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Packaging and Shipping Evaluation Tool



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INTRODUCTION

Purpose

APHL's Sentinel Laboratory Partnerships and Outreach Subcommittee of the Public Health Preparedness and Response Committee developed this Packaging and Shipping Evaluation Tool to provide a standardized resource for public health laboratories (PHLs) to assess shipments received in the laboratory. The tool is primarily intended for PHLs that are reference level members of the <u>Laboratory Response Network for Biological Threats Preparedness (LRN-B)</u> to assess use of the proper packaging and shipping of biological threat agent rule-out samples sent from sentinel laboratories and may also be utilized for assessments of general Division 6.2 Division 6.2 (Category A and B) and other shipments received.

Background

The shipment of hazardous materials (e.g., infectious substances) is regulated by the <u>US Department of Transportation (DOT) Hazardous Material Regulations (HMR)</u> for shipments transported by ground, and the <u>International Air Transport Association (IATA) Dangerous Goods Regulations (DGR)</u> for transportation by air with an IATA member carrier (e.g., FedEx). While DOT shipping regulations only apply to materials transported within the US, the IATA regulations apply to air transportation worldwide. In addition to regulations established by IATA and DOT, the <u>United Nations (UN)</u> provides recommendations for the transportation of dangerous goods in the <u>Technical Instructions for the Safe Transport of Dangerous Goods by Air</u>, on which the IATA and DOT requirements are based. The UN maintains a coding system to indicate universal identification of common hazardous materials, providing four-digit codes that are internationally recognized (e.g., UN2814 = Category A Infectious Substance). There are no UN codes for non-hazardous, exempt or non-regulated substances.

DOT requires employers to provide <u>training</u> to their employees working with hazardous materials and to certify them before they are authorized to package, ship or transport hazardous materials. As of January 2021, IATA requires certified dangerous goods (hazardous materials) shippers to receive recurrent training every 24 months, while DOT requires training every three years. Laboratories shipping infectious specimens must also conform to the training requirements from their accrediting body (e.g., College of American Pathologists, the Joint Commission, etc.).

Category A Materials

Category A infectious material for transport is classified as an infectious substance which is in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. Category A shipments must be triple packaged in a UN-certified package with appropriate and accompanying documentation.

Category A pathogens pose a higher degree of risk than Category B pathogens.

Category A shipments must be compliant in accordance with the applicable and current IATA Dangerous Goods Requirements following Packing Instruction (PI) 620 if transported by air by an IATA member carrier (e.g., FedEx), and the DOT HMR, § 173.196 listed within <u>Title 49 of the CFR, Parts 100–185</u> if transported by ground. They must be characterized as one of the following proper shipping names:

- UN 2814 Infectious Substances, Affecting Humans
- UN 2900 Infectious Substance, Affecting Animals

Category B Materials

Category B biological material for transport is classified as an infectious substance which 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 and which does not meet the criteria for inclusion in Category A. Category B shipments must be triple packaged, and a UN-certified package is not required.

Category B shipments must be compliant in accordance with the applicable and current IATA Dangerous Goods Requirements following PI 650 if transported by air by an IATA member carrier (e.g., FedEx), and the DOT HMR, § 173.199 listed within *Title 49 of the CFR, Parts 100–185* if transported by ground. They must be characterized only as: UN 3373 Biological Substance, Category B.

Exceptions

Material that is not infectious, or that may be transported by an exclusive use vehicle, may be subjected to less requirements than those for Category B and Category A shipping. This tool does not cover material exempted from the Hazardous Material Regulations. See 49 CFR § 173.134 for more information about exemptions and regulatory exceptions.

Instructions for Use

Those using this evaluation tool should already be familiar with the DOT Hazardous Material Regulations and the IATA Dangerous Goods Regulations in order to properly evaluate received shipments of infectious material.

The forms in this document include interactive elements (checklists, text and image fields), so they can be completed digitally if downloaded and opened in Adobe Acrobat. Their interactive elements will not be accessible if viewed on a browser.

To complete an evaluation:

- 1. Use either the Category A or Category B checklist evaluation forms below, depending on the type of shipment received to conduct an assessment. The forms can be used to evaluate triple packaging, required documents (e.g., itemized list of contents, test request forms), emergency response information, and other items associated with Category A and B shipping (e.g., use of overpack, dry ice) to determine their accuracy of completion.
- 2. Carriers (e.g., FedEx, UPS, etc.) and couriers can and will conduct their own inspections of requirements for packaging and documentation of dangerous goods they transport. Use the relevant evaluation form(s) within the Document Evaluation Section to further assess the accurate completion of required shipping related documents, such as those listed below, in order to conduct any follow up that may be needed with a shipping laboratory.
 - Air Waybill Evaluation Form An air waybill will be required by air carriers (e.g., FedEx) to acknowledge possession, receipt, tracking and payment information about shipments they transport. Air waybills are also referred to as a 'shipping label.'
 - Dangerous Goods Shipper's Declaration Evaluation Form A dangerous goods shipper's declaration form is required by IATA for transporting Category A shipments by air by an IATA member carrier (e.g., FedEx).
 - Shipping Papers Evaluation Form Shipping papers are required by DOT to accompany Category A shipments transported by ground. DOT outlines the information that must be present on a shipping paper but does not provide a template for shippers to use. Therefore, a shipper may either develop their own paperwork with the required information or use a dangerous goods shipper's declaration form to meet the DOT shipping paper requirement.
- 3. Inspect package(s) upon receipt and mark each item accordingly using the evaluation form(s).
- 4. Use the included diagrams in each section to assist with evaluations.
- 5. Use the completed form(s) as necessary to assist with any follow up with the shipping laboratory.

