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

Packing and Shipping Infectious Substances

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American Society for Microbiology

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Packing and Shipping Infectious Substances

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The information presented in this procedure is essentially the same information presented in the ASM publication *Clinical Microbiology Procedures Handbook* (2007 Update, ASM Press, Washington, DC) and is used with permission from the ASM.

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 author's interpretations of the current requirements and regulations (as of January 1, 2008) issued by the following:

- International Civil Aviation Organization (ICAO; a specialized United Nations agency which promotes the international standardization of essentially all technical aspects of aviation, including the transport of dangerous goods);
- 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 change frequently. Shippers are responsible for being aware of these changes, adhering to current regulations, and interpreting applicable regulations for themselves and their facilities.

A list of recent significant changes in IATA requirements and DOT regulations can be found in Appendix A (6,7,11).

See Appendix B for definitions of IATA and DOT terms used in this procedure.

I. GOVERNING AUTHORITIES AND REGULATIONS

A. 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 these IACO *Technical Instructions* to develop *Dangerous Good Regulations* which are used by essentially all commercial airlines involved in the transport of dangerous goods (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). On June 2, 2006, the DOT revised its regulations for the transportation of infectious substances to be in substantial

agreement (harmonization) with ICAO requirements (11). For practical purposes, shippers of infectious substances can consider compliance with IATA requirements to be compliance with DOT regulations (6,11).

B. 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).

C. 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, there are no reported cases of illness due to the release of an infectious substance during transport. Only 106 (0.002%) of the 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).

D. 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). DOT considers small quantities of such substances to be "materials of trade." 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 leakproof 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.

E. 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. 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.

F. 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.

II. CLASSIFICATION OF SUBSTANCES

A. 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.

B. Steps of Classification

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. **Second Step**
   Class 6 substances must be divided into either Division 6.1 (toxic substances) or Division 6.2 (infectious substances).
3. **Third Step**
   Division 6.2 infectious substances must be classified into one of nine IATA-specified types of infectious substances (Table 3):
   - Category A infectious substances
   - Category B infectious substances
   - Patient Specimens
   - Exempt Human or Animal Specimens
   - Genetically Modified Organisms
   - Exempt Substances
   - Biological Products
   - Infected Animals

- Medical Waste

If the substance is determined to be a patient specimen or a genetically modified microorganism 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 or a genetically modified organism, respectively (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 made in the third step can be subjective and can be difficult; however, these decisions 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.

C. 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).

1. List of Category A Substances

Deciding if an infectious substance is a Category A substance is relatively easy 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. Category A pathogens are essentially the same as those previously classified as "forbidden substances" and Risk Group 4 substances.

2. Decisions to Classify a Substances as Category A

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

- regarding judgement: "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 judgement 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." (7).

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) (Fig 1) (7).

4. **Agents of Bioterrorism**
   Some Category A pathogens have been designated as agents of bioterrorism and are known as select agents (Appendix C). United States federal regulations require shippers to have special permits to possess, use, transfer, and receive these agents (1,2,3,5).

D. 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), and
- 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.

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

E. 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 judgement and knowledge of patient medical history may used to determine if the specimen is an infectious risk or contains pathogens. Historically, such specimens were packed and shipped as Clinical Specimens or Diagnostic Specimens. 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).

F. Exempt Substances

Many substances commonly encountered in clinical laboratories are 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) (7,10). 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 10% formalin per primary container when the formalin is used as a preservative of an infectious substance.

G. 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). Patient specimens which have neither Category A nor Category B criteria should be packed and shipped as Exempt Human or Animal Specimens.

H. Genetically Modified Organisms

Genetically modified organisms usually meet either Category A or Category B criteria. If this is not the case, the organism must be classified as a genetically modified microorganism (Class 9; Miscellaneous Dangerous Goods) and packed and shipped as such (Table 3) (7).

I. 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.

J. 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) (7).

K. Infected Animals

A live 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 commercial carriers is advised if either live or dead infected animals need to be shipped.

III. NAMING CATEGORY A AND CATEGORY B SUBSTANCES

After classifying the substance, the shipper must identify (officially name) a Category A and Category B 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 genetically modified organisms, 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. Information in this table was taken directly from 2006 IATA *Dangerous Goods Regulations* (7).

IV. PACKING INSTRUCTIONS AND PACKING SUBSTANCES

A. Packing Instructions

DOT regulations, IATA requirements, and IATA Packing Instructions (PI) describe the minimum standards for the safe transport of various biological materials. 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 602); Category B infectious substances (PI 650); and dry ice (PI 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.

B. Comparison of Packing Instructions and Directions

Details of the similarities of and differences between PI 602, PI 650, and the directions for packing Exempt Human or Animal Substances are shown in Table 7. The major similarity these three instructions have in common 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 602 and PI 650

- a leakproof 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 leakproof secondary container which contains the primary container(s).
- rither the primary or secondary container must be able to withstand an internal pressure of at least 95 pKa (13.8 lbs/in^2) 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.

C. 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 602. However, such packaging must be composed of four important elements: (a) a leakproof primary container, (b) a leakproof 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).

