

**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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## **Table of Contents**

### **1 Governing Authorities and Regulations**

- 1.1 Origin of Regulations
- 1.2 Importance of Regulations
- 1.3 Effectiveness of Regulations
- 1.4 Exceptions
- 1.5 Specific Regulations
- 1.6 United States Postal Service

### **2 Classification of Substances**

- 2.1 Classification
- 2.2 Steps in Classification
- 2.3 Category A Infectious Substances
- 2.4 Category B Infectious Substances
- 2.5 Exempt Human or Animal Specimens
- 2.6 Exempt Substances
- 2.7 Patient Specimens
- 2.8 Genetically Modified Organisms
- 2.9 Biological Products
- 2.10 Medical Waste
- 2.11 Infected Animals

### **3 Proper Shipping Names**

### **4 Packing Instructions and Packing Substances**

- 4.1. Packing Instructions
- 4.2. Comparison of Packing Instructions and Directions
- 4.3 Packing Directions for Exempt Human or Animal Specimens
- 4.4. Packing Instructions for Genetically Modified Organisms

### **5 Marking and Labeling Packages Outer Packages**

- 5.1 Specific Markings and Labels
- 5.2 Examples of Marked and Labeled Outer Packages

### **6 Documentation (Shipper's Declaration of Dangerous Goods)**

### **7 Refrigerants**

## **8 Training and Certification**

- 8.1. Applicability
- 8.2. Essential Components of Training
- 8.3. Training Materials
- 8.4. Documentation and Certification of Training
- 8.5. Enforcement of Compliance

## **References**

### **Appendix A. Definitions of Terms Related to Packing and Shipping**

### **Appendix B. Transfer of Select Agents**

## **Tables**

## **Figures**

## Packing and Shipping Infectious Substances

Revised **December 12, 2012**

The information in this procedure is not and is not intended to be an all-inclusive guide to packing and shipping regulations. The information is a summary of the authors' interpretations of the current (as of **December 12, 2012**) requirements and regulations issued by the following:

- International Air Transport Association (IATA; a commercial airline trade association) and
- United States Department of Transportation (DOT; an agency of the federal government).

The requirements and regulations governing the transport of infectious substances by commercial carriers change frequently. Significant changes in IATA regulations are **available approximately six months prior to the annual January 1 publication of the regulations**. 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**.

Significant changes and amendments to the **2012** IATA regulation can be found on this website: [www.iata.org/whatwedo/cargo/dangerous\\_goods/Documents/DGR53\\_SignificantCanges.pdf](http://www.iata.org/whatwedo/cargo/dangerous_goods/Documents/DGR53_SignificantCanges.pdf)

See Appendix A for definitions of IATA and DOT terms related to packing and shipping and used in this procedure.

### 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 air transport of dangerous goods throughout the world originate as decisions (called Model Regulations) made by the United Nations Committee of Experts (15). ICAO uses these regulations 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 by air. IATA uses *Instructions* to develop the >1,000-page *Dangerous Good Regulations* which is the routine “go-to” published book of regulations used by virtually all commercial airlines, other carriers involved in the transport of dangerous goods, and shippers of infectious substances (7). IATA requirements have become the most widely recognized, copied, and used packing and shipping guidelines in the world. Most national and international regulations are based on or are at least in substantial agreement (harmonization) with IATA requirements (13).

In the United States, the DOT regulates the commercial transportation of dangerous goods by both air and ground carriers. 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 compliance with DOT regulations (6,11).

## **1.2 Importance of Regulations**

Laboratory workers who ship or transport dangerous goods, in general, and infectious substances, in particular, by a commercial land or air carrier 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 minimize the potential for damage to the contents of the package during transport and 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 show that these regulations are extremely effective in protecting both the contents of packages and the persons who handle the packages. To date, the author is not aware of reported cases of illness due to the release of an infectious substance during transport. Only 106 (0.002%) of the estimated 4,920,000 primary containers shipped in 2003 to worldwide laboratories and other destinations were reported broken during transit. In each of the 106 reported breakages, absorbent in appropriately prepared packages contained the leaking material, and none of the secondary or outer containers were reported damaged (15).

## **1.4 Exceptions**

The transportation of small quantities of non-Category A substances (usually specimens being transported for clinical, diagnostic, or other patient care purposes) is 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 relatively lenient and state that the substances need only be in leak proof 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.

## **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:

- training of individuals on the requirements for appropriate packaging and shipping of infectious substances, documentation of the training, and subsequent certification (by the employer) of the trainee;
- classification and naming of the material to be shipped;

- selection of packaging that will contain the contents if the package is damaged, and, thus, will protect carrier personnel 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.

## **1.6 United States Postal Service**

The United States Postal Service publishes its own regulations in the USPS *Domestic Mail Manual* (14). The USPS regulations for mailing hazardous materials generally adhere to DOT regulations.

## **2 Classification of Substances**

### **2.1 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.

### **2.2 Steps of Classification**

#### **2.2.1 First Step**

The material must be classified into one of the nine IATA-specified classes (Class 1 through Class 9) of dangerous goods (Table 2). Infectious and toxic substances are Class 6 dangerous goods; dry ice is a Class 9 dangerous good. Class 6 and Class 9 substances usually are the only dangerous goods shipped by clinical microbiologists.

#### **2.2.2 Second Step**

Class 6 substances must be divided into either Division 6.1 (toxic substances) or Division 6.2 (infectious substances).

#### **2.2.3 Third Step**

Division 6.2 infectious substances must be classified into one of nine IATA-specified types of infectious substances (Fig. 1) (Table 3):

- Category A infectious substances

- Category B infectious substances
- Patient Specimens
- Exempt Human or Animal Specimens
- Genetically Modified Organisms (GMO)
- Exempt Substances
- Biological Products
- Infected Animals
- Medical Waste

If the substance is determined to be a patient specimen and is not obviously a Category A or Category B substance but it *meets the criteria* of or *has characteristics* of a Category A or Category B substance, the shipper must classify it as a Category A or Category B substance. Otherwise, the substance must be classified as an exempt human or animal specimen (Table 3) (6,7,11). Fortunately, most clinical microbiologists will find essentially all of their substances are either Category A, Category B, or exempt human or animal substances.

Decisions regarding classification within class 6.2 are extremely important because they will determine exactly how a substance must be packed and shipped. Shippers must not arbitrarily classify all substances as Biological Substance, Category B, Exempt Human or Animal Specimen, or even Exempt Substances to avoid having to make important discriminatory shipping decisions or to make packing easier or less expensive. Such cavalier classification is illegal and can be overly expensive.

## 2.3 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).

### 2.3.1 List of Category A Substances

Deciding if an infectious substance is a Category A substance is relatively easy because [there are relatively few Category A substances](#) and because Category A substances are specifically designated and listed by IATA and DOT (Table 4). The list of Category A substances is not all-inclusive, and a thorough risk assessment must be performed before assigning a substance to Category A.

### 2.3.2 Decisions to Classify a Substances 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.”

### 2.3.3 UN Numbers of Category A Pathogens

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

### 2.3.4 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).

## 2.4 Category B Infectious Substances

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. In the author’s opinion, examples of possible Category B substances are the following:

- typical clinical, diagnostic, or patient specimens, e.g., blood, biopsies, swab specimens, excreta, secreta, 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.

In the author’s opinion, a clinical, diagnostic, or patient specimen suspected of containing or being tested for a “Culture Only” Category A organism may be shipped as a Biological Substance, Category B because the suspected Category A substance is not in culture form, e.g., sputa being tested for *M. tuberculosis* and 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).

## 2.5 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.

## 2.6 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 (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;
- substances to be tested for therapeutic drug monitoring, insurance purposes, alcohol or drugs, pregnancy indicators, cancer, and antibodies;
- 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;
- FDA-approved and FDA-licensed biological products; and
- $\leq 30$  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.

## 2.7 Patient Specimens

IATA has 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).

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). Patient specimens which do not meet either Category A or Category B criteria can be packed and shipped as Exempt Human or Animal Specimens.

## **2.8 Genetically Modified Organisms**

A genetically modified (micro) organism (GMO) is an organism in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally. Genetically modified organisms which meet either Category A or Category B criteria should be classified as a Category A or Category B substances. If a GMO is determined not to have 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 (Class 9; UN3245; proper shipping name: Genetically Modified Organism) and packed and shipped as GMO (Tables 3 and 6) (7).

## **2.9 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 or 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.

## **2.10 Medical Waste**

Medical waste which contains Category A or Category B infectious substances must be packed and shipped as such and assigned UN2814, UN2900, or UN3373 (Table 3) (7). Medical waste which is reasonably believed to have a low probability of containing infectious substances must be packed and shipped as Medical Waste, n.o.s. (UN3291; proper shipping name: Medical Waste) (7).

## **2.11 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.

## **3 Proper Shipping Names**

If the substance is classified as Category A, Category B, GMO, or medical waste, the shipper must identify (officially name) the substance by assigning the substance one of the over 3,000

IATA-specified and internationally recognized UN numbers and proper shipping names listed in the IATA requirements (7).

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. This 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 Shipper's Declaration. Fortunately, only seven of the 3,000 proper shipping names are used by most clinical microbiology laboratories: two names for Category A infectious substances which affect humans (one for liquids and one for solids), two names for Category A infectious substances which affect animals (one for liquids and one for solids), one name for Category B substances, one name for GMO, and one name for dry ice (Table 6). Table 6 shows the seven IATA- and DOT-designated infectious substances commonly shipped by clinical microbiologists. The table provides proper shipping names, UN numbers, packing instructions, quantity limits, and other information related to packing and shipping these substances.

## **4 Packing Instructions and Packing Substances**

### **4.1 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 their 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. 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). 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.

### **4.2 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 between the containers, and an outer shipping container. 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 and PI 650

- 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 liquid contained within the primary container(s) in case of breakage; placed between the primary and secondary containers. Absorbent material is not required if the material being shipped is a solid. Absorbent material should be used with liquids shipped in a frozen state.
- a leak proof secondary container which contains the primary container(s).
- either the primary or secondary container must be able to withstand an internal pressure of at least 95 pKa (13.8 lbs/in<sup>2</sup>) because shipments are likely to be placed into unpressurized cargo sections of aircraft which fly at high altitudes.
- a list of the contents and quantities of the primary container(s) must be attached to the outside of the secondary container.
- 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 at least 4" x 4" on at least one surface. For shipping Category A infectious substances, these outer containers must meet strict United Nations manufacturing and testing specifications.

### 4.3 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).

### 4.4 Packing Instructions for GMO

Genetically modified organisms which meet the criteria of Category A or Category B substances, must be packed and shipped according to PI 650 or 620, 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").

## 5 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 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).

## 5.1 Specific Markings and Labels

- **Shipper and Consignee** – the shipper’s 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 who is 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 may be provided either on the outer package or on the air waybill (7).
- **Category A Substances** -- (a) the Class 6 diamond-shaped label “Infectious Substance. In Case of Leakage...” label, and (b) a label which shows the proper shipping name, UN number, and quantity of the substance (Fig 2). The Class 6 infectious substance label is identical for all regulating agencies except the DOT version specifies notification of the CDC by use of an 800 number.
- **Category B Substances** -- (a) the label “Biological Substance, Category B” and (b) the marking or label “UN3373” (Fig. 3).
- **Exempt Patient Specimens** -- Patient specimens not classified as Category A or Category B must be labeled clearly as “Exempt Human Specimen” or “Exempt Animal Specimen” (Fig. 4). This requirement is specified only by IATA, not by DOT (7,11).
- **GMO – GMO which do not meet the criteria for Category A or B must be labeled with a diamond-shaped label containing UN3245 and” Genetically Modified Organism”** (Fig 5).
- **Dry Ice** -- Class 9 “Miscellaneous Dangerous Goods” label and the weight of dry ice (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 is used if infectious substance amounts over 50 mL (5g) but less than 4 L (4 kg) per outer package are shipped.

- **Overpack** -- “Overpack” markings if overpacks are used (Fig. 9).
- **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 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 outer packaging do 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).

## 5.2 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 which does not have to meet UN specifications. However, the overpack must be labeled “Overpack”, and all inner packages must be completely labeled according to applicable IATA regulations (Fig. 9).

## 6 Documentation (Shipper’s Declaration for Dangerous Goods)

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, must be accurate, 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 FedEx proprietary on-line software; some require the information to be completed on-line; and some require multiple copies be submitted](#). The original Shipper’s Declarations given to the carrier 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 is required for dry ice (a dangerous good) if dry ice is used as a refrigerant for a Category A substance but not if used for a Category B substance.

Regardless of 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*])
- class (e.g., 6.2)
- packing group, if applicable (e.g., III)
- quantity of substance and type of outer container (e.g., 2 ml - Packed in a Single Cardboard Box)
- packing instructions used (e.g., 620)
- authorization code, if applicable (e.g., A140)

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 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 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, and request documentation of adequate training of employees.

Figure 14 shows an example of a blank (manual old style) Shipper’s Declaration and the 11 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 (new style FedEx) Shipper’s Declaration. In this new 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 old and new 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, but not IATA, regulations state an “emergency response telephone number” must be provided on Shipper’s Declarations which accompany shipments of Category A infectious substances (12). The number must be monitored at all times 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, 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.

## 7 REFRIGERANTS

Wet and dry ice are two common refrigerants used to ship diagnostic specimens and infectious substances. Packaging must be leak proof when wet ice is used. Dry ice is a Class 9 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 CO<sub>2</sub>!

## 8 TRAINING AND CERTIFICATION

DOT and IATA provide surprising little direction and details for training shippers. Neither organization provides much helpful information regarding 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.

### 8.1 Applicability

Anyone involved in the shipping or transportation of dangerous goods (including infectious substances) must be trained and certified in the shipment of dangerous goods (6,7,11). **Training must be function-specific, i.e., directly relevant to 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 must receive clear instructions, guidance, and specific training for all functions involved in packing and shipping these substances, and be certified 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.

## 8.2 Essential Components of Training

The essential components of a training program must 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](#)
- marking and labeling
- documentation of shipments of dangerous goods
- safety training
- security training (if applicable to a trainee's job responsibilities)
- testing
- issuance of a certificate after successful completion of the training (6,7).

## 8.3 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 sources (all web sites accessed July 15, 2012):

- American Society for Microbiology ([www.asm.org](http://www.asm.org))
- International Air Transport Association (training manuals) ([www.iata.com](http://www.iata.com))
- regional and national clinical microbiology meetings (workshops and presentations)
- many major universities and medical centers
- many state departments of health and public health
- many professional scientific organizations
- SafTPak ([www.saftpak.com](http://www.saftpak.com))
- CARGOpak ([www.cargopak.com](http://www.cargopak.com))
- Dangerous Goods International ([www.dgitraining.com](http://www.dgitraining.com))
- World Courier Training Course ([www.worldcourier.com](http://www.worldcourier.com))
- MediaLab, Inc. ([http://www.medialabinc.net/?gclid=CPnI17Dj7KgCFU5qKgod2i\\_Gw](http://www.medialabinc.net/?gclid=CPnI17Dj7KgCFU5qKgod2i_Gw))

## 8.4 Documentation and Certification of Training

IATA and DOT require all aspects of training to be documented. Employers should keep a detailed record for each employee who is trained. The record should include employee's name, 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](#). IATA and DOT certification is valid for 2 and 3 years, respectively.

## 8.5 Enforcement of Compliance

The DOT and the Federal Aviation Administration 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!

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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 or

unfinished, are intended for use in the prevention, treatment, or diagnosis of disease in humans or animals, and are to be used for investigational, experimental, or development 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, United Parcel Service, Delta Airlines, and Northwest Airlines).

**Category A 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.

**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 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** -- material which, when not properly handled and contained, can pose a risk to the health, safety, property, or environment and which are shown the list of dangerous goods in IATA *Dangerous Goods Regulations*.

**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; replaced by “Biological Substance, Category B”.

**genetically modified organism** – 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.

**overpack** -- the outmost 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) 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 diagnostic specimen or infectious substance; composed of glass, metal, or plastic; must be leak proof; must be positively sealed if it contains an infectious substance.

**proper shipping name** -- any of over 3,000 internationally recognized names of dangerous goods specifically listed by IATA

**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- and DOT-mandated form which must accompany each shipment of dangerous goods; contains information which describes the dangerous goods; is helpful to persons who handle the shipment; must be completed by the shipper.

**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 U.S. Department of Health and Human Services (HHS) regulates and the CDC oversees the *possession, use, and transfer* of certain specifically listed biological agents and toxins (called “select agents”) that have the potential to pose a severe threat to public health and safety. The CDC oversees all activities with select agents and registers all U.S. laboratories, persons, and other entities that possess, use, and/or transfer select agents. The CDC provides technical assistance and guidance to registered entities to promote laboratory safety and security. CDC and APHIS maintain the National Select Agent Registry (<http://www.selectagents.gov/index.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 on the National Select Agent Registry website ([http://www.selectagents.gov/resources/List\\_of\\_Select\\_Agents\\_and\\_Toxins\\_2012-12-4.pdf](http://www.selectagents.gov/resources/List_of_Select_Agents_and_Toxins_2012-12-4.pdf); updated December 7, 2012). 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 infectious substance is packed according to the guidelines in this document, i.e., packaging for select agents is the same as that for Category A infectious substances: leak proof primary and secondary containers, absorbent, a sturdy and well-labeled outer container, shipper’s declaration for Category A substances, etc. However, the requirements regarding *the possession, use, and transfer* of select agents are intricate, strict, and aggressively enforced.

If a select agent, specimen containing a select agent, or [author’s opinion] a substance suspected of containing a select agent is intended to be shipped, both the sender and the recipient must (a) contact the appropriate federal authorities for guidance, instructions, and permission to ship or receive the select agent *before* such transfer occurs and (b) apply for and receive a site registration number from the CDC *before* the transfer occurs.\* In addition, the shipper must

confirm that the recipient is approved for receiving select agents. The aforementioned CDC 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.

### **B3 Examples of Specifically Designated Select Agents**

([http://www.selectagents.gov/resources/List\\_of\\_Select\\_Agents\\_and\\_Toxins\\_2012-12-4.pdf](http://www.selectagents.gov/resources/List_of_Select_Agents_and_Toxins_2012-12-4.pdf); updated December 7, 2012)

#### **Bacteria**

- *Bacillus anthracis*
- *Yersinia pestis*
- *Brucella abortus*, *B. melitensis*, *B. suis*
- *Burkholderia mallei*, *B. pseudomallei*
- *Francisella tularensis*

#### **Viruses**

- smallpox
- SARS-associated coronavirus (SARS-CoV)
- avian influenza virus
- 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**

- *R. prowazekii*
- *Coxiella burnetii*

#### **Toxins**

- ricin, *Staphylococcus* enterotoxins A-E, botulinum neurotoxin, botulinum neurotoxin-producing species of *Clostridium*

**Table 1. Agencies Governing Transportation of Dangerous Goods**

Governing authority	Agency	Regulations (Reference)
United Nations	ICAO <sup>*</sup>	<i>Technical Instructions for the Safe Transport of Dangerous Goods by Air</i>
commercial airline industry	IATA <sup>†</sup>	<i>Dangerous Goods Regulations</i>
United States	DOT <sup>‡</sup>	<i>United States Hazardous Materials Uniform Safety Act</i>
United States	USPS <sup>§</sup>	<i>Domestic Mail Manual. CO23 Hazardous Materials.</i>
Canada	Transport Canada	<i>Transportation of Dangerous Goods Regulations</i>
other nations		individual national regulations

<sup>\*</sup> International Civil Aviation Organization

<sup>†</sup> International Air Transport Association

<sup>‡</sup> Department of Transportation

<sup>§</sup> United States Postal Service

**Table 2. IATA-Defined Classes of Dangerous Goods**

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) <sup>*</sup>
7	Radioactive materials
8	Corrosives
9	Miscellaneous dangerous goods (e.g. dry ice) <sup>*</sup>

<sup>\*</sup> addressed in detail in this protocol

**Table 3. Types and classifications of IATA Division 6.2 infectious substances**

Type of Infectious Substance	IATA Classification
Category A Substance	Category A
Category B Substance	Category B
Patient Specimen	
meets Category A criteria	Category A
meets Category B criteria	Category B
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 Organism	
meets Category A criteria	Category A
meets Category B criteria	Category B
does not meet Category A or B criteria	Genetically Modified Organism
Exempt Substance	none
Biological Product *	
Infected Animal *	
Medical Waste *	

\* substance is not addressed in detail in this protocol

**Table 4. Examples of infectious substances included in Category A in any form unless otherwise indicated**

UN Number and Proper Shipping Name	Organism
UN 2814 Infectious Substance, Affecting Humans	<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) (cultures only)
	<i>Clostridium botulinum</i> (cultures only)
	<i>Coccidioides immitis</i> (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)
	hantavirus causing hemorrhagic fever with renal syndrome
	hantaan virus
	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.

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UN2900  
Infectious Substance,  
Affecting Animals

classical swine fever virus (cultures only)  
foot and mouth disease virus (cultures only)  
goat pox 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)

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**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 <sup>*</sup>	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 hazardous label required on the outer package
E	Packing group (N/A <sup>†</sup> )
F	Excepted quantity (N/A)
G	Limited quantity packing instructions (N/A)
H	Limited quantity maximum amount (N/A)
I	packing instructions ( <i>passenger and cargo aircraft</i> )
J	maximum allowable amount ( <i>passenger and cargo aircraft</i> )
K	packing instructions ( <i>cargo aircraft only</i> )
L	maximum allowable amounts ( <i>cargo aircraft only</i> )
M	applicable special provisions and exceptions
N	emergency response code

<sup>\*</sup> refers to the 14 columns in the IATA alphabetical *List of Dangerous Goods* (7)

<sup>†</sup> not applicable to infectious substances

**Table 6. The seven types of infectious substances in the IATA alphabetical *List of Dangerous Goods***

UN ID Number	Proper Shipping Name/Description	Class or Div	Hazard Label	Pk Gp	EQ code	Passenger or Cargo Aircraft					Cargo Aircraft Only		Spec Prov	ERG Code
						Ltd Quantity		Pack Inst	Max Net Qty/Pkg	Max Net Quant/Outer Pkg	Pack Inst	Max Net Quant/Outer Pkg		
						Pk Inst	Max Net Qty/Pkg							
A	B	C	D	E	F	G	H	I	J	K	L	M	N	
N2814	Infectious substance, affecting humans * (liquid)	6.2	infectious substance	---	E0	---	---	620	50 mL	620	4 L	A81 A140	11Y	
2814	Infectious substance, affecting humans * (solid)	6.2	infectious substance	---	E0	---	---	620	50 g	620	4 kg	A81 A140	11Y	
2900	Infectious substance, affecting animals only * (liquid)	6.2	infectious substance	---	E0	---	---	620	50 mL	620	4 L	A81 A140	11Y	
2900	Infectious substance, affecting animals only * (solid)	6.2	infectious substance	---	E0	---	---	620	50 g	620	4 kg	A81 A140	11Y	
3373	Biological substance, category B	6.2	none	---	E0	forbidden	650	4L / 4kg	650	4L / 4kg	---	6L		
3245	Genetically modified organisms	9	miscellaneous	---	E0	forbidden	959	no limit	959	no limit	A47	9L		
1845	Dry ice †	9	miscellaneous	III	E0	forbidden	954	200 kg	954	200 kg	A48 A151	9L		

\* On the Shipper's Declaration (but *not* on the outer package), the proper shipping name of the substance must be followed by the technical name (in parentheses) of the substance, e.g., "Infectious Substance, Affecting Humans (*Mycobacterium*)".

† not an infectious substance but relevant to this procedure

**Table 7. Packing Requirements for Exempt Human Specimens, Category B Substances, and Category A Substances**

Packing Requirement	Substance		
	Exempt Human Specimens *	Category B †	Category A ‡
<b>Inner Containers</b>			
leak proof primary (1°) and secondary (2°) containers	yes	yes	yes
pressure-resistant 1° or 2° container	-- §	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
<b>Outer Container</b>			
rigid outer packaging	--	yes	yes
strict manufacturing specifications	none #	few +	many +
name and number of responsible person *	--	yes	yes
markings and labels	yes ∞	less +	more +
<b>Quantity Limits for Either Passenger or Cargo Aircraft</b>			
maximum for each 1° container	--	1 L / 1 kg	50 mL / 50 g
maximum total for each outer package	--	4 L / 4 kg	50 mL / 50 g
<b>Documentation</b>			
Shipper's Declaration for Dangerous Goods	--	no	yes
emergency response telephone number	--	no	yes
<b>Costs</b>			
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 Specimens.)

† packing instructions 650

‡ packing instructions 620

§ 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 quote)

+ See text for details.

\* Cat B: may be placed either on the outer package or on the air waybill; Cat A: must be placed on the outer package

∞ Only "Exempt Human Specimen" or "Exempt Animal Specimen" is required.

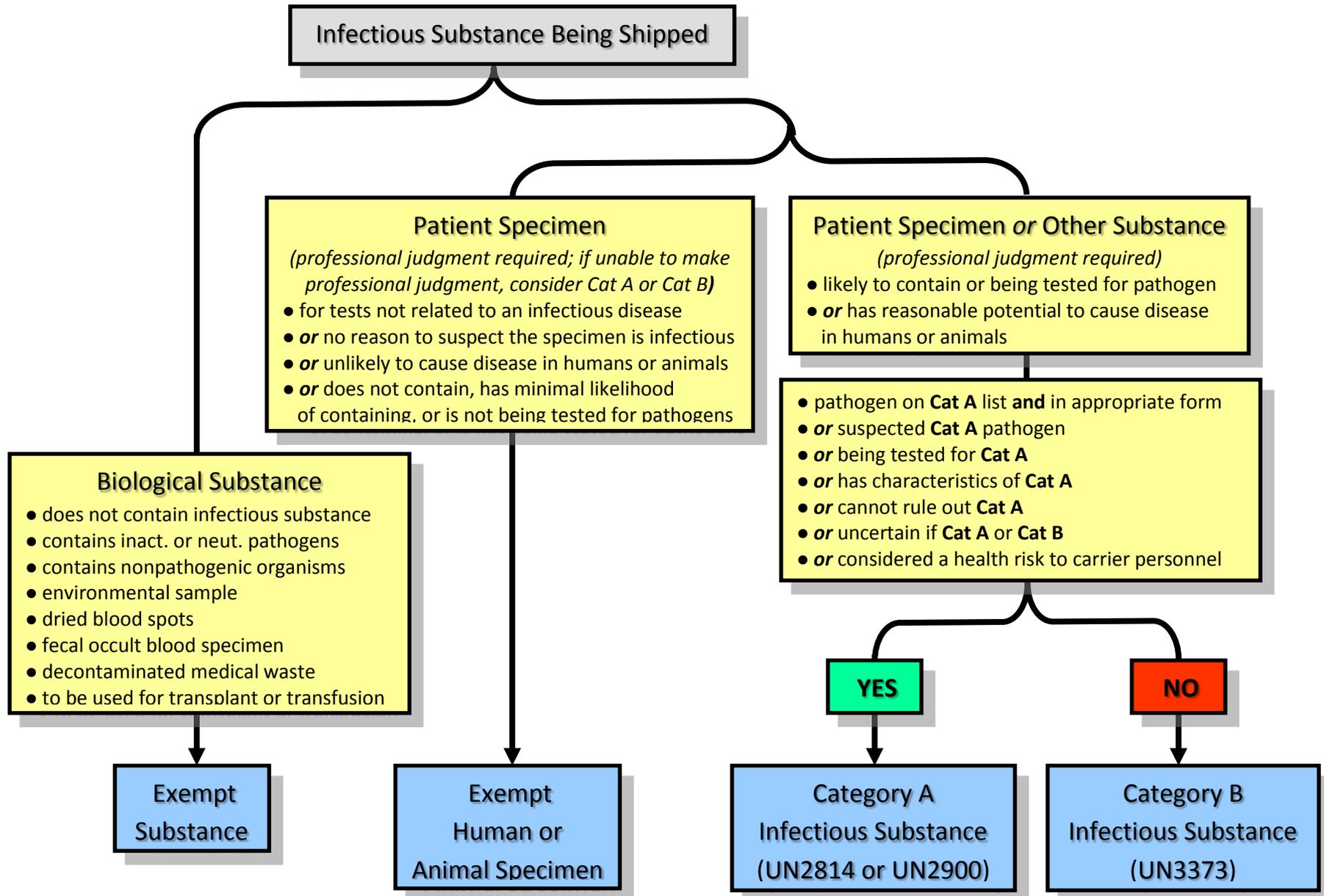


Figure 1. Algorithm for classifying infectious substances



**Infectious Substance,  
Affecting Humans  
UN 2814 4 mL**

**Figure 2.** Labels which indicate an infectious substance (Class 6), proper shipping name, UN number, and quantity of substance

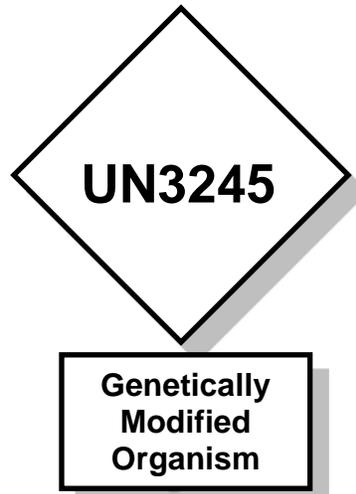


**Biological  
Substance,  
Category B**

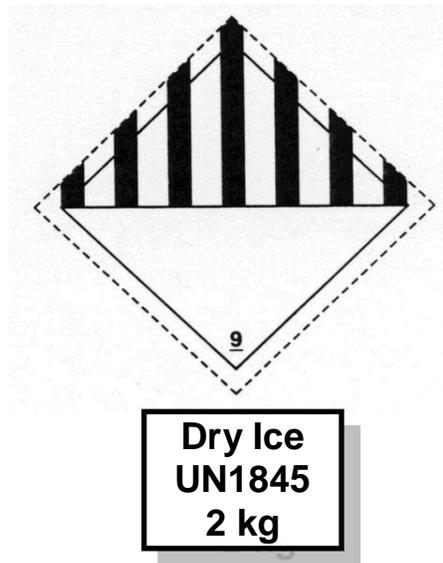
**Figure 3.** Labels which indicate a Biological Substance, Category B, appropriate UN number, and proper shipping name

**Exempt  
Human  
Specimen**

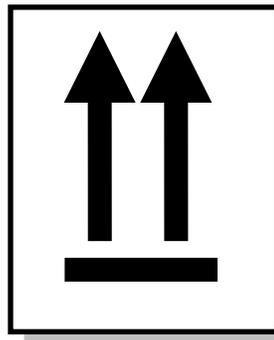
**Figure 4.** Label which indicates an Exempt Human Specimen



**Figure 5.** Labels which indicates GMO



**Figure 6.** Labels which indicate a miscellaneous (Class 9) dangerous good (2 kg of dry ice)



**Figure 7.** Label which indicates correct orientation of package during shipping



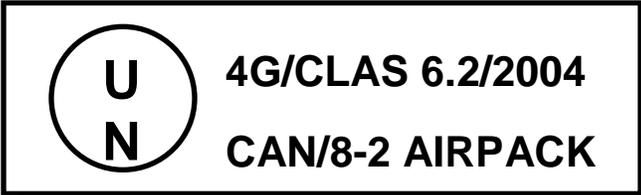
**Danger!**  
**DO NOT Load into**  
**Passenger Aircraft**

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



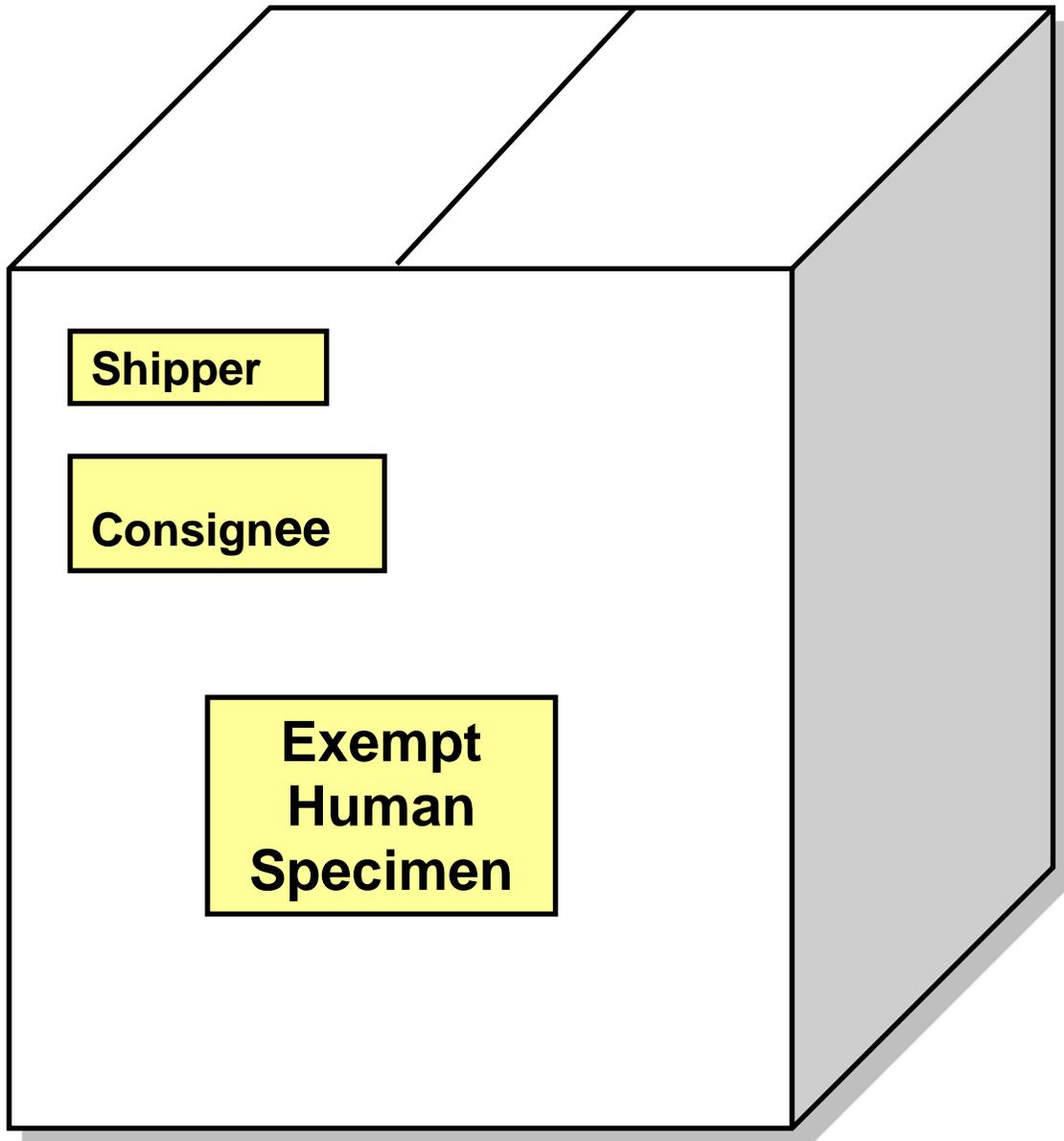
**OVERPACK**

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

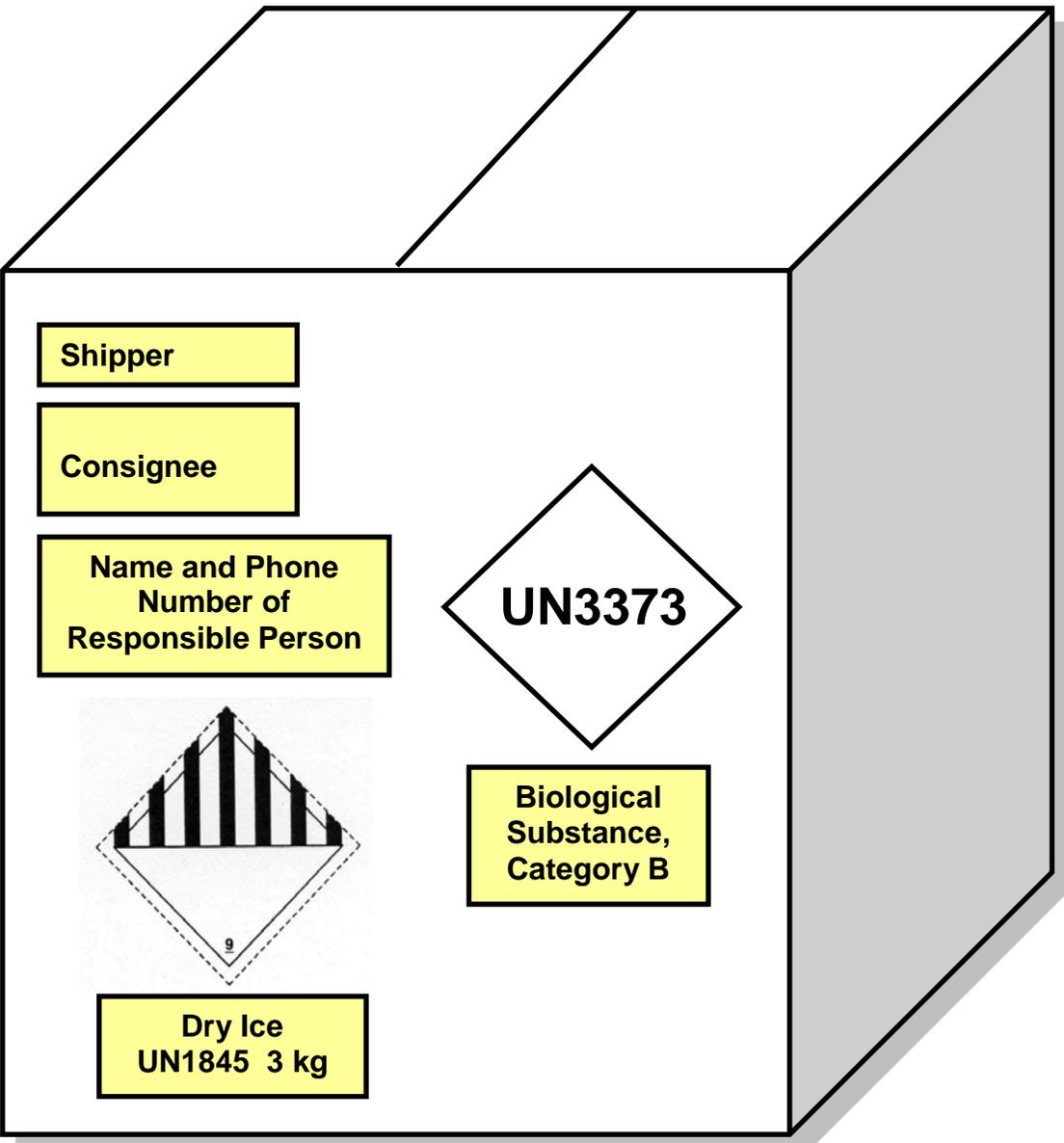


**U**  
**N** **4G/CLAS 6.2/2004**  
**CAN/8-2 AIRPACK**

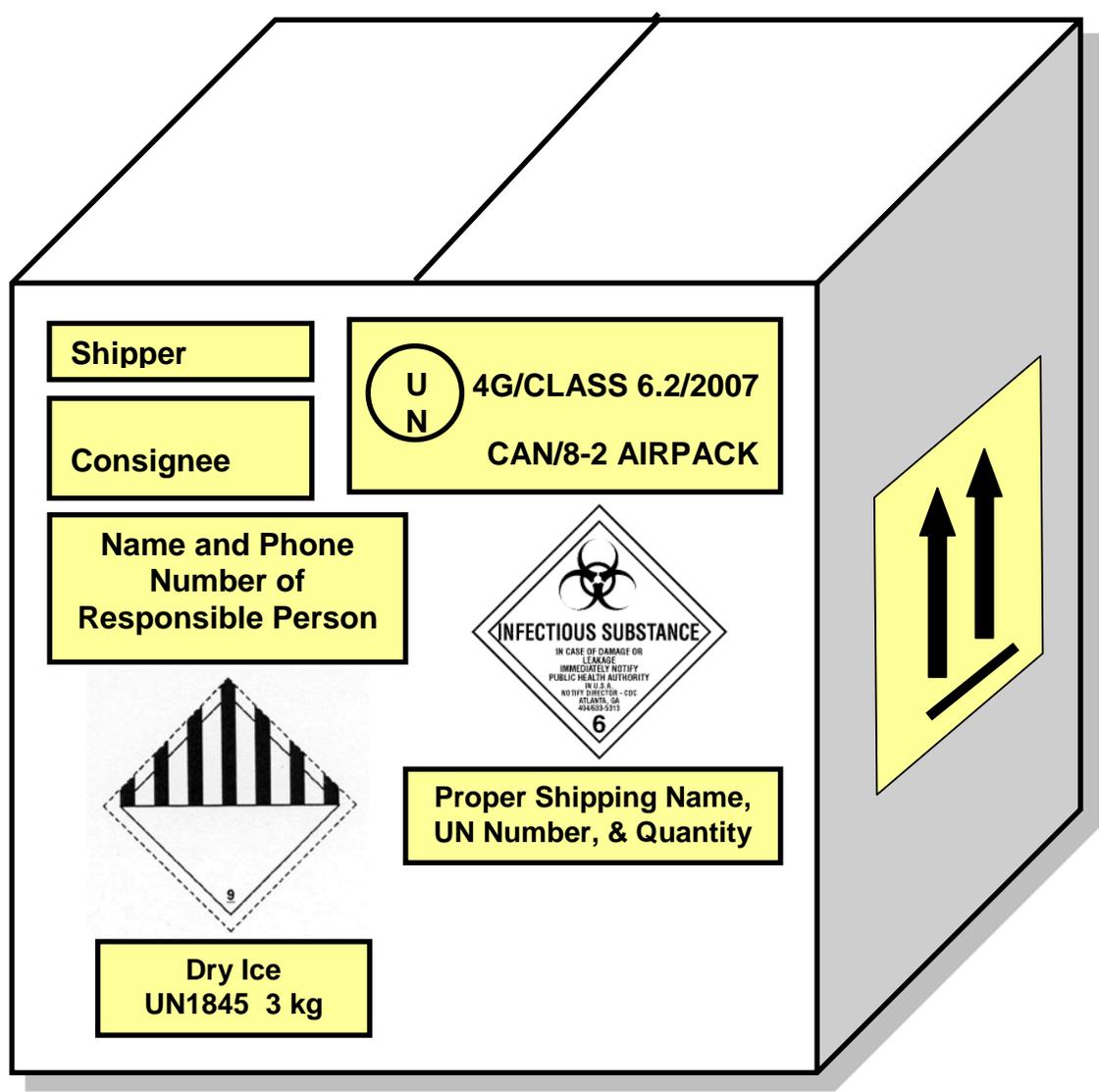
**Figure 10.** Label which indicates outer container has met UN-specified manufacturing standards