REQUIRED INCIDENT REPORTING

The Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) require certain types of hazmat incidents be reported. Section 171.15 of the HMR requires an immediate telephonic report (within 12 hours) to the National Response Center following an incident (call 1.800.424.8802). Section 171.16 requires incidents to be reported through PHMSA (the Pipeline and Hazardous Materials Safety Administration/DOT) within 30 days of the incident, and a follow-up written report within one year of the incident, based on certain circumstances, to be reported to PHMSA through the Hazardous Materials Incident Report Form DOT F 5800.1.

Shipments with either Category A or B infectious material would be subject to Section 171.15 if they were suspected to be contaminated (e.g., leaking) while in transit. You must report any release of an infectious substance (Category A or B) in any mode of transportation to DOT.

IATA AND DOT INDICATIVE CATEGORY A LIST

Category A Pathogens – Affecting Humans

Category A pathogens, indicative of infectious substances, affecting humans (UN2814) when transported in any form unless otherwise indicated:

- Bacillus anthracis (cultures only)
- Bacillus cereus Biovar anthracis (cultures only)
- Brucella abortus, Brucella melitensis, Brucella suis (cultures only)
- Burkholderia mallei, Burkholderia pseudomallei (cultures only)
- Chlamydia psittaci avian strains (cultures only)
- Clostridium botulinum (cultures only)
- Coccidioides immitis, Coccidioides posadasii (cultures only)
- Coxiella burnetii (cultures only)
- Crimean-Congo haemorrhagic fever virus
- Dengue virus (cultures only)
- Eastern Equine Encephalitis virus (cultures only)
- · Ebola virus
- Escherichia coli, verotoxigenic (cultures only)
- Flexal virus

- Francisella tularensis (cultures only)
- · Guanarito virus
- Hantaan virus
- Hantavirus causing hemorrhagic fever with renal syndrome
- · Hendra virus
- Hepatitis B virus (cultures only)
- Herpes B virus (cultures only)
- Highly pathogenic avian influenza virus (cultures only)
- Human immunodeficiency virus (HIV) (cultures only)
- Japanese encephalitis virus (cultures only)
- · Junin virus
- Kyasanur Forest disease virus
- Lassa fever virus
- · Lujo virus
- · Machupo virus
- Marburg virus
- Monkeypox virus
- Mycobacterium tuberculosis

- (cultures only)
- Nipah virus
- Omsk hemorrhagic fever virus
- Poliovirus (cultures only)
- · Rabies virus (cultures only)
- Rickettsia prowazekii, Rickettsia rickettsii (cultures only)
- Rift Valley fever virus (cultures only)
- Russian spring-summer encephalitis virus (cultures only)
- Sabia virus
- SARS-associated coronavirus (SARS-CoV)
- Shigella dysenteriae type 1 (cultures only)
- Tick-borne encephalitis virus (cultures only)
- Variola virus
- Venezuelan equine encephalitis virus (cultures only)
- West Nile virus (cultures only)
- Yellow fever virus (cultures only)
- Yersinia pestis (cultures only)

Category A Pathogens – Affecting Animals Only

Category A pathogens indicative of infectious substances, affecting animals only (UN2900) when transported:

- African swine fever virus (cultures only)
- Avian paramyxovirus Type 1— Velogenic Newcastle disease virus (cultures only)
- Classical swine fever virus (cultures only)
- Foot and mouth disease virus (cultures only)
- Goat pox virus (cultures only)
- Lumpy skin disease virus (cultures only)
- Mycoplasma mycoides— Contagious bovine pleuropneumonia (cultures only)
- Peste des petits ruminants virus (cultures only)
- Rinderpest virus (cultures only)
- Sheep pox virus (cultures only)
- Swine vesicular disease virus (cultures only)
- Vesicular stomatitis virus (cultures only)

This is an indicative, not all-inclusive list. New and emerging pathogens meeting the inclusion criteria, organisms closely resembling the criteria of microorganisms on this list (e.g., Select Agents identified by the Federal Select Agent Program) and microorganisms for which there may be a professional doubt concerning pathogenic criteria should also be considered for inclusion and classified as a Category A microorganisms, or a Suspected Category A. This list is subject to change, and the names of new and emerging pathogens may not always be included immediately on regulatory lists.

Shippers should consult the US Department of Health and Human Services/US Department of Agriculture Select Biological Agents and Toxins list available at www.selectagents.gov for the shipment of any potential select agent organism or toxin. Confirmed Select Agents must always be shipped as Category A, and potential or suspect Select Agents should be classified as "Suspected Category A, