about infectious substance special permits can be obtained from:

- DOT Special Permits
 - <https://www.phmsa.dot.gov/transporting-infectious-substances/infectious-substance-special-permits>

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Appendix A. Definitions of Terms Related to Packing and Shipping

Biological Product -- a substance which originated from living organisms (including humans and other mammals) and has been manufactured and distributed in accordance with compliance and licensing requirements set forth by the federal government; can be classified as an infectious substance if such is appropriate. Biological products can be finished (final product) or unfinished (components). The term “biological product” refers to both whole microorganisms and components such as proteins, polysaccharides etc., and are intended for use in the prevention, treatment, or diagnosis of disease in humans or animals, and can be used for investigational, experimental, or developmental purposes. Biological products include such common items as clinical microbiology reagents and kits, serological reagents, diagnostic reagents, and vaccines. In certain parts of the world, some licensed biological products are regarded as biohazardous and are either subject to compliance criteria specified for infectious substances or must adhere to other restrictions imposed by the government of that country.

Biological Substance, Category B -- any infectious substance which does not meet the criteria of a category A substance; formerly known as *Clinical Specimen* or *Diagnostic Specimen*; an infectious substance *not* in a form generally capable of causing disability, life-threatening illness, or fatal disease. Category B substances generally are (1) patient and clinical specimens reasonably expected to contain, or being cultured or otherwise tested for a non-Category A pathogen and (2) cultures of microorganisms not specifically listed in

Category A. The proper term for a Category B substance is: Biological Substance, Category B.

Carrier (Operator) -- individual or organization engaged in the commercial transportation of goods (e.g., DHL, Federal Express (**FedEx**), United Parcel Service (**UPS**), Delta Airlines, and Northwest Airlines).

Certified / Training Certification -- the employer is responsible for providing proper dangerous goods / hazardous material shipping training to their employees, and only an employer can 'certify' their employees are properly and completely trained. Upon successful completion of a shipping training course, the trainer will provide students a certificate of attendance which lists the content covered, dates, and other info about the training. In addition to the shipping training, the employer must also certify that the employee has been trained in other required topics for shipping such as safety (e.g., site specific Bloodborne Pathogens training), and security (e.g., site specific security awareness).

Courier -- courier services are usually used for delivering smaller shipments, e.g., 1 to 15 boxes depending on weight, volume and location. It is usually a door to door method of delivery that utilizes a professional specialized company. The main advantages to this type of service are that they are extremely fast and efficient. The main disadvantages to courier service are cost and size limits (usually meant for packages that are 150 lbs or less), most courier services have limits on the size of packages, and prices do increase dramatically the larger a particular parcel is.

Category A Infectious Substance -- an infectious substance or microorganism which is transported *in a form* that, when exposure to it occurs, is capable of causing permanent disability or life-threatening or fatal disease in an otherwise healthy human or animal.

Category A substances are individually designated and specifically listed by IATA and DOT.

Category B Substance – See biological substance, Category B.

Code of Federal Regulation (CFR) -- United States laws published in the *Federal Register* and which are available online at <http://www.gpoaccess.gov/fr/index.html>

Consignee -- the receiver or recipient of the shipment (e.g., a reference laboratory).

Culture -- the result of a process by which pathogens are intentionally propagated. This definition refers to typical clinical laboratory microorganisms grown in broth or on solid media. Typical clinical cultures may be classified as either Category A or Category B, depending on the organism concerned and the professional judgment of the shipper.

Dangerous Goods -- any substance or material capable of posing an unreasonable risk to health, safety, and property when transported in commerce. The term 'dangerous goods' is somewhat interchangeable with the terms hazardous materials or hazmat in relation to shipping.

Dangerous Goods Regulations (DGR) -- a commercially available book of IATA requirements; published by IATA; based on and incorporates ICAO regulations; provides packaging and shipping regulations for dangerous goods; generally recognized and accepted worldwide.

Diagnostic (or Clinical) Specimen -- term no longer used or allowed for classification; replaced by "Biological Substance, Category B".

Emergency Contact -- must be listed on the Shipper's Declaration form in the designated space. Must be a live person who is available the entire time the material is in transit, is knowledgeable of the material and has comprehensive emergency response mitigation information for the material.

Genetically Modified (Micro) Organism (GMO/GMMO) – microorganisms that have had their genetic material purposely modified or altered through genetic engineering in a manner that does not occur naturally; must be classified in the same manner and to the same extent as any infectious substance.

International Air Transport Association (IATA) -- a trade organization of the commercial airline industry; governs international aviation; publishes *Dangerous Goods Regulations* for use by anyone who packs, ships, transports, or handles dangerous goods.

International Civil Aviation Organization (ICAO) -- a specialized agency of the United Nations; governs international aviation; regulates the transportation of dangerous goods for all international civil air carriers; the source of IATA requirements and DOT regulations.

Infectious Substance -- a substance which is known to contain or reasonably expected to contain pathogens (microorganisms which can cause disease in humans and animals); material known to contain or reasonably suspected of containing a Category A or B pathogen or substance; can be a class (Class 6), a division (Division 6.2), or a category (Category A or B) of dangerous goods as defined by IATA and DOT.

Materials of Trade -- when certain hazardous materials are transported in small quantities as part of a business, they are subject to less regulation because of the limited hazard they pose. These materials are known as Materials of Trade (MOTs). 49 CFR 173.6

Overpack -- the outermost packaging used to enclose more than one complete package, each of which contains dangerous goods; usually used for convenience and to reduce shipping costs.

Package -- end product of the packing process.

Packaging -- all of the numerous materials used to contain a shipped substance and to prepare the substance for shipping; the container (receptacle) and its associated components (e.g., tubes, containers, absorbent material, boxes, and labels) used to contain and pack a substance and to ensure compliance with packing requirements.

Packing -- the physical action and method by which packaging is used to secure articles or substances for shipment.

Packing Instructions -- IATA-defined directions shippers must follow to select, assemble, mark, label, and document the packing process for shipping dangerous goods, including infectious substances; includes manufacturing testing and performance specifications for packaging materials. **NOTE:** On January 1, 2011, PI 602, 904, and 913 were renumbered to 620, 954, and 959, respectively.

Pathogen -- a microorganism (bacterium, mycobacterium, fungus, parasite, virus, plasmid, genetic element, proteinaceous infectious particle [prion], or GMO/GMMO) that is known to cause or is reasonably expected to be able to cause disease in humans or animals.

Patient Specimen -- material collected from humans or animals including but not limited to excreta, secreta, blood and its components, tissue, body fluids, body organs and parts, and swabs of human material being transported for purposes such as research, diagnosis, investigational activities, and disease treatment and prevention.

Primary Specimen Container -- the innermost packaging containing a biological substance, (e.g., patient specimen or infectious substance); composed of glass, metal, or plastic; must be leak proof; must be positively sealed if it contains an infectious substance (sealed by a positive method (e.g., heat seal, metal crimp, or taped screw-cap lid)).

Proper Shipping Name -- any of over 3,000 internationally recognized names of dangerous goods specifically listed by IATA.

Responsible Person -- Can be either the shipper or recipient, and the name and phone number of the responsible person must be listed on the outside of Category A and B packages and appear in the "Additional Handling" field of a Dangerous Goods Shipper's Declaration.

Secondary Specimen Container -- the container that contains the primary specimen container.

Shipper -- anyone who ships goods by a commercial carrier (usually an employee of a company or healthcare facility [e.g., laboratory staff member, contracted courier, and physician]); anyone who offers goods for transport to a member of IATA; anyone who completes and signs the Shipper's Declaration. The person who signs the Shipper's Declaration is the person who accepts responsibility for the accuracy of the information on the document.

Shipper's Declaration for Dangerous Goods (Shipper's Declaration) -- an IATA-defined and IATA-mandated form which must accompany each shipment of dangerous goods (e.g., Category A shipments); contains information which describes the dangerous goods; is helpful to persons who handle the shipment; must be completed by the shipper. Dangerous Goods Shipper Declarations are required for air transport of Category A substances. DOT requires "Shipping Papers" accompany Category A shipments transported by ground. The required elements of the DOT Shipping Papers are similar to what is found on a Dangerous Goods Shippers Declaration, however DOT does not provide a standardized form to meet this requirement, it only lists the elements required to be listed. Therefore, a shipper may use a completed Dangerous Goods Shippers Declaration form to also meet the DOT Shipping Papers requirement.

