Bassett Healthcare Network

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4.0	Approved and Current	Major revision	12/9/2022	12/19/2022	Indefinite
3.0	Retired	Initial version	8/5/2022	8/19/2022	12/19/2022

SHIPPING PATIENT SPECIMENS OR INFECTIOUS SUBSTANCES FROM THE CLINICAL LABORATORY

- *Shipping Infectious Substances - Category A and B* Infectious Substances are considered "Dangerous Goods" (DG) which may include Diagnostic Patient specimen(s) and/or culture(s).

INTRODUCTION

The information presented here is a summary of current interpretation requirements and Bassett Medical Center clinical laboratory shipping protocol. This guideline is taken from Chapter 21 of *Biological Safety – Principles and Practices*, 4th edition; *Sentinel Level Clinical Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases; Packaging and Shipping Infectious Substances, revised April 27,* 2021, American Society for Microbiology (website) and *Shipping Infectious Substances And Related Materials* SAF-T-PAK (website).

This document provides practical guidance to facilitate compliance with current national and international shipping regulations. The regulations governing the transport of infectious substances and diagnostic specimens change frequently. Shippers are responsible for being aware of these changes, adhering to current regulations, and interpreting applicable regulations for themselves and their facilities.

The purpose of "specialized" packing and shipping of infectious substances is to protect both the contents of the packages and the persons who handle the packages. Risk assessment is based on the *actual* health risk of transporting these substances, i.e., risks based on expert scientific and medical evaluation of the substances *in their shipped form* and the circumstances under which the substances can cause diseases. Historically, regulations have been based on *perceived* risks, i.e., risks based on epidemiological information which was not relevant to the transport of these substances.

GOVERNING AUTHORITIES AND REGULATIONS (Table 1)

Laboratory workers who ship or transport dangerous goods, in general, diagnostic specimens and infectious substances, by a commercial land or air carrier are required to follow a complex and often confusing set of national and international regulations and requirements. The purpose of these regulations and requirements is to protect the public, emergency responders, laboratory workers, and personnel in the transportation industry from accidental exposure to the contents of the packages.

The information presented here is a summary of interpretations of the current (as of April 27, 2021) requirements and regulations issued by the following:

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

Typically, air transport regulations are the most restrictive and the packaging specifications are the most rigorous. Shippers who comply with the air transport regulations also will meet the requirements of other transport modes. While there are some differences between the regulations for transport by air and by other modes (truck, rail, etc.), the vast majority of diagnostic specimens in the United States are packaged to comply with air transport requirements. Here, we have summarized the regulations of both the Department of Transportation (DOT) and the International Air Transport Association (IATA) into a single set of requirements. If there is a difference in meaning between the governing transport regulatory agencies published regulations, the more restrictive rule is cited.

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[e] 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

[e] C023 describes the general standards, restrictions, and prohibitions that apply to the mailability of hazardous materials.

CLASSIFICATION OF A SUBSTANCE

Classification is a mandatory process to define dangerous goods that are shipped by commercial carriers. Classification serves two purposes: (a) it allows the shipper to select the proper IATA packing instructions (PI) and (b) if the substance is a Category A infectious substance, it provides important information necessary to complete the Shipper's Declaration.

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

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

Second - Class 6 Toxic and Infectious substances must then be **divided into either Division 6.1 (Toxic substances) or Division 6.2 (infectious substances)**.

"An infectious substance is a material **known or reasonably expected to contain a pathogen**."

"Pathogens" are defined as micro-organisms (including bacteria, viruses, rickettsia, parasites, fungi) or other agents such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals."

A typical lab scenario deals strictly with Class 6, Division 6.2 Infectious substances and/or Class 9 Miscellaneous dangerous goods (dry ice). Refer to Table 2 – blue & yellow highlight.

Third - Class 6, Division 6.2 infectious substances (Patient sample, (micro) organism isolate, or genetically modified (micro) organism (GMMO/GMO) must be **placed into one of two IATA-specified categories: Category A or Category B.** A third category "Exempt Human or Animal Specimens is described in this document, yet at Bassett Medical Center the category "EXEMPT" is not used for packaging, shipping and/or labeling. An item considered in the category "EXEMPT" is treated as a Category B infectious agent. (Table 3)

a. Category A infectious substances (yellow highlight)

Category A Infectious Substance – High containment, highly-pathogenic deadly viruses, and cultures. An infectious substance in a form capable of causing permanent disability, or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.

UN2814 – Infectious substances, affecting humans
UN2900 – Infectious substances, affecting animals

b. Category B infectious substances (green highlight)

Category B Infectious Substance – Infectious material not considered to be highly pathogenic, or routine diagnostic specimens. An infectious substance that is NOT in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.

UN3373 – Biological Substance, Category B

1. 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),

2. Typical clinical laboratory cultures (usually on solid media) of routinely encountered non-Category A microorganisms grown and used in clinical microbiology laboratories.

3. Exempt Human or Animal Specimens (**pink highlight**). At Bassett Medical Center the category "EXEMPT" is not used for packaging, shipping and/or labeling. As mentioned above an item considered in the category "EXEMPT" is treated as a Category B infectious agent.

4. "Exempt human specimen" apply to patient specimens for which there is "minimal likelihood that pathogens are present", these samples are not subject to the above mentioned Regulations if the specimen is transported in triple packaging and which marked with the words "Exempt human specimen".

5. Exempt human and animal specimens are not assigned a UN number or proper shipping name.

i. Substances or specimens known to contain or suspected of containing a nonpathogenic micro-organisms
ii. Substances containing non-pathogenic micro-organisms
iii. Neutralized or inactivated pathogens
iv. Environmental samples
v. Blood and blood products collected for transfusion
vi. Organs and tissues intended for transplant
vii. Dried blood spots
viii. Fecal occult blood screening samples
ix. Biological product subject to federal approval – vaccines

c. Genetically Modified Organism (GMO)- Genetically modified organisms or microorganisms where the genetic material has been intentionally altered using genetic engineering in a manner that would not naturally occur. Pathogenic genetically modified organisms must be classified as either Category A or Category B Infectious substances.

GMO will not be addressed in this document

d. Medical Waste – Regulated medical waste or clinical waste or biomedical waste are wastes or reusable material derived from the medical treatment of an animal or human.

Medical Waste (not addressed in this document)

TABLE 3 Summary, Nine IATA-specified groups): (IATA, April 2021)

Class 6 Division 6.2 Infectious Substance	IATA Classification
Category A substances	Category A
Category B substances	Category B
Patient Specimens	
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 (Micro)organisms	
Meets Category A criteria	Category A
Meets Category B criteria	Category B
Does not meet Category A or B criteria	Genetically Midified (Micro-) Organism
Exempt Substance	none
Medical Waste [a]	
Biological Products [a]	
Infected Animals [a]	

[a] Substance is not addressed in detail in this protocol

Fourth, if the **substance can not be directly placed into Category A, Category B,** the shipper must determine if the "substance" or Patient Specimen meets the criteria for Category A, or Category B status (Tables 3 and 4).

"Patient Specimen" - material collected directly from humans or animals for diagnostic, treatment, prevention, investigational, or research purposes.

Whenever you cannot determine if it is Category A or Category B, the shipper should go with the more dangerous classification to ensure human safety.

NAMING A SUBSTANCE (Appendix D)

After classifying the substance, the shipper must identify (officially name) a Category A or Category B agent by assigning the substances one of the over 3,000 IATA-specified and internationally recognized UN numbers and proper shipping names listed in the IATA regulations (Tables 4).

TABLE 4 Types, proper shipping names, UN numbers, and packing instructions (or directions) for IATA class 6.2 infectious substances (IATA, 2016) and Class 9 substances GMO, Dry Ice.

Infectious Substance	Proper Shipping Name	UN Number	Packing Instructions	Spec Prov
Category A substances	Infectious Substance, affecting humans[a]	2814	620	A81 A140
	Infectious Substance, affecting animals[a]	2900	620	A81 A140
Category B substances	Biological Substance, category B	3373	650	
Exempt Human or Animal Specimens	none	none	none [c]	
Exempt Human or Animal Specimens	none	none	none [b]	
Exempt Substances	none	none	see text	
Patient Specimens				
Meets Category A criteria	Infectious Substance, affecting humans[a]	2814	620	A81 A140
	Infectious Substance, affecting animals[a]	2900	620	A81 A140
Meets Category B criteria	Biological Substance, category B	3373	650	
other (see Exempt Human or AnimalSpecimen)	none			
Genetically Modified Microorganisms				
Mmeets Category A criteria	Infectious Substance, affecting humans[a]	2814	620	A81 A140
	Infectious Substance, affecting animals[a]	2900	620	A81 A140
Meets Category B criteria	Biological Substance, category B	3373	650	
Does not meet Category A or B criteria [c]	Genetically Modified Microorganisms	3245	959[c,d]	A47
Dry Ice[b]		1845	954	A48 A151
Medical Waste [c]				
Biological Products [c]				
Infected Animals [c]				

[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)".
[b] not an infectious substance, but relative to this procedure
[c] Substance is not addressed in detail in this protocol.
[d] Except for the type of diamond-shaped label required on the outer package, PI 959 can be considered to have the same status, format, and content as PI 650.

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. Fortunately, only 4 of the 3,000 proper shipping names are used by most clinical laboratories: Category A – "Infectious substance affecting humans", Category A – "Infectious substance affecting animals", "Biological Substance category B" and "Dry Ice" or "Carbon Dioxide Solid" .

PACKING INSTRUCTIONS AND PACKING SUBSTANCES

DOT regulations, IATA requirements, and IATA Packing Instructions (PI – Table 4)) 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, and for packing substances correctly to ensure the safety of all personnel who handle the package before, during, and after shipment to the point of acceptance of the package by the consignee.

Generally, the PI (Packing Instructions) used in clinical laboratories are those that relate to shipping Category A infectious substances (PI 620); Category B infectious substances (PI 650); diagnostic, clinical, or biological substance, category B substances (PI 650); and dry ice (PI 954). See Table 5 for a comparison of the details of packing instructions and directions.

TABLE 5 Comparison of IATA packing instructions 650 and 602, and packing directions for exempt human specimens

Requirement	Exempt Human Specimens [a]	PI 650 [b] Cat B	PI 620 [c] Cat A
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 [g]	Many [g]
name and number of responsible person	--	Yes [h]	yes
markings and labels	yes [i]	Less [g]	More [g]
Quantity limits for Either passenger or Cargo aircraft			
maximum for each 1° container	--	1 L / 1 kg	50mL/50 g
maximum total for each outer package	--	4 L / 4 kg	50mL/50 g
Documentation			
Shipper's Declaration for Dangerous Goods	--	no	yes
Emergency response telephone number	--	no	yes
Infectious substances Guide 158[d]	--	no	yes
Cost			
cost of labor and materials to pack substance	least [g]	more [g]	most [g]

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

[b] packing instructions 650

[c] packing instructions 620
[d] requirement not specified by IATA/ICAO but required by DOT
[e] not required for solid substances such as tissue and solid agar media cultures or slants
[f] should be "of adequate strength for its intended capacity, mass, and intended use" (IATA quote)
[g] See text for details
[h] may be placed either in the outer package or on the air waybill
[i] Only "Exempt Human Specimen" or "Exempt Animal Specimen"

Internal Packaging Instructions

PI 650 and PI 620 contain several similar instructions, the most notable of which are those which mandate the use of triple packaging for infectious substances (Table 5). The major differences are those associated with documentation and with marking and labeling outer containers. The similarities of and differences between PI 650 and PI 620 are shown in Table 5. Triple packaging required by both PI 650 and PI 620 consists of a primary container, a secondary container, absorbent material, list of contents, and an outer shipping package.

The packaging requirements that follow are designed to ensure that the specimens arrive at the destination in good condition and also to protect the hundreds of people that will be handling your shipment until it arrives at its final destination.

- Primary receptacle: The primary container is a watertight glass, metal or plastic tube, vial, swab, etc. containing the Category A or Category B infectious substance or specimen. The primary containers must initially be placed in bubble wrap to protect them against incidental damage.

  All isolates should be grown on slants. The tubes must have a screw cap. Do **NOT** send plates or liquid media (including broths), unless absolutely necessary. The one exception being ETM (Carey Blair) which contain enteric pathogens. Incubate the slants overnight under appropriate atmospheric conditions or until growth is obtained. The screw cap lids must be secured to the tube using polyethylene tape or parafilm.

- Secondary Receptacle: The secondary container is a leak proof, watertight zip-lock bag designed to contain the bubble wrapped infectious substance or specimen (primary container). The secondary receptacle also contains absorbent material. Absorbent material will be included in your packaging, but if not, use kay drys, Kleenex, paper towels; any absorbent material is suitable as long as you use enough to absorb the entire contents of the primary receptacles. The secondary container is ultimately designed to protect against leakage.

Either the primary or secondary container must be able to withstand an internal pressure of at least 95 pKa (13.8 lbs/in2) because shipments are likely to be placed into unpressurized cargo sections of aircraft which fly at high altitudes.

- NYSDOH mailers provide an additional layer of internal packaging. This layer consists of a rigid outer Specimen Transport bag with a secure adhesive seal. The specimen transport bags are prelabeled with a red BIOHAZARD label and color coded symbols to indicate the Bacteriology specialty or subspecialty area where the package will be processed. These containers also aid in maintaining specimen integrity and allow for a maximum of 10 tubes per shipment or 50 ml (each tube is estimated to be 5 ml or 5g). For infectious substances being shipped in passenger aircraft, the maximum volume per primary container must not exceed 50 mL or 50 g. If this limit is exceeded, the

samples may only be shipped using "Cargo aircraft. For infectious substances being shipped in cargo aircraft, the maximum volume per primary container must not exceed 4 L or 4 kg.

- An itemized list of the contents and quantities of the primary container(s) must be attached to the outside of the secondary container mentioned above. This list informs the recipient what to expect before opening up the plastic or metal container. It also warns what is in the container if the outer box should come open during transit. The NYSDOH "Bacteriologic, Parasitology Examination History" forms fulfills the itemized list requirement. The Infectious Disease forms are accessed using the New York State Health Commerce System website, using the CLIMS option and Remote Order.

  Log on to the Health Commerce System (ny.gov)

- 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 infectious substances, these outer containers must meet United Nations manufacturing and testing specifications. NYSDOH supplies outer packaging with the infectious agent mailers mentioned above. The outer package or box is prelabeled with color coded mailing address labels, a color for each Bacteriology specialty or subspecialty where the package will be processed. The color of the address labels match the color of the color coded symbol of the Specimen Transport bags.

EXTERNAL PACKAGING INSTRUCTIONS (MARKING AND LABELING PACKAGES)

Marking is the act of writing or typing information onto the surface of an outer package.
Labeling is the act of placing informational labels or stickers onto the surface of an outer package. The shipper is responsible for the proper marking and labeling of the outer shipping container as described in the DOT and IATA regulations. The marking and labeling on the outer container communicates 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. The outer package must display markings and labels appropriate for the particular shipment. These labels and markings include the following (see figures below):

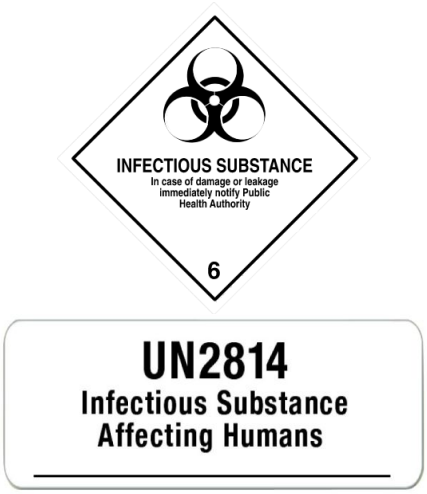
• Category A infectious substance:

a) The Class 6 diamond-shaped "Infectious Substance. In Case of Leakage..." label [This label is identical for the regulatory agencies except that the DOT version of the label specifies notification of CDC by telephone in case of damage or leakage.] and (b) a label which shows the proper shipping name, UN number.

b) The shipper's and consignee's name and address (To/From Label). 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.

c) The name and telephone number of a "responsible person" (IATA quote) who is knowledgeable of the contents of the shipment and can provide emergency information in case the package is damaged and the contents escape their containment must be on the outer container or the air waybill. If the substance being shipped is a diagnostic (or clinical) specimen, this information may be provided on either the air waybill or the outer package.

FIGURE 1 Labels which indicate an infectious substance (Class 6), proper shipping name, UN identification number.



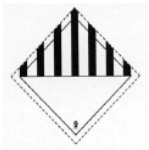
• Category B substance:
(a) “Biological Substance Category B” and the marking or label “UN3373” (IATA-Fig. 2)

FIGURE 2 Markings which indicate a Biological Substance, Category B and appropriate UN Number.

• If dry ice is used: a Class 9 “Miscellaneous Dangerous Goods” label and the weight of dry ice (Fig. 3). The packaging must permit the release of carbon dioxide gas and prevent the build-up of pressure that could rupture the package. UN 1845, PI 954.

NEVER put dry ice or cold packs inside the inner container of the secondary packaging

FIGURE 3 Label which indicates a miscellaneous (Class 9) dangerous good (2 kg of dry ice).



Dry Ice
2 kg

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

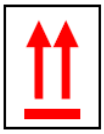


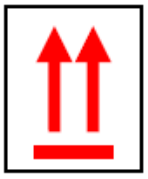
FIGURE 5 Label which indicates correct orientation of package during shipping.

Danger!
DO NOT Load in
Passenger Aircraft

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

• ↑↑ (Package Orientation Labels), *This Way Up.* Two package orientation labels must be placed on opposite sides of all packages which contain >50 mL of an infectious substance to indicate the correct orientation of the package.

FIGURE 4 Label which indicates correct orientation of package during shipping.



• "Cargo Aircraft Only" label if the substance (because of its quantity) can be transported only by cargo aircraft (Fig. 5). This label is used if infectious substance amounts over 50 mL (5g) but less than 4 L (4 kg) per package are shipped.

FIGURE 5 Label which indicates substance must be transported only in cargo (not passenger) Aircraft.

Danger!
DO NOT Load in
Passenger Aircraft

FIGURE 6 Marking which indicates an overpack is used and inner packages comply withregulations.

OVERPACK

FIGURE 7 Package Label which indicates outer container has met IATA-specified manufacturing standards.

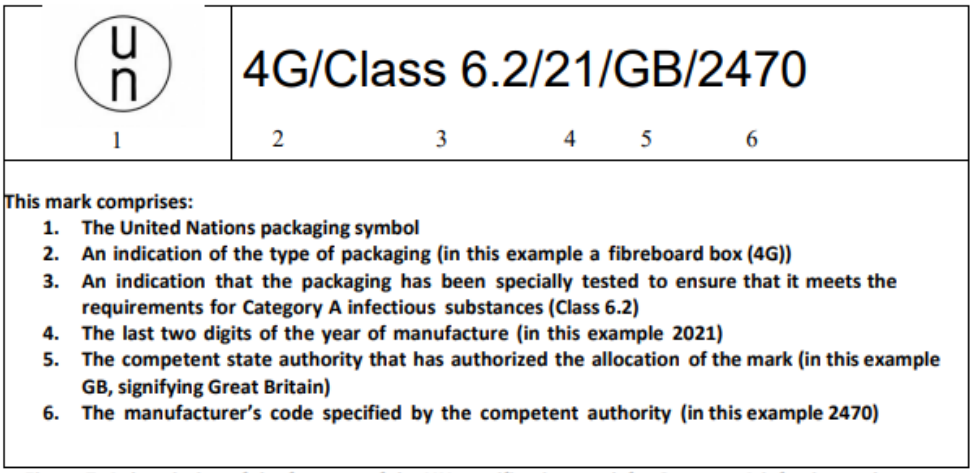


Figure 7. A description of the features of the UN specification mark for Category A infectious substances packaging (for UN 2814 and UN 2900).

FIGURE 8 NYSDOH Enhanced Mailers, have affixed one of the following address labels as appropriate: Bacteriology: (Blue), Parasitology: (Red), Mycology: (Green), Mycobacteriology: (Pink)

Specimen enhanced mailers can be ordered from NYSDOH by calling the Order Desk at (518) 474-4175.

For questions call the New York State Department of Health at (518) 474-4177 and ask for the department or specialty laboratory that the question pertains to: bacteriology, parasitology, mycobacteriology, virology, serology, mycology, biodefense.

Figures 9 and 10 show completely labeled and marked outer shipping containers which contain a Category A infectious substance, and a Biological Substance, Category B. respectively. Packages in

Figures 10 and 11 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 must be completely labeled according to applicable IATA regulations (Fig. 6).

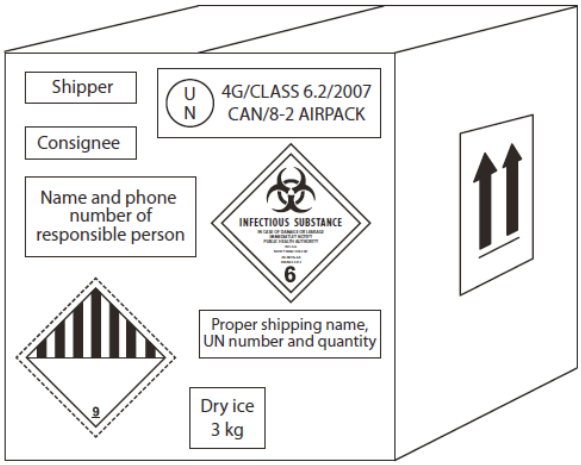


FIGURE 9. A completely labeled outer package. The primary container inside the package contains a Category A infectious substance and is packed according to PI 620.

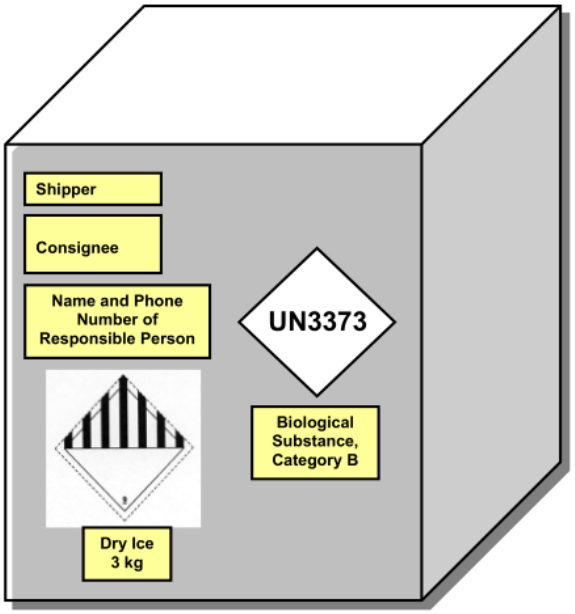


FIGURE 10. A completely labeled outer package. The primary container inside the package contains a Biological Substance, Category B substance (diagnostic or clinical specimen) and is packed according to PI 650.

DOCUMENTATION

1. Category A, Infectious Substance, affecting humans

For overnight shipment of Class 6, Division 6.2, Category A infectious agents: **Fed Ex is the only carrier certified for the transport of Class 6, Division 6.2, Category A infectious substances**. Shipment of Category A Infectious Substances requires a Shipper's Declaration. A Shipper's Declaration is a legal contract between the shipper and carrier. The Shipper's Declaration is required to document the shipment of all Class 6, Division 6.2, Category A Infectious substances. Fed Ex will **not** accept a handwritten Shipper's Declaration form. The Shipper's Declaration template is available at https://apps.saftpak.com/ , "shipping document assistant" (using Firefox default browser). The Shipper's Declaration given to the carrier must have vertical red candy stripes along the left and right edges of the document. . The form must be accurate, and legible or the carrier will reject the package for transport.

Shippers are advised to retain a copy for their records. 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, and inspect facilities from which the package 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. Figure 14 shows a completed and acceptable Shipper's Declaration. If a Shipper's Declaration is not correct to the carrier's satisfaction, the shipment will be rejected by the carrier. An "emergency response telephone number" is required to be provided on Shipper's Declarations which accompany shipments of Category A infectious substances. The number must be monitored at all times by a person who has knowledge of the following: (a) the hazards of the material being shipped, (b) emergency response and accident mitigation information in case a handler contacts the released contents of the package, or (3) appropriate first aid information. 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 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.

Figure 11. Shipper's Declaration for Dangerous Goods and 13 sections which must be completed by the shipper.

SHIPPER'S DECLARATION FOR DANGEROUS GOODS (Provide at least three copies to the airline.)

Shipper 1

Air Waybill No. 3

Page of Pages 4

Shipper's Reference Number (optional)

Consignee 2

FedEx Express

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

WARNING

Failure to comply with 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

Dangerous Goods Identification				Quantity and type of packaging	Packing Inst.	Authorization
UN or ID No.	Proper Shipping Name	Class or Division (Subsidiary Hazard)	Packing Group			
9a	9b	9c	9d	9e	9f	9g

Additional Handling Information

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 thatall of the applicable air transport requirements have been met.

Name/Title of Signatory 11

Place and Date 12

Signature *(see warning above)* 13

10 Emergency Telephone Number

[A typed signature may be used if the shipper and consignee are in the United States or its territories]

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

1. **Enter the full name and address of the shipper.** ***Information must be entered by the shipper***. The name and address which appears on the Shipper's Declaration may differ from that on the Air Waybill (IATA 8.1.6.1).

2. **Enter the full name and address of the consignee.** *Must be entered by the shipper* (IATA 8.1.6.2).

3. **Enter the number of the Air Waybill to which the Shipper's Declaration will be attached.** *This information may be entered or changed by the shipper, the shipper's agent, the airline or the airline's handling agent* (IATA 8.1.6.3).

4. **Enter the page number and total number of pages.** *Information must be entered by the shipper.* If there is no extension list, enter "Page 1 of 1" (IATA 8.1.6.4).

5. **Indicate whether the shipment is packed to comply with limitations for passenger aircraft.** *Information must be entered by the shipper.* Delete either "Passenger and Cargo Aircraft" or "Cargo Aircraft Only" to indicate whether or not the shipment can be carried on passenger aircraft, or must be carried only on cargo aircraft. It is sufficient if just the applicable aircraft type is shown. (IATA 8.1.6.5).

6. **Enter the full name of the airport or city of departure.** *This information may be entered or changed by the shipper, the shipper's agent, the airline or the airline's handling agent (IATA 8.1.6.6).*
Note: This information is optional and may be left blank.

7. **Enter the full name of the airport or city of destination.** *This information may be entered or changed by the shipper, shipper's agent, the airline or the airline's handling agent.* (IATA 8.1.6.7)
Note: This information is optional and may be left blank.

8. **Delete "Radioactive" to indicate the shipment does not contain radioactive material.** *Information must be entered by the shipper.* Radioactive material must not be included on the same Declaration form as other dangerous goods, except as authorized in IATA 8.1.6.8. It is sufficient if just "Non-Radioactive" is shown.

   Exception: Special Provision A130, A194.

9. **Enter the required information strictly in accordance with IATA 8.1.6.9.**

   NOTE: Columns indicated are those in the List of Dangerous Goods (IATA 4.2).

   a. **UN Number or ID Number** (Column A), preceded by "UN" or "ID" as appropriate.
   b. **Proper Shipping Name** as shown in (Column B), as determined by 4.1.2 and 8.1.3, technical name(s) are only to be entered for proper shipping name shown with the (☛) notation.
   c. **Class Number or Division Number** as appropriate, for Class 1 - Compatibility Group (Column C). Subsidiary Hazard(s) as indicated (Column D) in parentheses following the class or division.

      Note: The word "Class" or "Division" may be included preceding the primary and/or subsidiary hazard class or division numbers.

   d. The applicable **Packing Group** (Column E) content which may be preceded by "PG" (e.g. "PGII").
   e. **Number of packages** (of the same packaging type and content) and their type of packaging (spelled out in full) **and the net quantity or gross weight as applicable** (as specified in IATA 8.1.6.9.2 Step #6).

      When two or more different dangerous goods items are packed in the same outer package, the words "**All Packed in One**" must immediately follow the relevant entries.

      When an overpack is used, the wording "**Overpack Used**" must be inserted on the declaration form immediately after all relevant entries relating to the packages within the overpack.

      Additional requirements for multiple overpacks noted (see IATA 8.1.6.9.2 and 7.1.7.1).

   f. **Number of the Packing Instruction or of the Limited Quantity Packing Instruction** (Column G, I, or K as appropriate).
   g. **Authorizations** as applicable (in accordance with IATA 8.1.6.9.4 Step #9).
      - Note: See Operator Variations for FedEx Express Restrictions.
      - When a competent authority/exemption is used:
        - a copy must accompany the shipment
        - the approval number must appear on the shipper's declaration
        - the statement "Classified in accordance with 3.0.1.6 of the DGR." must be included on the shipper's declaration, if the competent authority classifies the shipment as per IATA 3.0.1.6.

        Authorizations and/or exemptions which must accompany your shipment must either be in English, or be accompanied by an accurate translation in English.
      - Fireworks of UN 3336 and UN 3337 require a reference issued by the appropriate national authority (IATA 8.1.6.11.5).

      Note: Amendments and alterations. Operators will not accept a declaration form that has been amended or altered unless the entry has been signed by the shipper shown in the signature block of the declaration form (8.1.2.6)

10 **Enter any special handling information relevant to your shipment.** *Information must be entered by the shipper.*

a. All dangerous goods shipments to, from, within, or transiting through the U.S. must include a 24-hour emergency response telephone number (IATA 2.8.1, USG-12).

Exceptions:
See USG-12 for exceptions.

b. When shipping Division 4.1 self-reactive substances, other substances having similar properties, and Division 5.2 organic peroxides with Special Provision A20, the shipper must indicate that the packages containing such substances must be protected from direct sunlight and stored away from all heat sources in a well ventilated area (IATA 8.1.6.11.1).

c. When a sample of a self-reactive substance or an organic peroxide is transported, a statement to this effect must be included in the "Additional Handling Information" box.

d. Infectious Substances and Controlled Substances. The name and telephone number of a responsible person must be included on the Shipper's Declaration. (IATA 8.1.6.11.4)

e. Viscous flammable liquids assigned to Packing Group III in accordance with the provisions of 3.3.3.1.1 a statement must be included on the shipper's declaration and should appear in the Additional Handling Information section. "UN xxxx 3.3.3.1.1" (IATA 8.16.11.6)

f. The statement "I declare that all of the applicable air transport requirements have been met" must either be after the certification statement or in the Additional Handling section. (IATA 8.1.6.12.2)

The name must be entered by the shipper, may be printed or stamped **.Enter the name of the person actually signing the Declaration. The title is optional and may be left blank.** (IATA 8.1.6.13).

Enter the date of signing the form. *Date must be entered by the shipper. The place is optional and may be left blank (*IATA 8.1.6.14).

NOTE: Title and Place are optional and may continue to display on the Shipper's Declaration as shown above through 12/31/2024. (IATA 8.1.7 Note) or the Shipper's Declaration may be shown without it. (IATA Figure 8.1.A and 8.1.B)

11 **Sign the Shipper's Declaration.**
Information must be entered by the shipper (IATA 8.1.6.15).

a. The signature should be written by hand; however, facsimile signatures are acceptable where applicable laws and regulations recognize the legal validity of facsimile signatures (IATA 8.1.4.1).

12 b. Typewritten signatures are not acceptable.

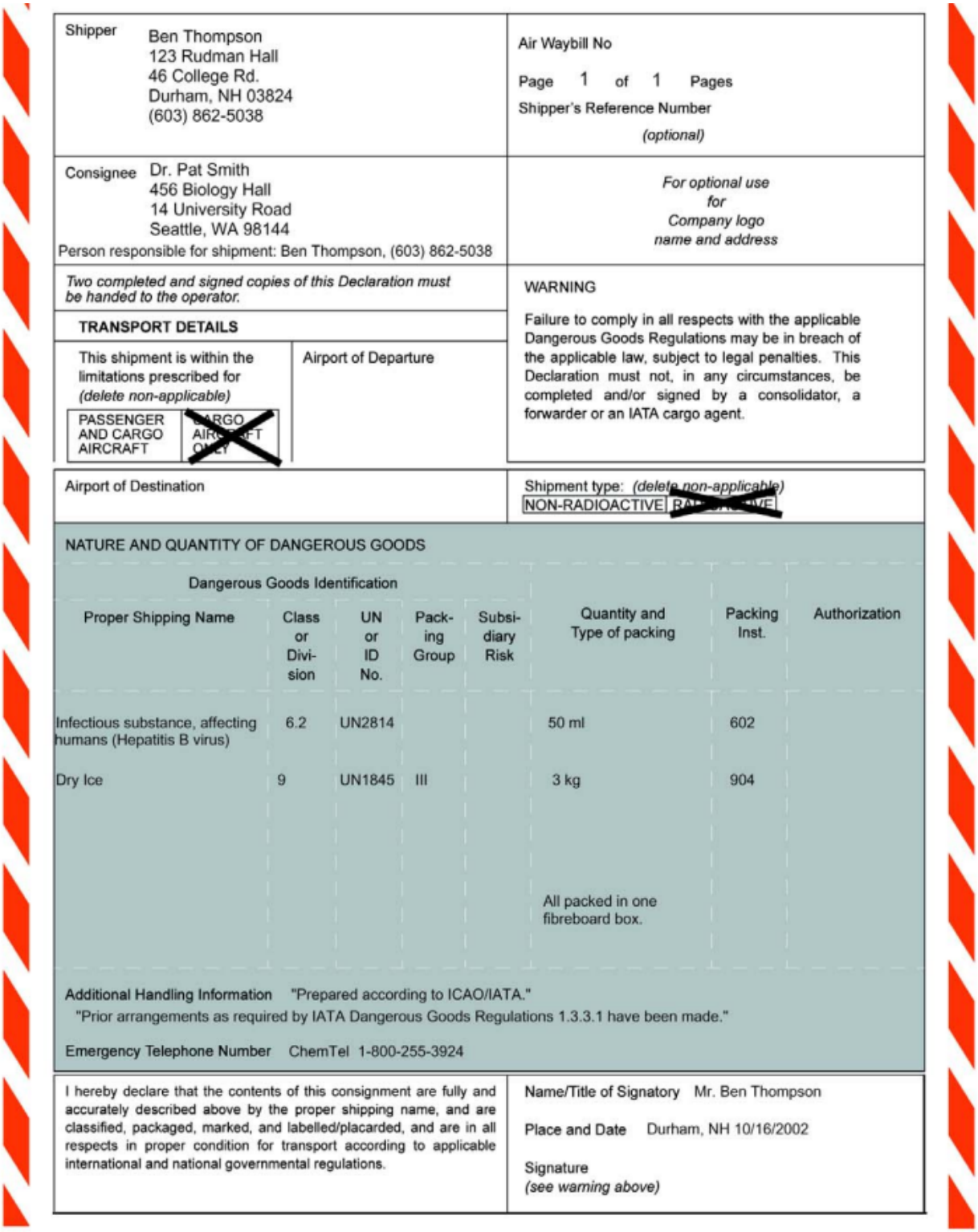
13 **FedEx Express requires all Shipper's Declarations to be prepared using software with dangerous goods compliance edit checks and by one of the following methods.**

- Certain FedEx® electronic shipping solutions.
- Recognized shipper proprietary software.
- FedEx recognized dangerous goods vendor software.

FX-18 excludes:

- Shipments originating in non-U.S. locations as well as US territories.
- U.S. shipments originating on an IATA 023 air waybill including FedEx International Express Freight® and FedEx International Premium® .
- *Shipments containing Class 7 radioactive materials.*
- *Contact the FedEx Express Dangerous Goods Hotline for additional inquires.*

FIGURE 12. Example of a completed (column form) Shipper's Declaration.



Shipper
Ben Thompson
123 Rudman Hall
46 College Rd.
Durham, NH 03824
(603) 862-5038

Air Waybill No

Page 1 of 1 Pages

Shipper's Reference Number
(optional)

Consignee Dr. Pat Smith
456 Biology Hall
14 University Road
Seattle, WA 98144

Person responsible for shipment: Ben Thompson, (603) 862-5038

For optional use for Company logo name and address

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. This Declaration must not, in any circumstances, be completed and/or signed by a consolidator, a forwarder or an IATA cargo agent.

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 ~~RADIOACTIVE~~

NATURE AND QUANTITY OF DANGEROUS GOODS

Dangerous Goods Identification							
Proper Shipping Name	Class or Division	UN or ID No.	Packing Group	Subsidiary Risk	Quantity and Type of packing	Packing Inst.	Authorization
Infectious substance, affecting humans (Hepatitis B virus)	6.2	UN2814			50 ml	602	
Dry Ice	9	UN1845	III		3 kg	904	
					All packed in one fibreboard box.		

Additional Handling Information "Prepared according to ICAO/IATA."
"Prior arrangements as required by IATA Dangerous Goods Regulations 1.3.3.1 have been made."

Emergency Telephone Number ChemTel 1-800-255-3924

I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked, and labelled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations.

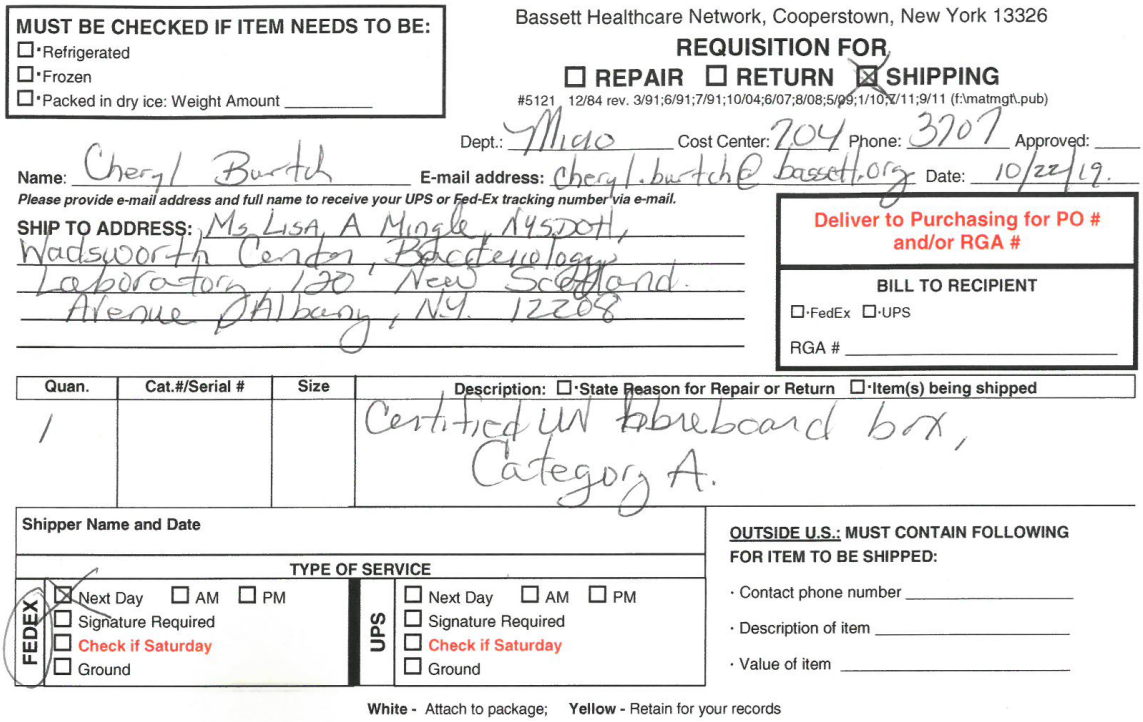
Name/Title of Signatory Mr. Ben Thompson