V. 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).

A. Specific Markings and Labels

1. **Shipper and Consignee** – the shipper's and consignee's name and address
2. **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).
3. **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.
4. **Category B Substances --** (a) the label "Biological Substance, Category B" and (b) the marking or label "UN3373" (Fig. 3)
5. **Dry Ice** -- Class 9 "Miscellaneous Dangerous Goods" label and the weight of dry ice (Fig. 4)
6. **Package Orientation** -- package orientation label (Fig. 5). 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.
7. **Cargo Only** -- "Cargo Aircraft Only" label if the substance (because of it's quantity) must be transported only by cargo aircraft (Fig. 6). This label is used if infectious substance amounts over 50 mL (5g) but less than 4 L (4 kg) per outer package are shipped.
8. **Overpack** -- "Overpack" markings if overpacks are used (Fig. 7)
9. **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. 8). This requirement is specified only by IATA, not by DOT (7,11).
10. **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. 9). 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).

B. Examples of Labeled and Marked Outer Packages

Figures 10, 11, and 12 show simplifed 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 11 and 12 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. 7).

VI. DOCUMENTATION

A. Importance of Shipper's Declarations

A Shipper's Declaration 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 or the carrier may reject the package for transport. 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 for a Category B substance. Some carriers require the Shipper's Declaration to be typed; some require multiple copies. The original Shipper's Declaration given to the carrier must have vertical red candy stripes along the left and right edges of the document. Shippers must retain copies of Shipper's Declarations for two years (10). All corrections must be neatly "lined out" and all change must be signed (not initialed) by the *same* person who signed the document. A carrier may 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 Decalaration 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 13 shows a blank Shipper's Declaration and the 13 sections which shippers must complete. Essentially all of the IATA-specified technical information required to complete the seven subsections of section nine (Nature and Quantity of Dangerous Goods) of the document can be found in Table 6 and reference 7. Figure 14 shows a completed and acceptable Shipper's Declaration.

B. Emergency Response Telephone Number

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 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.

VII. REFRIGERANTS

Wet and dry ice are two common refrigerants used to ship diagnostic specimens and infectious substances. Packaging must be leakproof when wet ice is used. Dry ice is a Class 9 dangerous good, it must be packaged according to PI 904, 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. 4, 11, and 12). 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_2!

VIII. 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.

A. 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). 2005 WHO guidelines state that only persons who pack and ship Category A infectious substances must receive the aforementioned formal training and certification (15). Persons who pack and ship Category B infectious substances and exempt human and animal specimens need to receive only general and practical training such as "clear instructions on the use of packaging" and "training and awareness" of the importance of packing substances appropriately certification (15). Such persons should and receive clear instructions, guidance, and training appropriate for packing and shipping Category B infectious substances and diagnostic specimens, addressing spills, and protecting themselves certification (15). **NOTE:** As of October 16, 2007, IATA and DOT have *not* adopted these recently relaxed and separate training requirements for shippers of Category B substances. Until such requirements are adopted by DOT, shippers should be formally trained and certified as if they will pack and ship both Category A and Category B substances.

B. Essential Components

The essential components of a training program must include the following:

1. general awareness and familiarity with the many aspects of shipping dangerous goods
2. importance, nature, and contents of IATA and DOT regulations
3. function-specific training (hands-on and/or demonstrations of packaging and packing techniques)
4. marking and labeling
5. documentation of shipments of dangerous goods
6. safety training
7. security training (if applicable to a trainee's job responsibilities)
8. testing
9. issuance of a certificate after successful completion of the training (6,7).

C. 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:

1. American Society for Microbiology (www.asm.org)
2. International Air Transport Association (training manuals) (www.iata.com)
3. regional and national clinical microbiology meetings (workshops and presentations)
4. many major universities and medical centers
5. many state departments of health and public health
6. many professional scientific organizations
7. SafTPak (www.saftpak.com)
8. CARGOpak (www.cargopak.com)
9. Dangerous Goods International (www.dgitraining.com)
10. ICC The Compliance Center (www.thecompliancecenter.com)
11. World Courier Training Course (www.worldcourier.com)
12. Casing Scientific (www.casingcorp.com)

D. Documentation of Training

IATA and DOT require all aspects of training to be documented. The most important document used to prove appropriate and timely training is a certificate which is issued after training is complete. Employers should keep a 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, documentation of testing, and a copy of the certificate of training. IATA and DOT certification is valid for 2 and 3 years, respectively.

E. 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 the these facilities for compliance with the training regulations and to inspect training records at these facilities. Facilities which do not comply with prescribed regulations are subject to substantial fines.

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X. APPENDIX A Recent Significant Changes in IATA Requirements and DOT Regulations

1. Classification of infectious substances according to risk groups has been replaced by classification of substances into either Category A substance, Category B substance, Exempt Human or Animal Specimen, Exempt Substance, and Patient Specimen.
2. The terms c*ulture* and *patient specimen* have been defined, and the definitions are more user-friendly. The term *laboratory culture* is no longer used.
3. Minimal packing directions for Exempt Human or Animal Specimen have been provided. There are no specific, detailed, and numbered packing instructions such as PI 602 and PI 650.
4. The technical name of a Category A substance packed according to PI 602 is no longer required on the outer package. For example, a package formerly labeled "Infectious Substance, Affecting Humans (Hepatitis C Virus)" now should be labeled "Infectious Substance, Affecting Humans." The technical name is still required on Shipper's Declarations.
5. Packing Instruction 650
   - The only acceptable proper shipping name for a Category B substance is "Biological Substance, Category B". The terms *Clinical Specimen* and *Diagnostic Specimen* are no longer allowed.
   - Quantity limits have been revised to allow up to 1 L of liquid/ primary container.
   - now mandates use of rigid outer containers
   - Packages must be marked with a diamond symbol which contains "UN3373", and a "Biological Substance, Category B" marking adjacent to the diamond.
6. If an air waybill is used, the "Nature and Quantity of Goods" box (or equivalent area on the air waybill) should indicate the appropriate proper shipping name, e.g., "Biological Substance, Category B (UN3373)", "Category A Substance (UN2814)", and "Exempt Human Specimen". NOTE: As of September 11, 2007, IATA and DOT do not require the aforementioned information be provided on an air waybill; however, such a requirement is anticipated in the near future.

7. The "Prior arrangements as required…" statement in the Additional Handling Information section of the Shipper's Declaration is no longer required.
8. The requirement for an "air eligibility" label or marking (airplane symbol inside of a circle) has been replaced by the following certification statement on the Shipper's Declaration: "I declare that all of the applicable air transport requirements have been met."
9. The sequence of information within the Nature and Quantity of Dangerous Goods section of the Shipper's Declaration of Dangerous Goods must begin with the UN number in the first column.
10. Overpacks must be labeled "Overpack" instead of the previously required "Inner Packages Comply…"
11. Several exemptions to regulations have been defined.
12. Persons who pack and ship select agents and toxins, and Category A agents must receive security training commensurate with their responsibilities.
13. Some hazardous materials, e.g., 10% formalin, used as a preservative are exempt from requirements and regulations if the quantity is ≤30 mL per primary container.

XI. APPENDIX B 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 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 either are 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 -- an infectious substance which does not meet Category A criteria. Category B substances generally are considered to be the following: (a) patient or clinical specimens reasonably expected to contain, or being cultured or otherwise tested for a pathogen, and (b) microorganisms not specifically listed in Category A. The proper term for a Category B substance is Biological Substance, Category B.

***Code of Federal Regulation* (CFR) --** United States laws published in the *Federal Register* and 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 judgement 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 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 microorganism (GMO) -- 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.

pathogen -- a microorganism (bacterium, mycobacterium, fungus, parasite, virus, plasmid, genetic element, proteinaceous infectious particle [prion], or genetically modified organism) 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 leakproof; 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.

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 and in substantial agreement with ICAO regulations.

XII. APPENDIX C Select Agents

Select agents are microorganisms, biological agents, or biological toxins that have been deemed by the United States Government to be major threats to public health and safety because they could be used as agents of bioterrorism. Examples of select agents are the following:

- *Bacillus anthracis*
- *Yersinia pestis*

- *Brucella abortis*
- *Francisella tularensis*
- smallpox virus
- *Clostridium botulinum* neurotoxin
- *Coccidioides immitis*
- hemorrhagic fever viruses
- reconstructed replication competent forms of the 1918 pandemic influenza H1N1 virus
- all agents of bioterrorism including zoonotic agents and agents of significant animal diseases.

The Department of Health and Human Services and the Department of Agriculture have similar but certainly not identical lists of select agents and rules for the possession, use, and transfer of such agents (1,2,3). If a select agent or a specimen or item suspected of containing a select agent must be shipped or otherwise transported from one facility to another, both the shipper and the consignee must contact the appropriate state and federal authorities for guidance, instructions, and permission before such transfer occurs. In addition, the shipper must confirm that the recipient is approved for receiving select agents. Select agent regulations and a list of select agents can be found in the references (1,2,3,5).

TABLE 1
Agencies Governing Transportation of Dangerous Goods

Governing authority	Agency	Regulations (Reference)
United Nations	ICAO [a]	*Technical Instructions for the Safe Transport of Dangerous Goods by Air*
Commercial airline industry	IATA [b]	*Dangerous Goods Regulations*
United States	DOT [c]	*United States Hazardous Materials Uniform Safety Act*
United States	USPS [d]	*Domestic Mail Manual. CO23 Hazardous Materials.*
Canada	Transport Canada	*Transportation of Dangerous Goods Regulations*
Other nations		individual national regulations

[a] International Civil Aviation Organization
[b] International Air Transport Association
[c] Department of Transportation
[d] 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 [a])
7	Radioactive materials
8	Corrosives
9	Miscellaneous dangerous goods (e.g. dry ice) [a]

[a] 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 [a]
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 Microorganism	
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 [b]	
Infected Animal [b]	
Medical Waste [b]	

[a] The only acceptable proper shipping name for Category B substances is Biological Substance, Category B. The proper shipping names Diagnostic Specimen and Clinical Specimen are no longer allowed.

[b] 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	Bacillus anthracis *(cultures only)*
	Brucella abortus *(cultures only)*
	Brucella melitensis (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei (cultures only)
	Burkholderia pseudomallei (cultures only)
	Chalamydia psittaci (avian) (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
	Crimean-Congo hemorrhagic fever virus
	dengue virus (cultures only)
	eastern equine encephalitis virus (culture only)
	Escherichia coli, verotoxigenic (cultures only)
	Ebola virus
	Francisella tularensis *(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
	Mycobacterium tuberculosis *(cultures only)*
	poliovirus virus (cultures only)
	rabies virus (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Shigella dysenteriae type 1 (cultures only)
	variola virus
	Venezuelan equine encephalitis virus (cultures only)
	West Nile virus (cultures only)
	yellow fever virus (cultures only)
	Yersinia pestis (cultures only)

Table continues on next page

Table 4 continued

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)

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[a]	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	N/A[b]
E	the hazardous label required on the outer package
F	N/A
G	N/A
H	N/A
I	packing instructions to use for *passenger and cargo aircraft*
J	maximum allowable amounts to be shipped in *passenger and cargo aircraft*
K	packing instructions to use for *cargo aircraft only*
L	maximum allowable amounts to be shipped in *cargo aircraft only*
M	applicable special provisions and exceptions
N	emergency response code

[a] refers to the 14 columns in the IATA alphabetical *List of Dangerous Goods*

[b] not applicable to infectious substances

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

					Passenger or Cargo Aircraft					Cargo Aircraft Only			
						Ltd Quantity							
UN ID Number A	Proper Shipping Name/Description B	Class C	Sub Risk D	Hazard Label(s) E	Pk Gp F	Pk Inst G	Max Net Qty/Pkg H	Pack Inst I	Max Net Qty/Pkg J	Pack Inst K	Max Net Qty/Pkg L	Spec Prov M	ERG Code N
2814	Infectious substance, affecting humans [a] (liquid)	6.2	---	infectious substance	---	---	---	602	50 mL	602	4 L	A81 A140	11Y
2814	Infectious substance, affecting humans [a] (solid)	6.2	---	infectious substance	---	---	---	602	50 g	602	4 kg	A81 A140	11Y
2900	Infectious substance, affecting animals only [a] (liquid)	6.2	---	infectious substance	---	---	---	602	50 mL	602	4 L	A81 A140	11Y
2900	Infectious substance, affecting animals only [a] (solid)	6.2	---	infectious substance	---	---	---	602	50 g	602	4 kg	A81 A140	11Y
3373	Biological substance, category B	---	---	none	---	---	---	650	4L / 4kg	650	4L / 4kg	---	6L
3245	Genetically modified micro-organisms	9	---	miscellaneous	---	---	---	913	no limit	913	no limit	A47	9L
1845	Dry ice [b]	9	---	miscellaneous	III	---	--	904	200 kg	904	200 kg	A48	9L

[a] 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 tuberculosis*)".
[b] not an infectious substance but relevant to this procedure

TABLE 7
Comparison of IATA and DOT Packing Requirements for Infectious Substances

Packing Requirement	Substance		
	Exempt Human Specimens [a]	Category B [b]	Category A [c]
Inner Containers			
leakproof primary (1°) and secondary (2°) containers	yes	yes	yes
pressure-resistant 1° or 2° container	-- [d]	yes	yes
absorbent between 1° and 2° containers [e]	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 [f]	few	many
name and number of responsible person	--	yes [g]	yes
markings and labels	yes [h]	Less	more
Quantity Limits for Either Passenger or Cargo Aircraft			
maximum for each 1° container	--	1 L (1 kg)	50 mL (50 g)
total maximum for outer package	--	4 L (4 kg)	50 mL (50 g)
Documentation			
Shipper's Declaration for Dangerous Goods	--	no	yes
emergency response telephone number	--	no	yes
Costs			
cost of labor and materials to pack substance	least	more	most

[a] packing directions (IATA and DOT provide only minimal standards [i.e., no detailed and numbered packing instructions] for packing and shipping Exempt Human Specimens.)
[b] packing instructions 650
[c] packing instructions 602
[d] requirement not specified by IATA or DOT
[e] not required for solid substances such as tissue and solid agar media cultures or slant
[f] should be "of adequate strength for its intended capacity, mass, and intended use" (IATA quote)
[g] may be placed either on the outer package or on the air waybill
[h] Only "Exempt Human Specimen" or "Exempt Animal Specimen" is required.

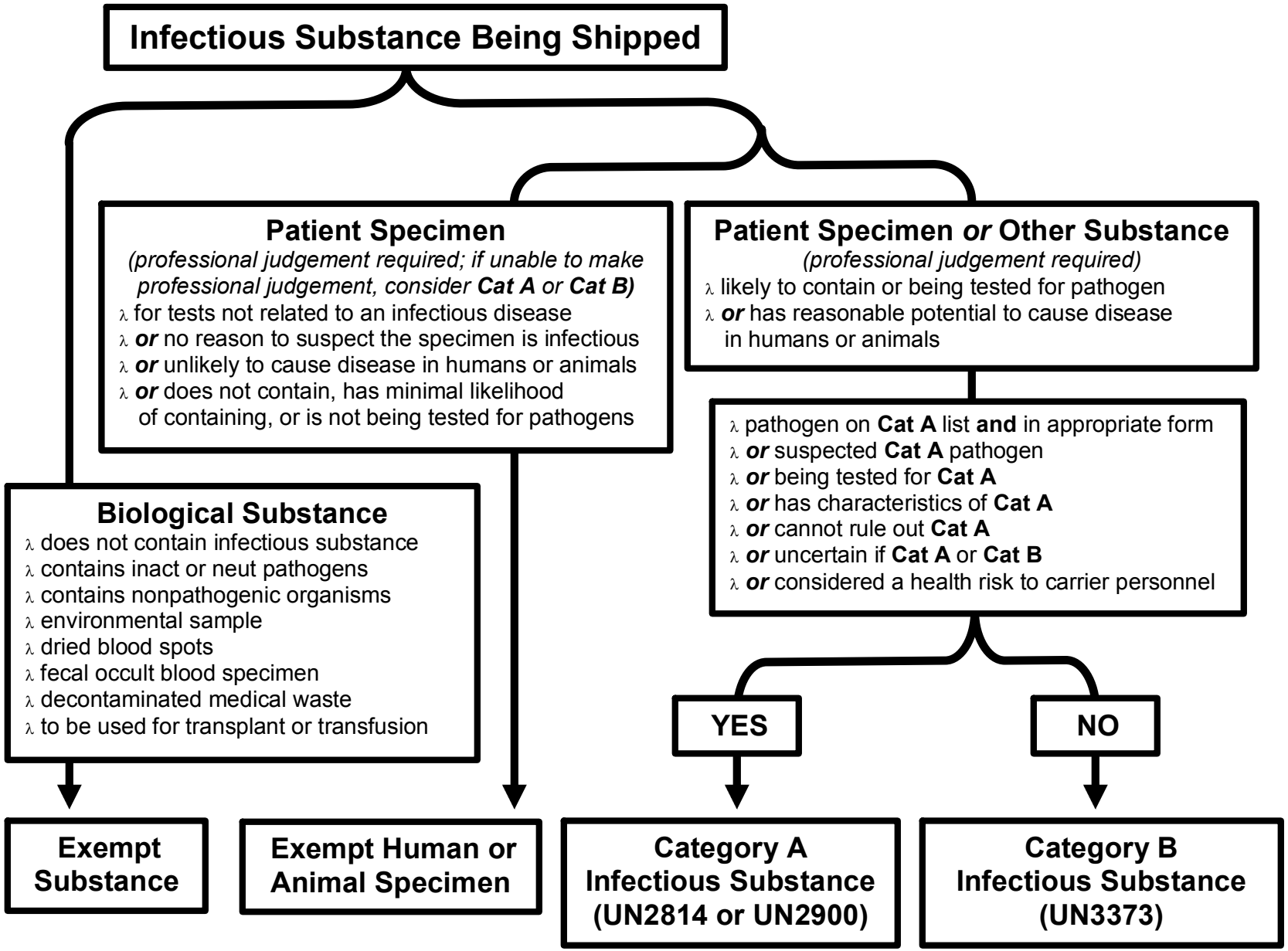


FIGURE 1 Algorithm for Classifying Infectious Stances

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

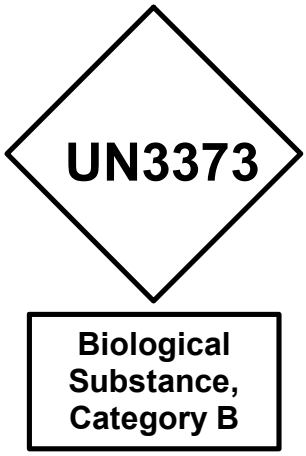
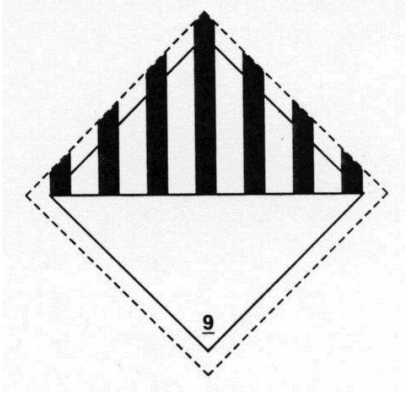


FIGURE 3 Labels which indicate a Biological Substance, Category B and appropriate UN number.



Dry Ice

2 kg

FIGURE 4 Labels which indicate a miscellaneous (Class 9) dangerous good (2 kg of dry ice).

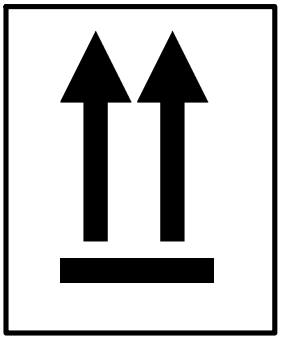


FIGURE 5 Label which indicates correct orientation of package during shipping.

Danger!
DO NOT Load in
Passenger Aircraft

FIGURE 6 Label which indicates substance must be transported only in cargo (not passenger) aircraft.

OVERPACK

FIGURE 7 Label which indicates an overpack is used and inner packages comply with regulations.

Exempt Human Specimen

F**IGURE 8** Label which indicates an Exempt Human Specimen

UN

4G/CLAS 6.2/2004

CAN/8-2 AIRPACK

FIGURE 9 Example of a label which indicates outer container has met UN-specified manufacturing standards

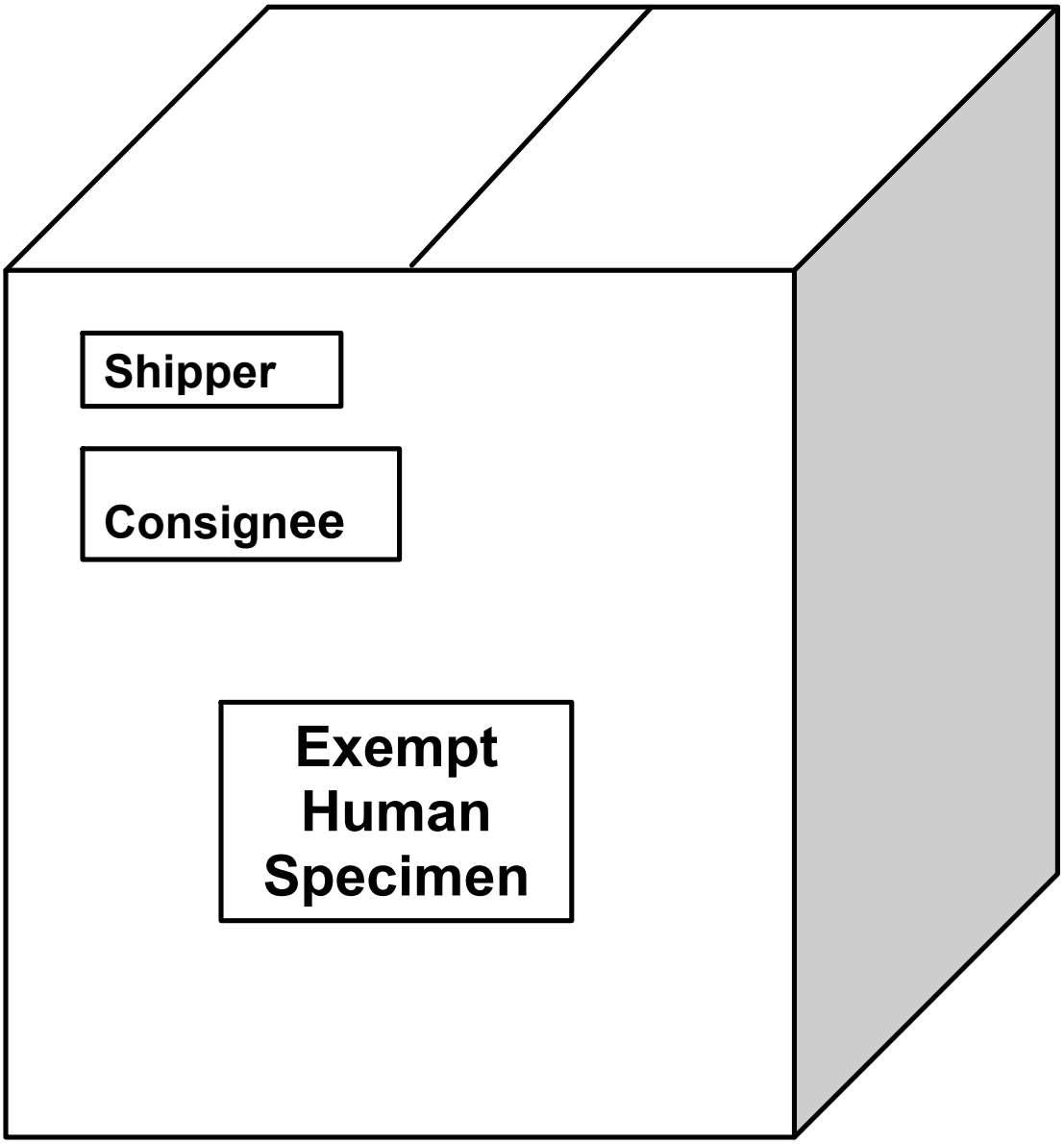


FIGURE 10 Example of an appropriately labeled outer package. The primary container inside the package contains an Exempt Human Specimen and is packed according to IATA instructions.