Special Provisions – Special provisions are authorizations, allowances, permissions, exceptions, and exemptions which allow shippers to bypass some regulations; provide information in addition to that required in a Shipper's Declaration; describe special substances, conditions, and situations which pertain to certain shipments.

UN Certified Container -- packaging material (usually a cardboard box) that has passed UN manufacturing standards and is labeled by the manufacturer as such for the transport of certain dangerous goods.

United States Department of Transportation (DOT) -- the federal agency which regulates domestic transportation of all dangerous goods into and within the United States through regulations published in the *Federal Register*; publishes regulations which are based on and are in substantial agreement with ICAO regulations.

Appendix B. Transfer of Select Agents

The Federal Select Agent Program (FSAP) regulates the possession, use, and transfer of biological select agents and toxins that have the potential to pose a severe threat to the public, animal or plant health, or to animal or plant products. The program is jointly managed by the Division of Select Agents and Toxins (DSAT) at the Centers for Disease Control and Prevention (CDC) which is part of the U.S. Department of Health and Human Services (HHS), and the Agriculture Select Agent Services (AgSAS) at the Animal and Plant Health Inspection Services (APHIS), which is part of the U.S. Department of Agriculture (USDA). DSAT regulates those agents that cause disease in humans, while AgSAS regulates those that can cause disease in animals and plants (1, 2, and 3). The FSAP provides technical assistance and guidance to

registered entities to promote laboratory safety, security, and incident response. CDC and APHIS maintain the National Select Agent Registry (<https://www.selectagents.gov/SelectAgentsandToxinsList.html>). The Registry includes applicable regulations, guidance documents, frequently asked questions, links to guidelines, and other helpful information.

B1 Select Agents

Select agents are microorganisms, biological agents, or biological toxins that have been deemed by the U.S. government to be major threats to public health and safety because they could be used as agents of bioterrorism. Select agents are listed in the National Select Agent Registry (<https://www.selectagents.gov/regulations.html>). (updated August 10, 2020). Representative select agents are listed below in section B3.

B2 Packing and Shipping Select Agents

A select agent may be packaged and prepared for shipment as any other Category A infectious substance is packed according to the guidelines in this document: leak proof primary and secondary containers, absorbent, a sturdy and well-labeled outer container, shipper's declaration for Category A substances, etc. However, the additional requirements regarding *the possession, use, and transfer* of select agents are intricate, strict, and aggressively enforced.

Shipments containing an identified select agent must also be accompanied with a completed CDC/APHIS Form 2 (<https://www.selectagents.gov/form2.html>). Both the sender and the recipient must contact the appropriate federal authorities for guidance, instructions, and permission/authorization to ship and/or receive the select agent *before* such transfer occurs. Only laboratories that are previously registered with the CDC Select Agent Program may possess or receive an identified select agent. In addition, the shipper must confirm that the recipient is approved for receiving select agents (a registered entity) *before* the transfer occurs. The aforementioned FSAP website provides complete information about select agents, the strict regulations related to transferring select agents, possession and transfer application forms, and additional resources.

NOTE: There are several exceptions to this requirement; however, the exception most relevant to clinical microbiologists is the following: Clinical or diagnostic laboratories and other entities that possess, use, or transfer a select agent or toxin that is contained in a specimen presented for diagnosis or verification (proficiency testing) are exempt from these requirements provided that:

- Within 7 or 90 calendar days of identification of the agent in the clinical specimen or proficiency sample, respectively, the agent or specimen must be destroyed or transferred to an individual or entity registered to possess, use, or transfer that agent.
- The agent or specimen is secured against theft, loss, or release during the aforementioned times.

Sentinel clinical laboratories may ship a diagnostic specimen to a LRN reference laboratory without a Form 2 when the specimen has not yet been identified as a select agent.

B3 Examples of Specifically Designated Select Agents

<https://www.selectagents.gov/SelectAgentsandToxinsList.html> (updated August 10, 2020)

Bacteria

- *Bacillus anthracis*
- *Yersinia pestis*
- *Brucella abortus*, *B. melitensis*, *B. suis*
- *Burkholderia mallei*, *B. pseudomallei*
- *Francisella tularensis*
- *Coxiella burnetii*
- Botulinum neurotoxin-producing species of *Clostridium*

Viruses

- Smallpox
- SARS-associated coronavirus (SARS-CoV)
- Avian influenza viruses (highly pathogenic viruses)
- Reconstructed and competent forms of the 1918 pandemic influenza virus
- Crimean-Congo, Junin, and Machupo hemorrhagic fever viruses
- Monkeypox, Lassa fever, Marburg, Hendra, Ebola, Nipah, Rift Valley fever, and Eastern Equine encephalitis viruses

Rickettsia

- *Rickettsia prowazekii*

Toxins

- Ricin, *Staphylococcus* enterotoxins A-E, botulinum neurotoxins

Appendix C. Packaging and Shipping Supplies

The following is a list of commonly used, commercially available suppliers of packaging and shipping materials. While ASM does not specifically endorse these companies, they are being listed to serve as a resource for those seeking shipping materials that would satisfy DOT, IATA, ICAO and Division 6.2 infectious substance shipping container requirements.

Air Sea Containers, Inc. (<http://www.airseacontainers.com>)

Berlin Packaging, LLC (<http://berlindangerousgoods.com/en/products>)

CARGOpak Corporation (<http://www.cargopak.com>)

Labeline (http://www.labeline.com/store_uk)

Inmark, Inc. and Saf-T-Pak/InMark (<https://inmarkinc.com/>)

O'Berk International, Inc. (Elemental Container, Inc.) (<http://aluminumbottles.com>)

SCA ThermoSafe (formerly Polyfoam Packers Corp.) (<http://www.thermosafe.com>)

Table 1. Agencies Governing Transportation of Dangerous Goods

| Governing authority | Agency | Regulations (Reference) |
|-----------------------------|-------------------|-----------------------------------------------------------------------------------------------------|
| United Nations | ICAO [*] | <i>Technical Instructions for the Safe Transport of Dangerous Goods by Air</i> ^a |
| Commercial airline industry | IATA [†] | <i>Dangerous Goods Regulations</i> ^b |
| United States | DOT [‡] | <i>U.S. Hazardous Material Regulations (49 CFR Parts 100-180)</i> ^c |
| United States | USPS [§] | <i>Domestic Mail Manual Publication 52, Hazardous, Restricted, and Perishable Mail</i> ^d |
| Canada | Transport Canada | <i>Transportation of Dangerous Goods Regulations</i> ^e |
| Other nations | | Individual national regulations ^f |

^{*} International Civil Aviation Organization

[†] International Air Transport Association

[‡] Department of Transportation

[§] United States Postal Service

^a <https://www.icao.int/safety/dangerousgoods/pages/technical-instructions.aspx>

^b <https://www.iata.org/en/publications/dgr/>

^c <https://www.phmsa.dot.gov/standards-rulemaking/hazmat/hazardous-materials-regulations>

^d <https://pe.usps.com/text/pub52/welcome.htm>

^e <https://tc.canada.ca/en/dangerous-goods/transportation-dangerous-goods-canada>

^f <https://www.icao.int/safety/DangerousGoods/Pages/StateVariationPage.aspx>

Table 2. DOT & IATA Hazardous Material Table

| Class | Substance |
|-------|-----------------------------------------------------------|
| 1 | Explosives |
| 2 | Gasses |
| 3 | Flammable liquids |
| 4 | Flammable solids |
| 5 | Oxidizing substances and organic peroxides |
| 6 | Toxic and infectious substances |
| | Division 6.1 (toxic substances) |
| | Division 6.2 (infectious substances) [*] |
| 7 | Radioactive materials |
| 8 | Corrosives |
| 9 | Miscellaneous dangerous goods (e.g. dry ice) [*] |

^{*} Addressed in detail in these guidelines

Table 3. Types and Classifications of IATA & DOT Division 6.2 Infectious Substances

| Type of Infectious Substance | IATA and DOT Classifications |
|--------------------------------------------------------|-----------------------------------------------------------------------------------|
| Category A | Category A, Infectious Substance (UN2814 or UN2900*) |
| Category B | Biological Substance, Category B (UN3373) |
| Patient Specimen | |
| meets Category A criteria | Category A, Infectious Substance (UN2814 or UN2900*) |
| meets Category B criteria | Biological Substance, Category B (UN3373) |
| does not meet Category A or B criteria | Exempt Human or Animal Specimen |
| Exempt Human or Animal Specimen | Exempt Human or Animal Specimen |
| Genetically Modified (Micro)Organism | |
| meets Category A criteria | Category A, Infectious Substance (UN2814 or UN2900*) |
| meets Category B criteria | Biological Substance, Category B (UN3373) |
| does not meet Category A or B criteria | Genetically Modified Organism (UN3245), (when transported by air) |
| DOT HMR Exception Substance | None, non-regulated (non-infectious) |
| Biological Product * | |
| Infected Animal * | |
| Medical Waste * | UN3291 (*Classification may vary) |

** Substance not addressed in detail in these guidelines. See Table 6 for additional waste classifications.*

Note: Exempt Human Specimen and Exempt Animal Specimen are IATA classifications.

Table 4. Selected Examples of Category A Infectious Substances in Any Form Unless Otherwise Indicated*

| UN Number and Proper Shipping Name | Organism |
|-------------------------------------------------------------------------------------------|-----------------------------------------------------------|
| <p style="text-align: center;">UN 2814 Infectious Substance, Affecting Humans</p> | <i>Bacillus anthracis</i> (cultures only) |
| | <i>Brucella abortus</i> (cultures only) |
| | <i>Brucella melitensis</i> (cultures only) |
| | <i>Brucella suis</i> (cultures only) |
| | <i>Burkholderia mallei</i> (cultures only) |
| | <i>Burkholderia pseudomallei</i> (cultures only) |
| | <i>Chlamydia psittaci</i> (avian strains) (cultures only) |
| | <i>Clostridium botulinum</i> (cultures only) |
| | <i>Coccidioides</i> spp. (cultures only) |
| | <i>Coxiella burnetii</i> (cultures only) |
| | Crimean-Congo hemorrhagic fever virus |
| | Dengue virus (cultures only) |
| | Eastern equine encephalitis virus (culture only) |
| | <i>Escherichia coli</i> , verotoxigenic (cultures only) |
| | Ebola virus |
| | <i>Francisella tularensis</i> (cultures only) |
| | Hantaan virus |
| | Hantavirus causing hemorrhagic fever with renal syndrome |
| | Hepatitis B virus (cultures only) |
| | Herpes B virus (cultures only) |
| | Human immunodeficiency virus (cultures only) |
| | Lassa virus |
| | Marburg virus |
| | Monkeypox virus |
| | <i>Mycobacterium tuberculosis</i> (cultures only) |
| | Poliovirus virus (cultures only) |
| | Rabies virus (cultures only) |
| | <i>Rickettsia rickettsii</i> (cultures only) |
| | Rift Valley fever virus (cultures only) |
| | <i>Shigella dysenteriae</i> type 1 (cultures only) |
| Variola virus | |
| Venezuelan equine encephalitis virus (cultures only) | |
| West Nile virus (cultures only) | |
| Yellow fever virus (cultures only) | |
| <i>Yersinia pestis</i> (cultures only) | |
| (Table continues on next page) | |

| | |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| UN2900 Infectious Substance, Affecting Animals Only | Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Goatpox virus (cultures only) Lumpy skin disease virus (cultures only) Newcastle disease virus (cultures only) Sheep pox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only) |
|-----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

**This list is not all inclusive of the organisms that appear on the current IATA Indicative list, and organisms shown are selected examples of organisms that may be encountered more frequently in the U.S. and in clinical laboratories.*

Table 5. Information Provided for Each Proper Shipping Name in the IATA Alphabetical List of Dangerous Goods and Applicable to Completing a Shipper’s Declaration

| Column * | Information |
|----------|-------------------------------------------------------------------|
| A | United Nations ID number of the proper shipping name/description |
| B | Proper shipping name/description |
| C | Class or division of dangerous good |
| D | The hazard label required on the outer package |
| E | Packing group (N/A †) |
| F | Excepted quantity (N/A) |
| G | Limited quantity packing instructions (N/A) |
| H | Limited quantity maximum amount (N/A) |
| I | Packing instructions (PI) (<i>passenger and cargo aircraft</i>) |
| J | Maximum allowable amount (<i>passenger and cargo aircraft</i>) |
| K | Packing instructions (PI) (<i>cargo aircraft only</i>) |
| L | Maximum allowable amounts (<i>cargo aircraft only</i>) |
| M | Applicable special provisions and exceptions |
| N | Emergency response code |

* Refers to the 14 columns in the IATA alphabetical List of Dangerous Goods (7)

† Not applicable to all infectious substances

Table 6. IATA Dangerous Goods Summary Table

| UN ID Number | Proper Shipping Name / Description | Class or Div | Hazard Label | Pk group | EQ code | Passenger or Cargo Aircraft | | Cargo Aircraft only | | Special Provision | ERG Code | | |
|--------------|-------------------------------------------------------|--------------|----------------------|----------|---------|-----------------------------|---|---------------------|----------|-------------------|----------|---------------------|-----|
| | | | | | | Ltd Quantity | | | | | | | |
| A | B | C | D | E | F | G | H | I | J | K | L | M | N |
| 1845 | Dry ice | 9 | Miscellaneous | --- | E0 | Forbidden | | 954 | 200 kg | 954 | 200 kg | A48 A151 A805 | 9L |
| 2814 | Infectious Substance, Affecting Humans (liquid) | 6.2 | Infectious Substance | --- | E0 | Forbidden | | 620 | 50 mL | 620 | 4 L | A81 A140 | 11Y |
| 2814 | Infectious Substance, Affecting Humans (solid) | 6.2 | Infectious Substance | --- | E0 | Forbidden | | 620 | 50 g | 620 | 4 kg | A81 A140 | 11Y |
| 2900 | Infectious Substance, Affecting Animals Only (liquid) | 6.2 | Infectious Substance | --- | E0 | Forbidden | | 620 | 50 mL | 620 | 4 L | A81 A140 | 11Y |
| 2900 | Infectious Substance, Affecting Animals Only (solid) | 6.2 | Infectious Substance | --- | E0 | Forbidden | | 620 | 50 g | 620 | 4 kg | A81 A140 | 11Y |
| 3245 | Genetically Modified Organisms | 9 | Miscellaneous | --- | E0 | Forbidden | | 959 | No limit | 959 | No limit | A47 | 9L |
| 3245 | Genetically Modified Microorganisms | 9 | Miscellaneous | --- | E0 | Forbidden | | 959 | No limit | 959 | No limit | A47 | 9L |
| 3291 | Medical Waste, n.o.s | 6.2 | Infectious Substance | II | E0 | Forbidden | | 622 | No limit | 622 | No limit | A117 | 11L |
| 3291 | Biomedical Waste, n.o.s | 6.2 | Infectious Substance | II | E0 | Forbidden | | 622 | No limit | 622 | No limit | A117 | 11L |
| 3291 | Clinical Waste, Unspecified, n.o.s. | 6.2 | Infectious Substance | II | E0 | Forbidden | | 622 | No limit | 622 | No limit | A117 | 11L |
| 3291 | Regulated Medical Waste, n.o.s | 6.2 | Infectious Substance | II | E0 | Forbidden | | 622 | No limit | 622 | No limit | A117 | 11L |
| 3373 | Biological Substance, Category B | 6.2 | none | --- | E0 | Forbidden | | 650 | 4L/4kg | 650 | 4L/4kg | --- | 11L |

Note: In column F, “EQ Code” stands for “Excepted Quantities” code. And “E0” means there are ‘no quantity exceptions’ or that the material is not permitted as an excepted quantity when transported by air. In column N, “ERG Code” stands for “Emergency Response Drill Code” and the corresponding code (letter and number) represents suggested responses to incidents involving the specific dangerous good.

Table 7. Packing Requirements for Exempt Human and Animal Specimens, Category B Biological Substances, and Category A Infectious Substances

| Packing Requirement | Substance | | |
|------------------------------------------------------------------------------------------------|-------------------------------------------|--------------|--------------|
| | Exempt Human or Exempt Animal Specimens * | Category B † | Category A ‡ |
| Inner Containers | | | |
| Leak-proof (for liquids) or sift-proof (for solids) primary (1°) and secondary (2°) containers | yes | yes | yes |
| Pressure-resistant 1° or 2° container (air requirement for liquid samples) | -- § | yes | yes |
| Absorbent between 1° and 2° containers ¶ | yes | yes | yes |
| List of contents between 2° and outer package | -- | yes | yes |
| Positively sealed 1° container | -- | no | yes |
| Outer Container | | | |
| Rigid outer packaging | -- | yes | yes |
| Strict manufacturing specifications | none # | few + | many + |
| Name and number of responsible person * | -- | yes | yes |
| Markings and labels | yes ∞ | yes + | yes + |
| Quantity Limits for Either Passenger or Cargo Aircraft | | | |
| Maximum for each 1° container | -- | 1 L / 1 kg | 50 mL / 50 g |
| Maximum total for each outer package (passenger) | -- | 4 L / 4 kg | 50 mL / 50 g |
| Maximum total for each outer package (cargo) | -- | 4 L / 4 kg | 4 L / 4 kg |
| Documentation | | | |
| Shipper's Declaration for Dangerous Goods (air) Shipping Papers (ground) ± | -- | no | yes |
| Emergency response telephone number | -- | no | yes |
| Costs | | | |
| Cost of labor and materials to pack substance | least + | more + | most + |

* Packing directions (IATA and DOT provide only minimal standards [i.e., no detailed and numbered packing instructions] for packing and shipping Exempt Human or Animal Specimens.)

† Packing instructions 650 (Category B by air) and 49 CFR § 173.199 (Category B by ground)

‡ Packing instructions 620 (Category A by air) and 49 CFR § 173.196 (Category A by ground)

§ Requirement not specified by IATA or DOT

¶ Not required for solid substances such as tissue and solid agar media cultures or slants

Should be “of adequate strength for its intended capacity, mass, and intended use” (IATA)

+ Category B shipments will have less marking and labeling requirements than Category A shipments. See text within the document for more details.

* For Category B, the info may be placed either on the outer package or on the air waybill, and for Category A, the info must be placed on the outer package

∞ Only a label stating “Exempt Human Specimen” or “Exempt Animal Specimen” is required

± Use and inclusion of a Shipper's Declaration for Dangerous Goods form will satisfy DOT shipping paper requirement

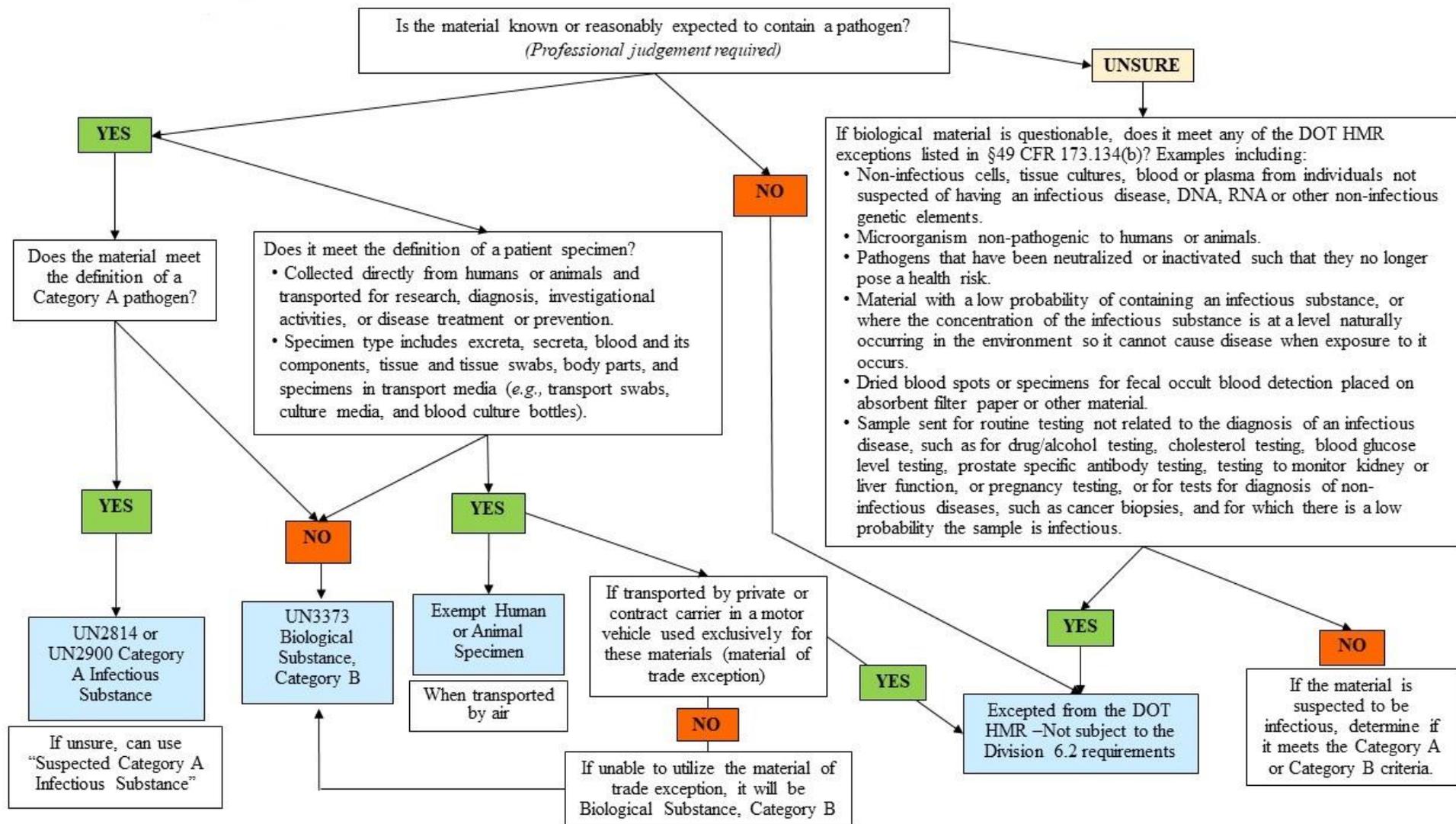


Figure 1. Classification Flowchart



**Infectious Substance,
Affecting Humans
UN 2814
_____ Qty**

Or

**Infectious Substance,
Affecting Animals
UN 2900
_____ Qty**

Figure 2. Labels which indicate an Infectious Substance, Category A, proper shipping name, UN number, and quantity of substance.

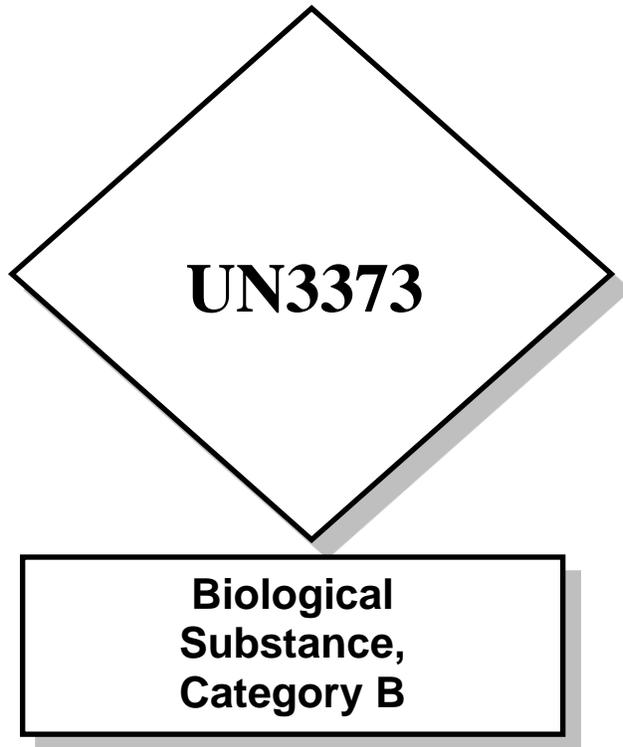


Figure 3. Labels which indicate a Biological Substance, Category B, appropriate UN number, and proper shipping name



Figure 4. Label which indicates an Exempt Human Specimen

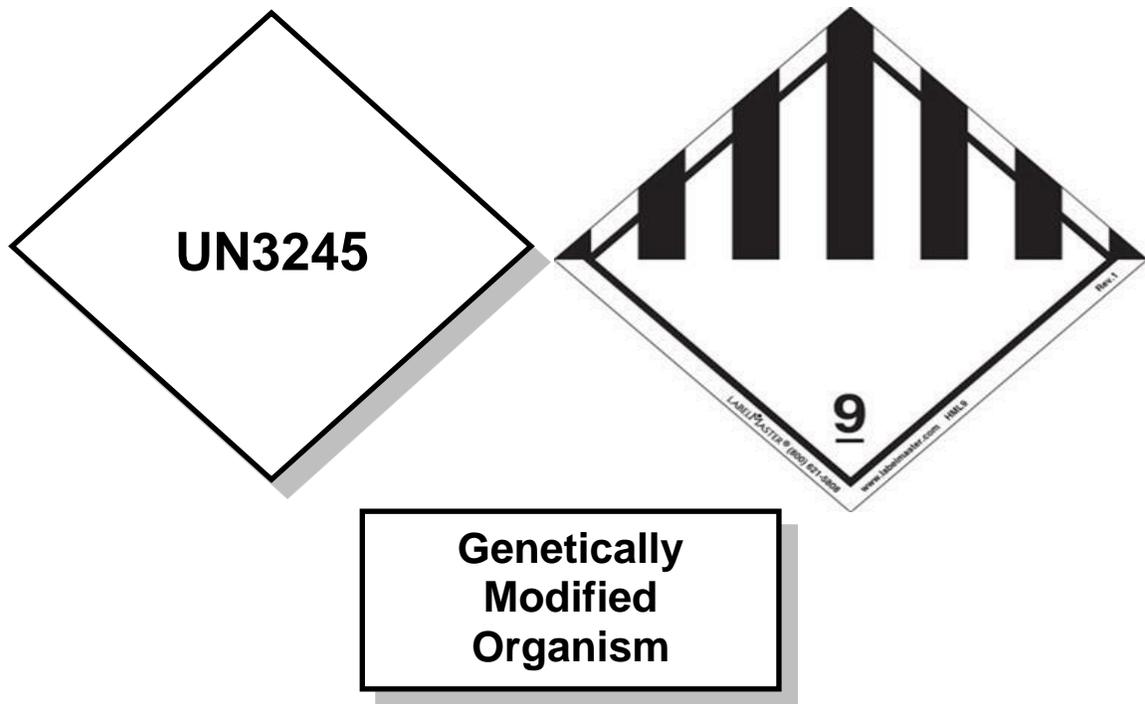


Figure 5. Labels which indicate a GMO or GMMO shipment that does not meet the criteria for Category A or Category B.

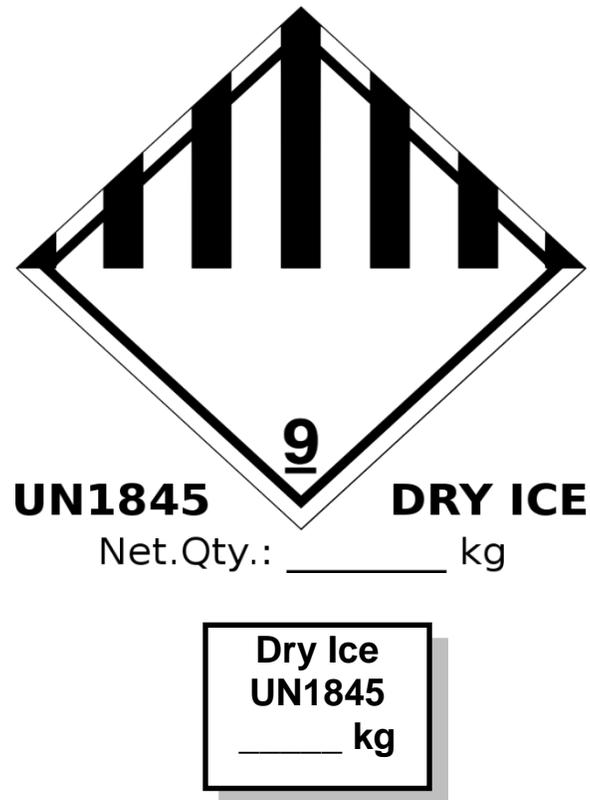


Figure 6. Labels which indicate a miscellaneous (Class 9) dangerous goods (Quantity needs to be listed in kg)

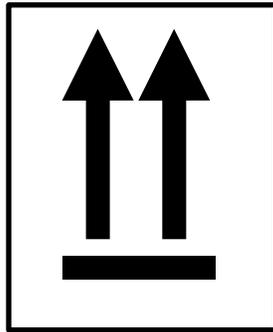


Figure 7. Label which indicates correct orientation of package during shipping. Required when shipping liquids over 50 mL.



Figure 8. Label which indicates substance must be transported only in cargo (*not passenger*) aircraft.



Figure 9. Label which indicates an overpack is used and inner packages comply with regulations.

SAMPLE OF UN PACKAGE CERTIFICATION MARK

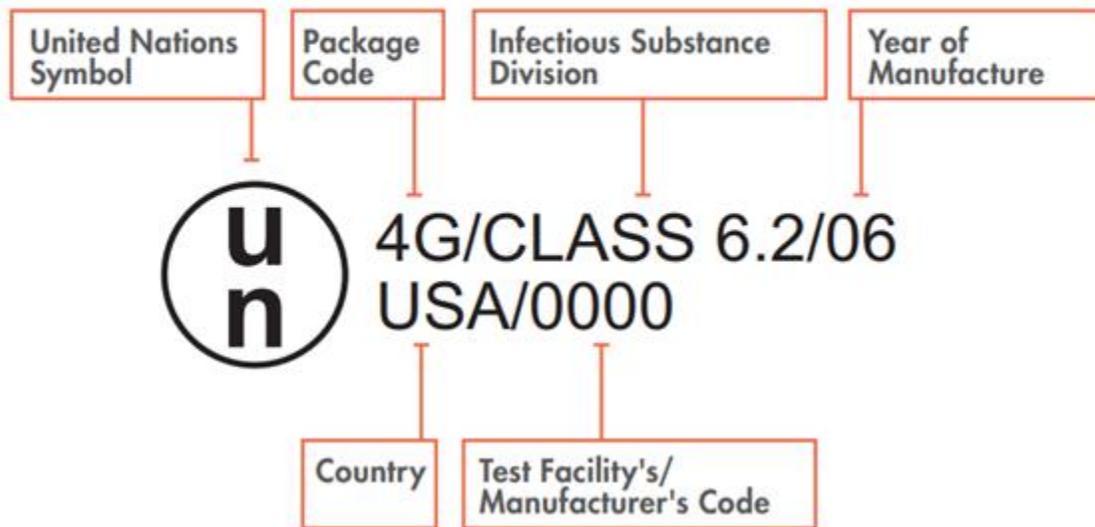


Figure 10. Example marking which indicates shipping container has met UN-specified manufacturing standards. Will be present on outer packaging when applicable. (20)