Place and Date Durham, NH 10/16/2002

Signature
(see warning above)

For Federal Express requests (items to travel to the MIB mailroom from the laboratory), complete a MIBH requisition for Repair and Returns form (see *Figure 13*). Include the type of service on the bottom of the form (Fed Ex Next Day AM, UPS, etc.) a statement declaring the contents of the package (UN certified fibreboard box, Category A), department (micro), cost center (704), Name (technologist specific), email address: cheryl.burtch@bassett.org, date and ship to address (identical to the ship to: package label). Detach the bottom ply of the completed form. This copy is retained in the microbiology department, shipping log, stapled to a signed copy of the Shippers Declaration and the yellow copy of the laboratory requisition. Tape the remaining plies of the Repair and Returns form on the package. A 1st Class Mail tag is also required for all outgoing packages. The 1st Class Mail tag is used for billing purposes and gives department specific contact information; in the event the package is returned to the hospital or there are questions concerning the package or packaging (see *Figure 14*).

Figure 13



MUST BE CHECKED IF ITEM NEEDS TO BE:
☐ Refrigerated
☐ Frozen
☐ Packed in dry ice: Weight Amount _____

Bassett Healthcare Network, Cooperstown, New York 13326

REQUISITION FOR
☐ REPAIR ☐ RETURN ☒ SHIPPING

#5121 12/84 rev. 3/91;6/91;7/91;10/04;6/07;8/08;5/09;1/10;7/11;9/11 (f:\matmgt\.pub)

Dept.: Micro Cost Center: 704 Phone: 3207 Approved: ____

Name: Cheryl Burtch E-mail address: cheryl.burtch@bassett.org Date: 10/22/19.

Please provide e-mail address and full name to receive your UPS or Fed-Ex tracking number via e-mail.

SHIP TO ADDRESS: Ms Lisa A Mingle, NYSDOH, Wadsworth Center, Bioterrology Laboratory, 120 New Scotland Avenue, Albany, N.Y. 12208

Deliver to Purchasing for PO # and/or RGA #

BILL TO RECIPIENT
☐ FedEx ☐ UPS
RGA # _____

Quan.	Cat.#/Serial #	Size	Description: ☐ State Reason for Repair or Return ☐ Item(s) being shipped
1			Certified UN fibreboard box, Category A.

Shipper Name and Date

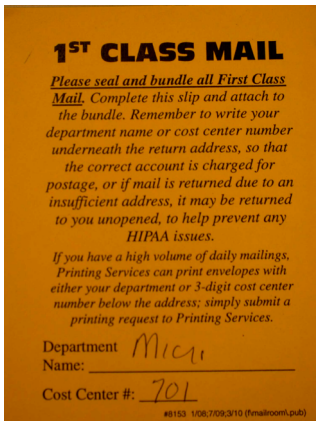
TYPE OF SERVICE

FEDEX: ☒ Next Day ☐ AM ☐ PM; ☐ Signature Required; ☐ Check if Saturday; ☐ Ground

UPS: ☐ Next Day ☐ AM ☐ PM; ☐ Signature Required; ☐ Check if Saturday; ☐ Ground

OUTSIDE U.S.: MUST CONTAIN FOLLOWING FOR ITEM TO BE SHIPPED:
· Contact phone number _____
· Description of item _____
· Value of item _____

White - Attach to package; Yellow - Retain for your records



1ST CLASS MAIL

Please seal and bundle all First Class Mail. Complete this slip and attach to the bundle. Remember to write your department name or cost center number underneath the return address, so that the correct account is charged for postage, or if mail is returned due to an insufficient address, it may be returned to you unopened, to help prevent any HIPAA issues.

If you have a high volume of daily mailings, Printing Services can print envelopes with either your department or 3-digit cost center number below the address; simply submit a printing request to Printing Services.

Department Name: Micro

Cost Center #: 701

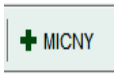
#8153 1/08;7/09;3/10 (f\mailroom\.pub)

2. Category B, Infectious Substance

For overnight shipment of Class 6, Division 6.2, Category B infectious agents, United Parcel Service (UPS) is the carrier employed by Bassett Medical Center laboratory services. An on-line blank shipping template is available at www.campusship.ups.com (see CLP procedure).

BASSETT HEALTHCARE FACILITY – FINAL PREPARATION

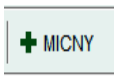
- **Infectious Substance Category A**
  - Close box and seal the seams of the box with packing tape found in CLP.
  - **Shipper's Declaration for Dangerous Goods** form is required. If the item is to be shipped overnight via FED-EX, 4 copies of the Dangerous Goods Form must be taped to the lid of the box, along with the Requisition for Repair/Return form and a 1st Class Mail tag.
  - In the LIS select the MICNY icon on the "culture" browser bar.

    Once selected the test MICNY is added on the same accession number as the culture. MICNY expands to "Microbiology Reference Laboratory Referral". MICNY contains 3 components: MICNY results show 2 options (once the test result is complete): "See Scanned Report" or "Referred Test – No Results Expected". The 2nd component is "Test name/number". This component is free text (Category A substance name). The 3rd component is "Reference Lab" which contains only one option: New York State.

    MICNY test code will appear on the Lab Microbiology Outstanding list for tracking purposes.
  - Place the package in outgoing mail before 11 am. If the 11 am deadline cannot be met, contact transport to ensure delivery to the Bassett mail room prior to 1:00 pm (M-W).
  - Fill out the microbiology send out log and file a copy of the paperwork (CLIMS Infectious Disease lab requisition, repair and return form, FED EX signed Shipper's Declaration for Dangerous Goods form) in the send out notebook. Shipping documents must be maintained for up to 2 years.

- **Infectious Substance Category B**
  - Dangerous Goods form is **NOT** required.
  - Close box and seal the seams of the box with packing tape.
  - In the LIS select the MICNY icon on the "culture" browser bar.