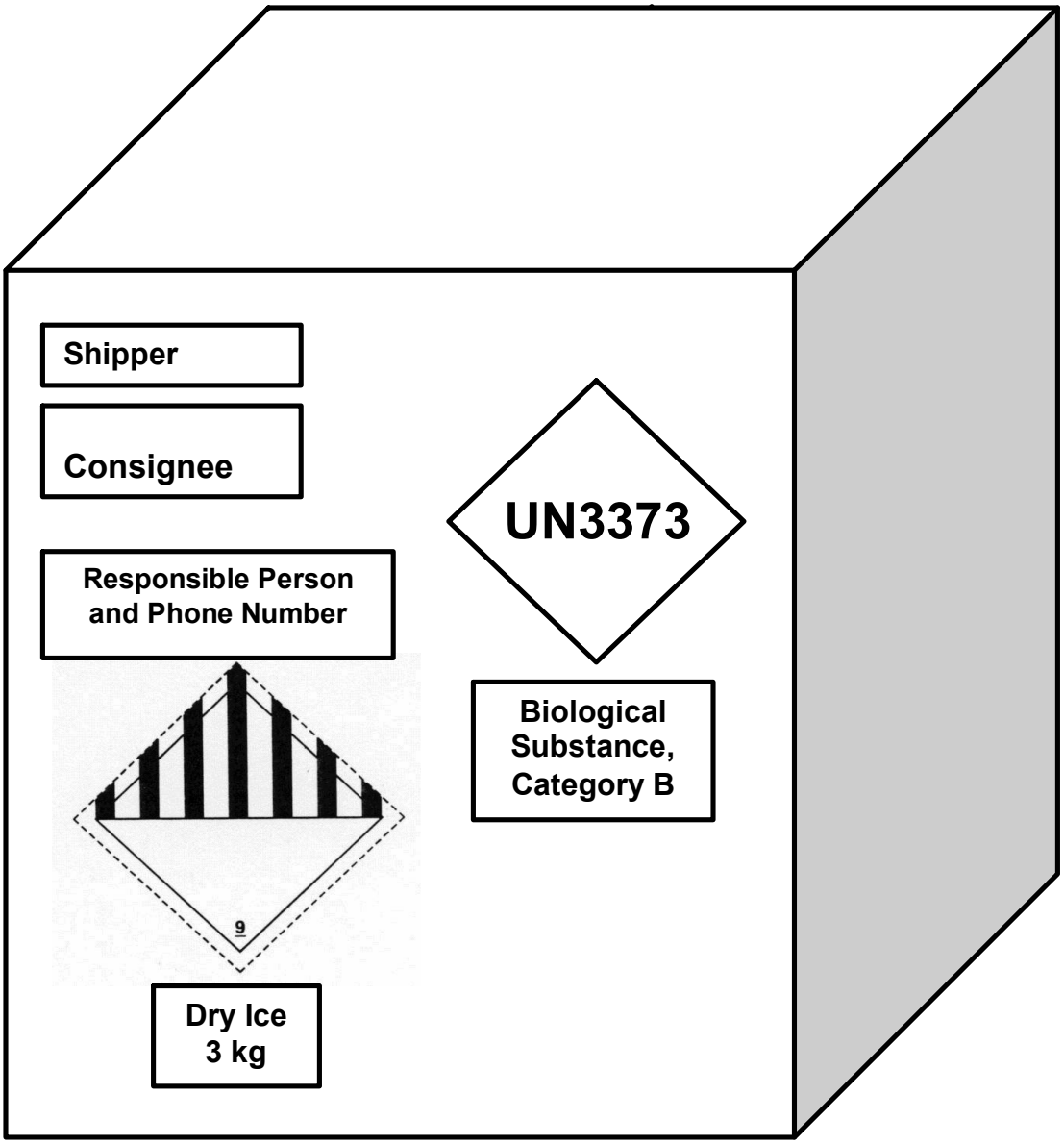


FIGURE 11 A completely labeled outer package. The primary container inside the package contains a Biological Substance, Category B substance and is packed according to PI 650.