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

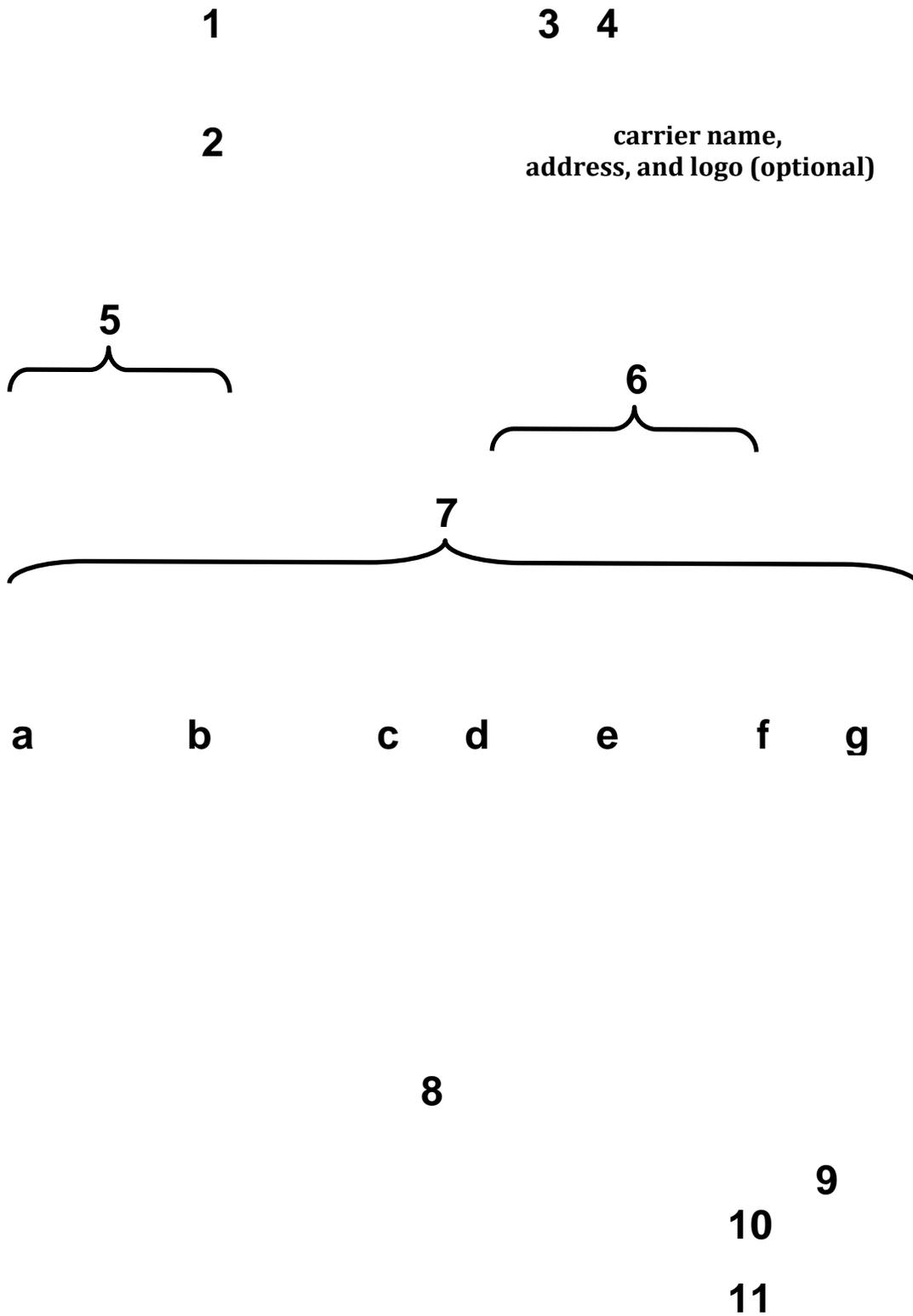


**Figure 12.** Example of a completely labeled outer package. The primary container inside the package contains a Biological Substance, Category B substance and is packed according to PI 650.



**Figure 13.** Example of a completely labeled outer package. The primary container inside the package contains a Category A infectious substance and is packed according to PI 620.

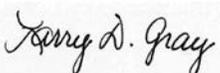
SHIPPER'S DECLARATION FOR DANGEROUS GOODS	
Shipper	Air Waybill No. Page of Pages Shipper's Reference Number <i>(optional)</i>
Consignee	<i>For optional use for Company logo name and address</i>
<i>Two completed and signed copies of this Declaration must be handed to the operator.</i>	
<b>WARNING</b>	
Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.	
<b>TRANSPORT DETAILS</b>	
This shipment is within the	Airport of Departure:



**Figure 14.** Example of a blank *older* (column form) Shipper's Declaration and the 11 sections which must be completed by the shipper.

**SHIPPER'S DECLARATION FOR DANGEROUS GOODS**

(Provide at least three copies to airline.)

Shipper KATHY WIETMARSCHEN BETHESDA HOSPITAL LAB 619 OAK STREET  CINCINNATI OH 452061690 US		Air Waybill No. 492533466079  Page 1 of 1 Page(s)  Shipper's Reference Number (optional)	
Consignee SPECIMEN RECEIVING ODH LABORATORIES BUILDING 22 8995 EAST MAIN STREET  REYNOLDSBURG OH 43068 US			
Two completed and signed copies of this Declaration must be handed to the operator		<b>WARNING</b>  Failure to comply with all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.	
<b>TRANSPORT DETAILS</b>			
This shipment is within the limitations prescribed for: (delete non applicable)	Airport of Departure CINCINNATI		
PASSENGER AND CARGO AIRCRAFT	Airport of Destination: REYNOLDSBURG NAGQQA	Shipment type: (delete non applicable) NON-RADIOACTIVE	
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b> UN Number or identification Number, proper shipping name, Class or Division (subsidiary risk), packing group (if required), and all other required information.			
UN 2814, Infectious substance, affecting humans ( <i>Mycobacterium</i> ), 6.2 // 1 Fiberboard Box X 10 ml // 620 Infectious Substance, Responsible Party: LARRY D GRAY 3214567891			
<b>Additional Handling Information</b>  I declare that all of the applicable air transport requirements have been met.			
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. I declare that all of the applicable air transport requirements have been met.		Name/Title of Signatory LARRY GRAY/DIRECTOR  Place and Date CINCINNATI, OHIO 05/15/2012  Signature (see warning above) 	
8005355053		Emergency Telephone Number	
FOR RADIOACTIVE MATERIAL SHIPMENT ACCEPTABLE FOR PASSENGER AIRCRAFT, THE SHIPMENT CONTAINS RADIOACTIVE MATERIAL INTENDED FOR USE IN OR INCIDENT TO RESEARCH, MEDICAL DIAGNOSIS OR TREATMENT. ADR EUROPEAN TRANSPORT STATEMENT: CARRIAGE IN ACCORDANCE WITH 1.1.4.2.1			

LOGOS #157295 6/01 WCS

**Figure 15.** Example of a completed newer (non-column form) Shipper's Declaration.