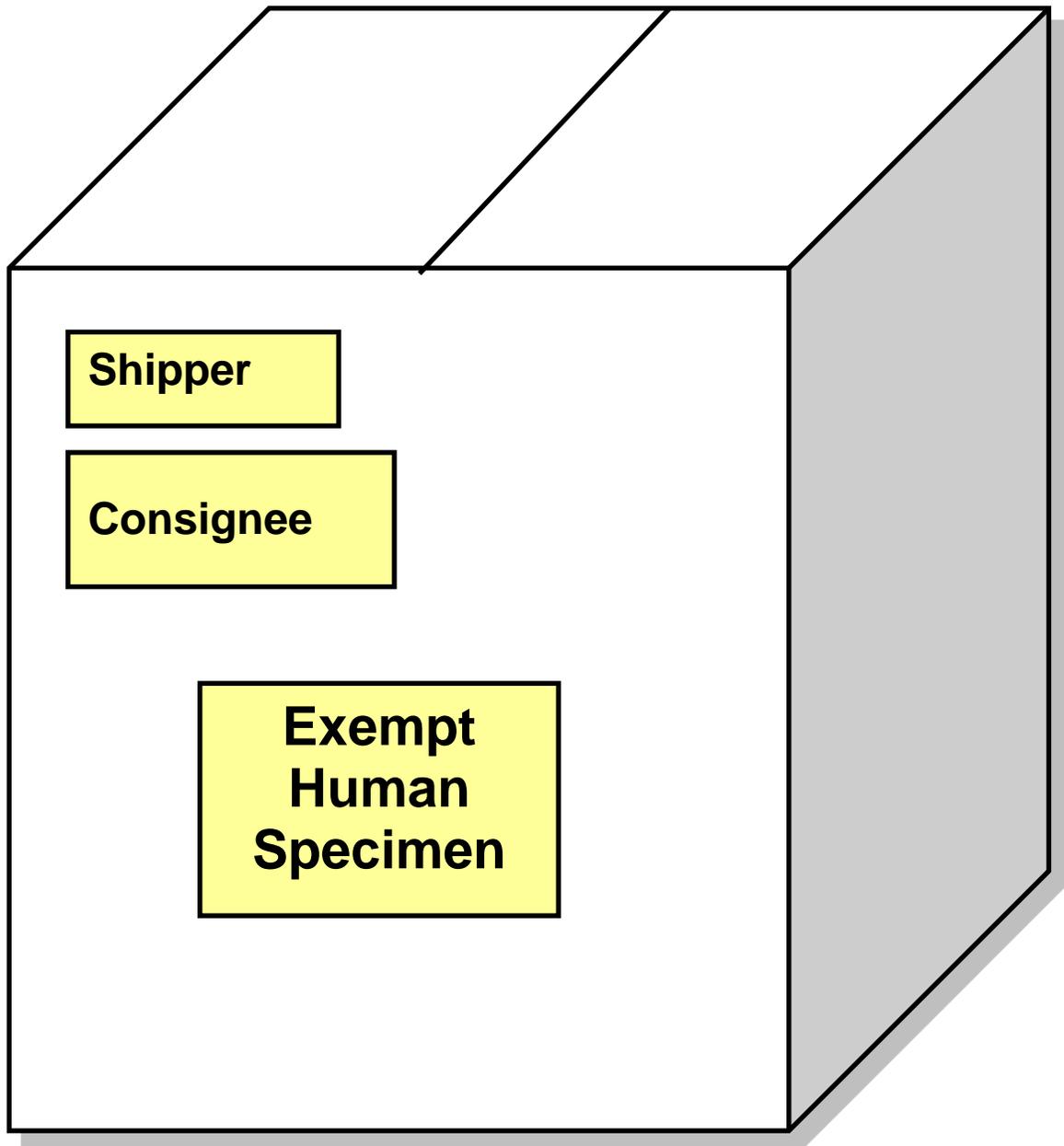


Figure 11. Example of an appropriately labeled outer Exempt Human Specimen package. The primary container inside the package contains an Exempt Human Specimen and is packed according to IATA instructions.

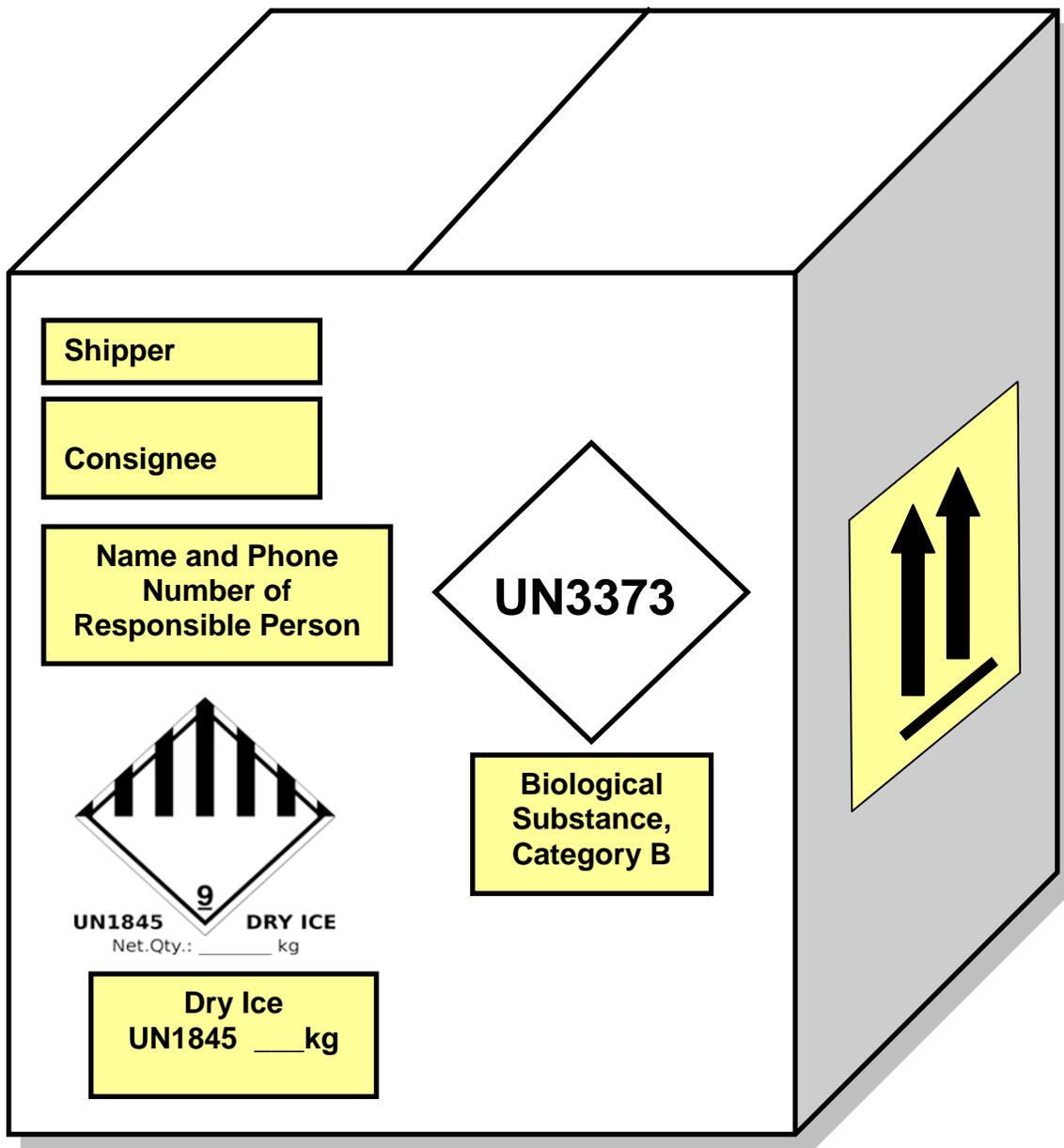


Figure 12. Example of a completely labeled outer Category B package containing dry ice. The primary container inside the package contains a Biological Substance, Category B substance and is packed according to PI 650. Notes: (1) The dry ice labels and markings will only be required if dry ice is included; (2) the orientation labels are only required when shipping liquids over 50 mL; (3) the responsible person information must be on the outer package (as shown) or may be on the air waybill.