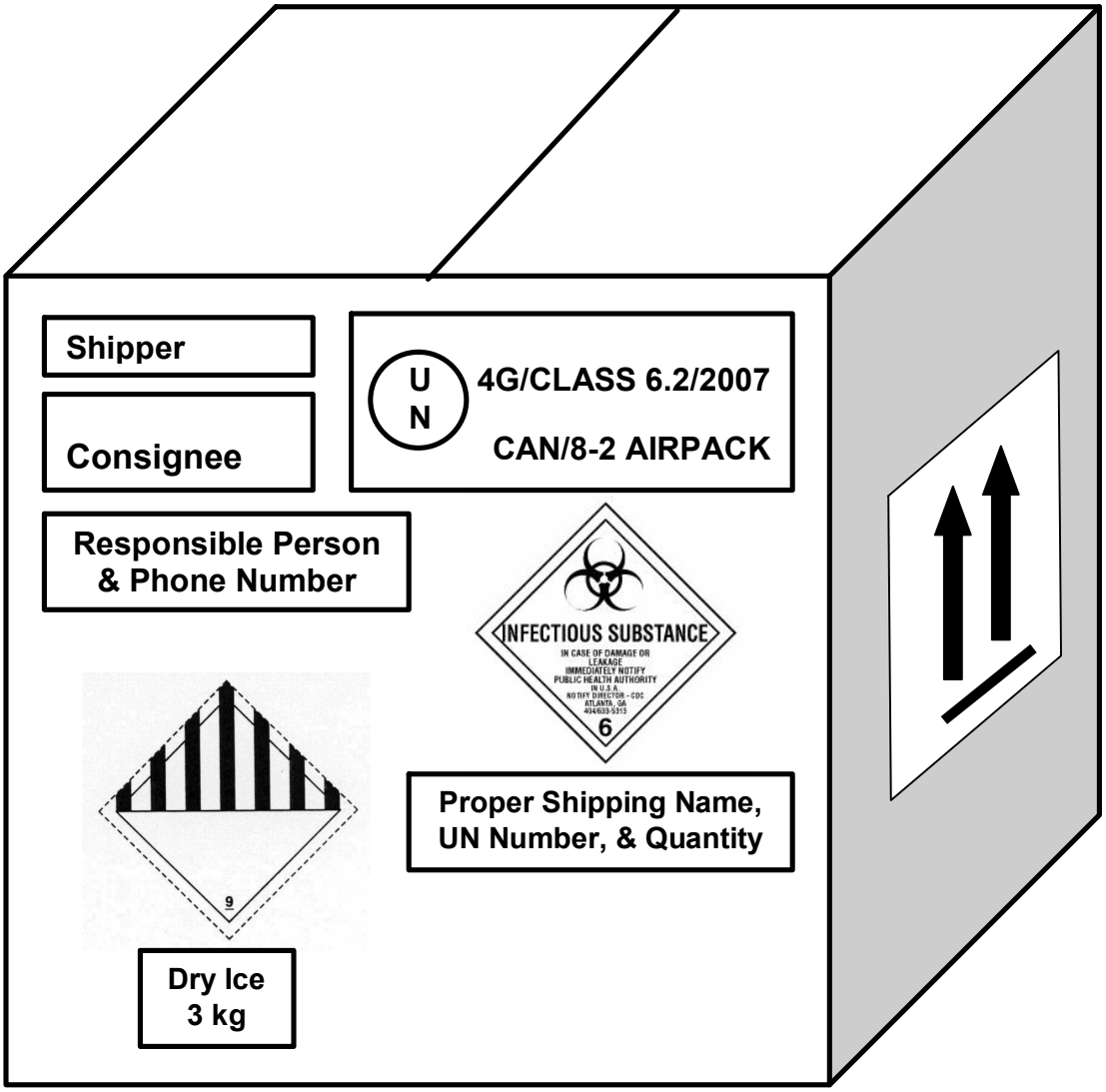


FIGURE 12 A completely labeled outer package. The primary container inside the package contains a Category A infectious substance and is packed according to PI 602.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper **1**

Air Waybill No.

Page **3** of **4** Pages

Shipper's Reference Number *(optional)*

Consignee **2**

***name, address, and logo of company* (optional)**

Two completed and signed copies of this Declaration must be handed to the operator.

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.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for: *(delete non-applicable)* **5**

PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY

Airport of Departure: **6**

Airport of Destination: **7**

Shipment type: *(delete non-applicable)* **8**

NON-RADIOACTIVE	RADIOACTIVE

NATURE AND QUANTITY OF DANGEROUS GOODS **9**

Dangerous Goods Identification

UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Pack-ing Group	Quantity and type of packing	Packing Inst.	Authorization
a	**b**	**c**	**d**	**e**	**f**	**g**

Additional Handling Information **10**

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 **11**

Place and Date **12**

Signature *(see warning above)* **13**

FIGURE 13 Shipper's Declaration for Dangerous Goods and 13 sections which must be completed by the shipper.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS

Shipper
Wilkins Laboratories
1970 Tarheel Avenue
Pacolet, SC 27105

Air Waybill No.

Page **1** of **1** Pages

Shipper's Reference Number
(optional)

Consignee **Dr. William Truitt**
7 Elephants Foot Trail
Charlotte, NC 45227
Responsible Person and Number:
Janet Irwin (919) 271-5432

Wilkins Laboratories

Clinical Microbiology Services

Two completed and signed copies of this Declaration must be handed to the operator.

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.

TRANSPORT DETAILS

This shipment is within the limitations prescribed for:
(delete non-applicable)

PASSENGER AND CARGO AIRCRAFT	~~CARGO AIRCRAFT ONLY~~

Airport of Departure:

Airport of Destination:

Shipment type: *(delete non-applicable)*
NON-RADIOACTIVE [redacted]

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification						
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Risk)	Packing Group	Quantity and type of packing	Packing Inst.	Authorization
UN 2814	**Infectious substance, affecting humans (*Mycobacterium tuberculosis*)**	**6.2**		**2 mL**	**602**	
UN 1845	**Dry ice**	**9**	**III**	**4 kg packed in a single cardboard box**	**904**	

Additional Handling Information

Emergency Contact: (800) 745-1122

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
John E. Wilkins, Director

Place and Date
Pacolet, SC October 29, 2005

Signature
(see warning above) *John E. Wilkins*

FIGURE 14 Completed Shipper's Declaration for Dangerous Goods.