    Once selected the test MICNY is added onto the same accession number as the culture. MICNY expands to "Microbiology Reference Laboratory Referral". MICNY contains 3 components: MICNY test contains 2 result options (once the test result is complete): "See Scanned Report" or "Referred Test – No Results Expected". The 2nd component is "Test name/number". This

component is free text (Cryptosporidium, STEC, Strep pneumoniae, Salmonella …). The 3rd component is "Reference Lab" which contains only one results option: New York State.

MICNY test code will appear on the Lab Microbiology Outstanding list for tracking purposes.

- Shipment options (excluding Mayo clinic, ARUP and FOCUS laboratory):
  UPS - Place the package in outgoing mail before 11 am. If the 11 am deadline cannot be met, contact transport to ensure delivery to the Bassett mail room prior to 1:00 pm (M-W).

  UPSP (Postal Service) - Place the package in the outgoing mail bin. A completed 1st class mail tag must be attached to the top of the package.

- Fill out the microbiology send out log and file a copy of the paperwork (CLIMS Infectious Disease requisition and [if used] UPS CampusShip:Shipment Label) in the send out notebook. Shipping documents must be maintained for up to 2 years.

TRAINING AND CERTIFICATION

Anyone involved in the shipping or transportation of infectious substances must be trained in the shipment of dangerous goods. The essential components of a training program must include the following: (a) general awareness and familiarity with the many aspects of shipping dangerous goods, (b) importance, nature, and contents of IATA and DOT regulations, (c) function-specific training (hands-on and/or demonstrations) on packaging, marking, labeling and documentation of shipments of dangerous goods, (d) safety training, (e) testing, and (f) issuance of a certificate after successful completion of the training. IATA requires 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 certified 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.

- **Category A**: Specific **formal** training and documentation of it is required for all staff who package or transport items in this category.
- **Category B**: Documented training is required for all staff who package or transport items in this category. Those who ship Category B infectious substances such as samples for routine testing must be trained on the information and compliant packaging techniques presented in 49 CFR 173.199. Even though the training may be **informal** and in-house, it must be documented.

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.

APPENDIX B - INDICATIVE LIST (DOT & IATA FORMERLY“SELECT AGENTS

- **Category A Infectious Substances UN 2814 - Infectious substances meeting these criteria which cause disease in humans or both in humans and animals must be assigned to UN 2814.**
- **Category A Infectious Substances UN 2900 - Infectious substances which cause disease only in animals must be assigned to UN 2900.**

  The assignment to UN 2814 or UN 2900 must be based on known medical conditions, or professional judgment concerning individual circumstances of the source human or animal. There is a separation of UN2814 and UN 2900 on “the Indicative List (DOT and IATA).

Category A Infectious Substances 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. The table below is not meant to be all inclusive and cannot account for emerging pathogens. Any infectious substance that meets the definition of a Category A substance as defined above must be shipped and packaged as a Category A.

Table 3-1 Indicative List of Category A Infectious Substances

UN Number and Proper Shipping Name	Microorganism Classified as Category A in any Form (Always Classified as Category A)	Microorganisms Classifies as Category B when in Patient Specimen and as Category A only when Cultured
1	2	3
UN 2814 **Infectious substances, affecting humans**	Crimean-Congo hemorrhagic fever virus Ebola virus Flexal virus Guanarito virus Hantaan virus Hantavirus causing hemorrhagic fever with renal syndrome Hantavirus causing pulmonary syndrome Hendra virus Herpes B virus (Cercopithecine Herpesvirus-1) Junin virus Kyasanur Forest disease virus Lassa virus Machupo virus Marburg virus Monkeypox virus Nipah virus Omsk hemorrhagic fever virus Russian spring-summer encephalitis virus Sabia virus Variola virus	*Bacillus anthracis* *Brucella abortus* *Brucella melitensis* *Brucella suis* *Burkholderia mallei – Pseudomonas mallei – Glanders* *Burkholderia pseudomallei – Pseudomonas pseudomallei* *Chlamyda psitteci – avian strains* *Clostridium botulinum* *Coccidioides immitis* *Coxiella burnetii* Dengue virus Eastern equine encephalitis virus *Escherichia coli, verotoxigenic* *Francisella tularensis* Hepatitis B virus Herpes B virus Human immunodeficiency virus Human Coronavirus – Severe acute respiratory Syndrome (SARS) Highly pathogenic avian influenza virus Japanese Encephalitis virus *Mycobacterium tuberculosis* Poliovirus Rabies virus *Rickettsia prowazekii* *Rickettsiae rickettsii* Rift Valley fever virus Russian spring-summer encephalitis virus *Shigella dysenteriae type 1* Tick borne encephalitis virus Venezuelan equine encephalitis virus West Nile virus Yellow fever virus *Yersinia pestis*
UN 2900 **Infectious substances, affecting animals** only		African swine fever virus Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus Classical swine fever virus Foot and mouth disease virus Goatpox virus Lumpy skin disease virus *Mycoplasma mycoides – Contagious bovine pleuropneumonia* Peste de petits ruminants virus Rinderpest virus Sheep-pox virus Swine vesicular disease virus Vesicular stomatitis virus

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 (APHIS/CDC: https://www.selectagents.gov/). 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 (APHIS/CDC: https://www.selectagents.gov/forms.html).

SHIPPING REFERENCE TEXTS

1. Sentinel Laboratory Guidelines for Suspected Agents of Bioterrorism, Emerging Infectious Diseases; Packaging and Shipping Infectious Substances, **American Society for Microbiology, revised April 27, 2021. Internet website: Packing and Shipping Infectious Substances | ASM.org**

2. UN 3373, Medical Packaging; Website for professional information about Biological Substances transport, part of DaklaPack group, Reference WHO June 2018. http://www.un3373.com/

3. CDC/FDA Federal Select Agent Program; **Centers for Disease Control and Prevention 11** Division of Select Agents and Toxins 1600 Clifton Road, NE, Mailstop A-46Atlanta, GA 30329, 2021. https://www.selectagents.gov/

4. WHO Guidance on regulations for the **Transport of Infectious Substances** 2015–2016; WHO/HSE/GCR/2015.2, Applicable as from 1 January 2021. Guidance on regulations for the transport of infectious substances 2021-2022 (who.int)

5. How to Transport Infectious Substances, U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration. http://hazmat.dot.gov

6. Emergency Response Guidebook 2020 (ERG) - GUIDE 158. ERG2020-WEB.pdf (dot.gov)

7. Emergency Response Guidebook, U.S. Department of Transportation, Guide 158 (pp. 254-255). http://phmsa.dot.gov/sites/PHMSA.dot.gov/Files/2021-01/ERG2020.pdf

8. Healthcare Environmental Resource Center, Department of Transportation Regulation; 2015 http://www.hercenter.org/regsandstandards/dot.cfm

9. Mingle, Lisa - Email correspondence with New York State Department of Health; August 2019