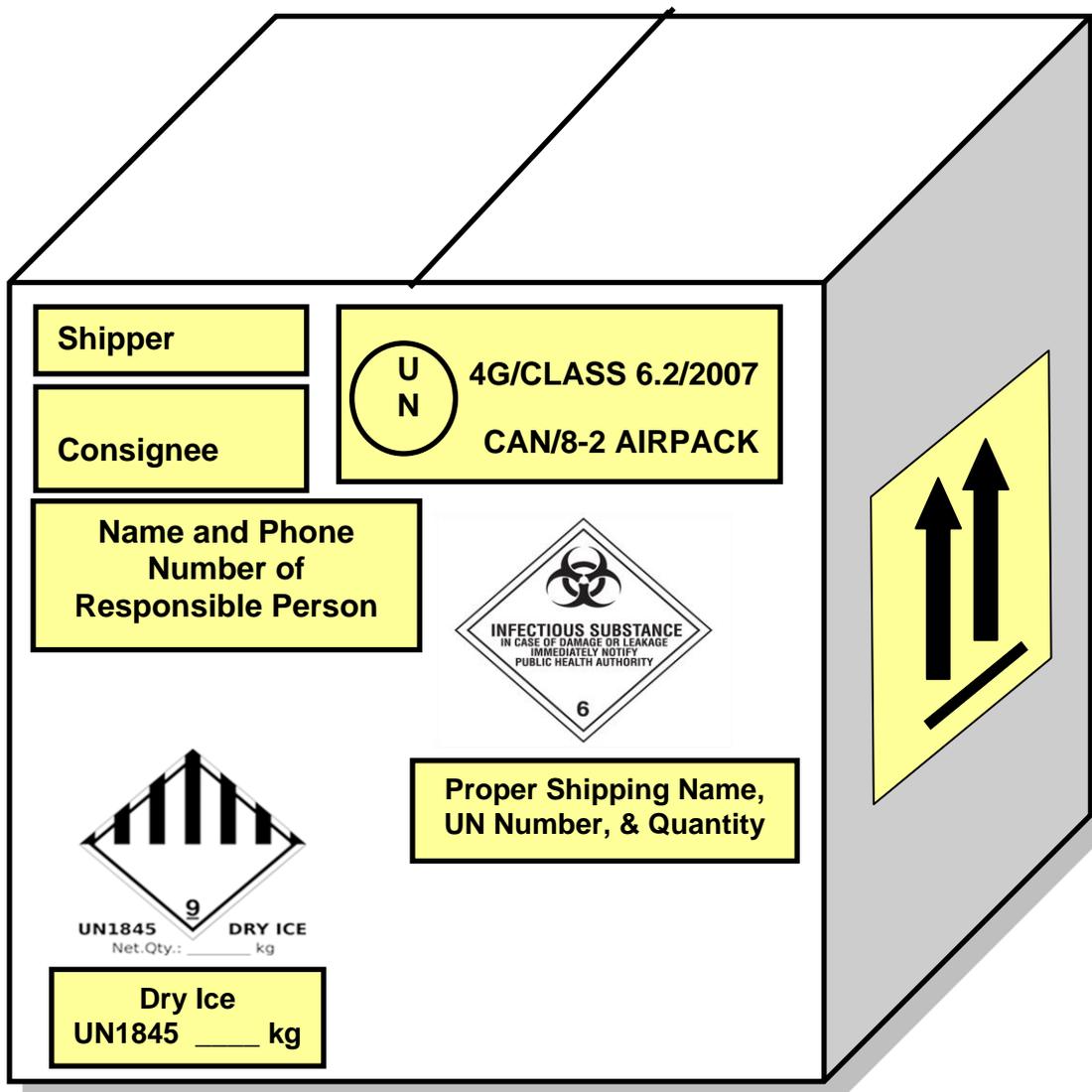


Figure 13. Example of a completely labeled outer Category A package containing dry ice. The primary container inside the package contains a Category A infectious substance and is packed according to PI 620. Notes: (1) The dry ice labels and markings will only be required if dry ice is included; (2) the orientation labels are only required when shipping liquids over 50 mL; (3) the Shipper's Declaration of Dangerous Goods form (when transported by air), or the Shipping Papers (when transported by ground), will be attached to outer package and accessible while in transport (e.g., in a clear pouch where documents are accessible).

Show Fields

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

| Shipper <div style="border: 1px solid black; height: 40px; margin-top: 5px; display: flex; align-items: center; justify-content: center;"> A </div> | Air Waybill No.: Page of Pages B Shipper's Reference Number (optional): | | | | | | | | | | |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Consignee <div style="border: 1px solid black; height: 40px; margin-top: 5px; display: flex; align-items: center; justify-content: center;"> C </div> | | | | | | | | | | | |
| <p><i>Two completed and signed copies of this Declaration must be handed to the operator.</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th colspan="2">TRANSPORT DETAILS</th> </tr> </thead> <tbody> <tr> <td style="width: 50%; font-size: small;"> This shipment is within the limitations prescribed for: (delete non-applicable) </td> <td style="width: 50%; font-size: small;"> Airport of Departure </td> </tr> <tr> <td style="font-size: x-small;"> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center; font-size: x-small;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width: 50%; text-align: center; font-size: x-small;">CARGO AIRCRAFT ONLY</td> </tr> </table> </td> <td style="font-size: x-small;"> <div style="border: 1px solid black; height: 20px; margin-top: 5px; display: flex; align-items: center; justify-content: center;"> D </div> </td> </tr> <tr> <td colspan="2" style="font-size: small;"> Airport of Destination: </td> </tr> </tbody> </table> | TRANSPORT DETAILS | | This shipment is within the limitations prescribed for: (delete non-applicable) | Airport of Departure | <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center; font-size: x-small;">PASSENGER AND CARGO AIRCRAFT</td> <td style="width: 50%; text-align: center; font-size: x-small;">CARGO AIRCRAFT ONLY</td> </tr> </table> | PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY | <div style="border: 1px solid black; height: 20px; margin-top: 5px; display: flex; align-items: center; justify-content: center;"> D </div> | Airport of Destination: | | <p>WARNING</p> <p>Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.</p> <p style="font-size: x-small;">Shipment type: (delete non-applicable)</p> <div style="border: 1px solid black; padding: 2px; display: flex; justify-content: space-between;"> NON-RADIOACTIVE RADIOACTIVE </div> |
| TRANSPORT DETAILS | | | | | | | | | | | |
| This shipment is within the limitations prescribed for: (delete non-applicable) | Airport of Departure | | | | | | | | | | |
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| PASSENGER AND CARGO AIRCRAFT | CARGO AIRCRAFT ONLY | | | | | | | | | | |
| Airport of Destination: | | | | | | | | | | | |
| NATURE AND QUANTITY OF DANGEROUS GOODS | | | | | | | | | | | |
| Dangerous Goods Identification | | | | | | | | | | | |
| Proper Shipping Name | Class or Division | UN or ID No. | Pack- ing group: | Subsidi- ary Risk | Quantity and type of packing | Packing Inst. | Authorization | | | | |
| <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> E </div> | <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> F </div> | <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> G </div> | <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> H </div> | <div style="border: 1px solid black; width: 20px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> I </div> | <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> J </div> | <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> K </div> | <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> L </div> | | | | |
| Additional Handling Information | | | | | | | | | | | |
| <div style="border: 1px solid black; height: 20px; margin-top: 5px; display: flex; align-items: center; justify-content: center;"> M </div> | | | | | | | | | | | |
| 24 hr. Emergency Contact Tel. No.: | | | | shipment is made under the provisions of ICAO | | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. | | | | | Name/Title of Signatory | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. | | | | | Place and Date | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. | | | | | Signature (see warning above) | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. | | | | | <div style="border: 1px solid black; width: 40px; height: 20px; margin: 0 auto; display: flex; align-items: center; justify-content: center;"> O </div> | | | | | | |

Figure 14. Example of a blank (manually fillable), column form, Shipper's Declaration of Dangerous Goods form and the sections which must be completed by the shipper.

Corresponding list for Figure 14

- A-** Full name, address and phone number of shipper
- B-** Enter the Airway Bill No. used
Enter: Page __1__ of __1__ Pages
(Optional): Enter your specimen ID # for reference
- C-** Full name, address and phone number of recipient/consignee
- D-** Cross out the type of shipment which does not apply (cargo vs. passenger aircraft)
Note: Greater than 50 mL or 50 g of Category A will require Cargo Aircraft Only.
Quantities below this limit are allowed as cargo on passenger aircraft.
Airport of departure and destination will be filled out by carrier (leave blank).
The words “Radioactive” should be crossed out when no radioactive material is present.
- E-** Proper shipping name of sample followed by organism name in parenthesis
May use “Suspected Category A, Infectious Substance” for Category A pathogens when specimen is not yet confirmed.
- F-** Hazard Class or Division (6.2 or 9 for dry ice)
- G-** UN ID number of shipment (UN2814, UN1845 etc.)
- H-** Packing Group in Roman Numerals (can leave blank for 6.2 material and dry ice)
- I-** Subsidiary Risk (can leave blank)
- J-** Quantity (in mL or g)
(All) Packaged in one fiberboard box
Overpack Used
- K-** Packing Instruction (620 for Category A, and 954 for dry ice)
- L-** Authorization (can leave blank)
- M-** Additional Information (list Responsible Person name and number)
- N-** 24-Hour Emergency phone number
- O-** Full Name, place of shipment origin and date. Signature of Shipper

[Show Fields](#)

| SHIPPER'S DECLARATION FOR DANGEROUS GOODS | | | | | | | | | | | | | | | | | | | | |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-------------------|----------------------------------------------------|------------------------------|-------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|---------|--|-----------------------------------------------------------------------------------------------------------|----------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|-----------------|---------|--|--|
| Shipper Dr. Joe Smith (Phone #) ABC Laboratory 123 East Street, City, State, Zip | | Air Waybill No. 0001234512345 Page 1 of 1 Pages Shipper's Reference Number <i>(optional): Specimen 000123123</i> | | | | | | | | | | | | | | | | | | |
| Consignee Dr. Jane Smith (Phone #) XYZ Laboratory 987 West Ave., City, State, Zip | | | | | | | | | | | | | | | | | | | | |
| <i>Two completed and signed copies of this Declaration must be handed to the operator.</i> | | WARNING Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent. | | | | | | | | | | | | | | | | | | |
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| TRANSPORT DETAILS | | | | | | | | | | | | | | | | | | | | |
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| PASSENGER AND CARGO AIRCRAFT | XXXXXXX | | | | | | | | | | | | | | | | | | | |
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| NON-RADIOACTIVE | XXXXXXX | | | | | | | | | | | | | | | | | | | |
| NATURE AND QUANTITY OF DANGEROUS GOODS | | | | | | | | | | | | | | | | | | | | |
| Dangerous Goods Identification | | | | | | | | | | | | | | | | | | | | |
| <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 40%;">Proper Shipping Name</th> <th style="width: 5%;">Class or Division</th> <th style="width: 5%;">UN or ID No.</th> <th style="width: 5%;">Pack- ing group</th> <th style="width: 5%;">Subsi- diary Risk</th> <th style="width: 20%;">Quantity and type of packing</th> <th style="width: 5%;">Packing Inst.</th> <th style="width: 10%;">Authorization</th> </tr> </thead> <tbody> <tr> <td style="padding: 5px;">UN2814 Infectious Substance, Affecting Humans (Suspected Category A Infectious Substance)</td> <td style="padding: 5px;">6.2</td> <td style="padding: 5px;">UN2814</td> <td style="padding: 5px;"></td> <td style="padding: 5px;"></td> <td style="padding: 5px;">5 mL solid All packed in one fiberboard box</td> <td style="padding: 5px;">620</td> <td style="padding: 5px;"></td> </tr> </tbody> </table> | Proper Shipping Name | Class or Division | UN or ID No. | Pack- ing group | Subsi- diary Risk | Quantity and type of packing | Packing Inst. | Authorization | UN2814 Infectious Substance, Affecting Humans (Suspected Category A Infectious Substance) | 6.2 | UN2814 | | | 5 mL solid All packed in one fiberboard box | 620 | | | | | |
| Proper Shipping Name | Class or Division | UN or ID No. | Pack- ing group | Subsi- diary Risk | Quantity and type of packing | Packing Inst. | Authorization | | | | | | | | | | | | | |
| UN2814 Infectious Substance, Affecting Humans (Suspected Category A Infectious Substance) | 6.2 | UN2814 | | | 5 mL solid All packed in one fiberboard box | 620 | | | | | | | | | | | | | | |
| Additional Handling Information Responsible Person Name and Number (Dr. Smith, 1-800-555-1234) | | | | | | | | | | | | | | | | | | | | |
| 24 hr. Emergency Contact Tel. No.: 1-800-555-5555 shipment is made under the provisions of ICAO | | | | | | | | | | | | | | | | | | | | |
| I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. | | | Name/Title of Signatory Dr. Joe Smith, Microbiologist Place and Date City, state 4/1/2020 | | | | | | | | | | | | | | | | | |
| | | | Signature <i>(see warning above)</i> | | | | | | | | | | | | | | | | | |

Figure 15. Example of a completed Shipper' Declaration Form completed by an online edit-checked software. The form must be signed by a trained shipper.

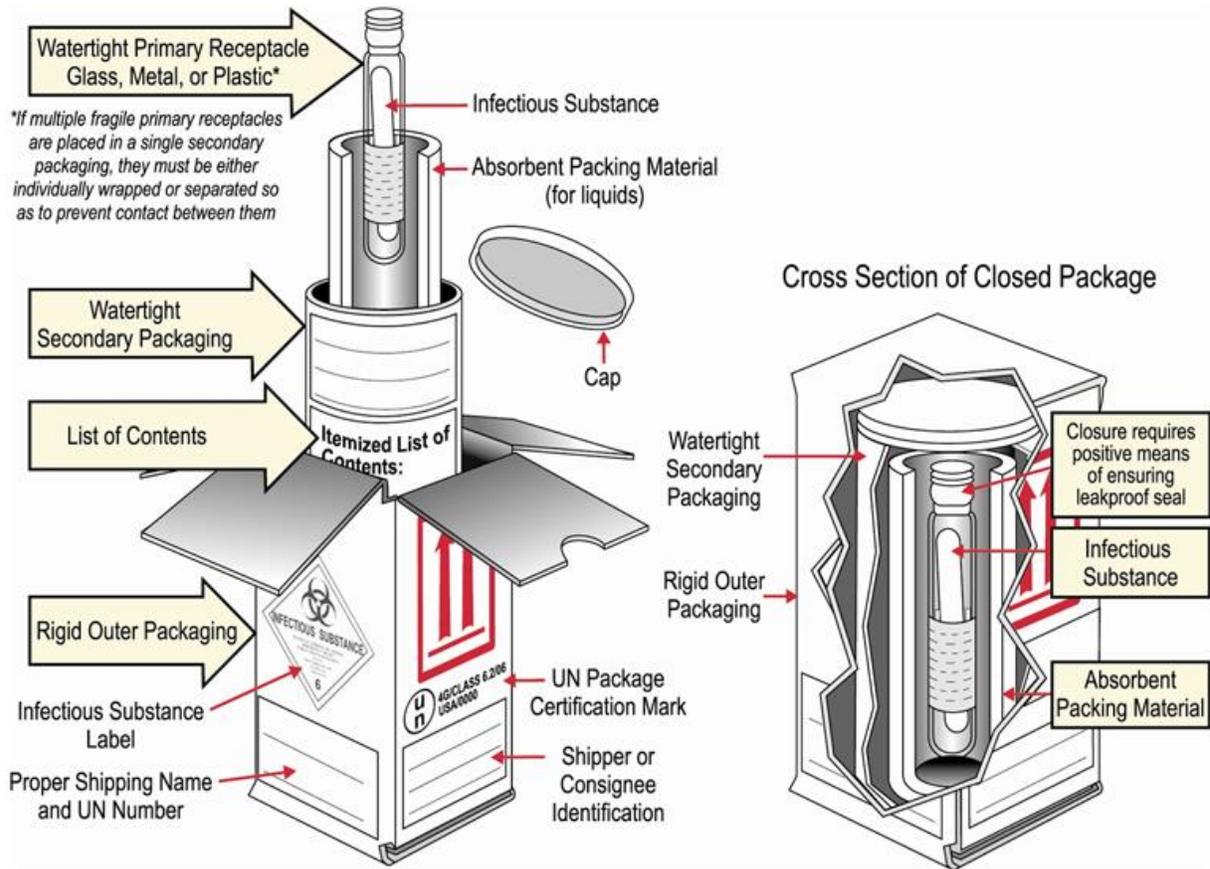


Figure 16. Example of a Category A triple packaging system. (16, 17, 20)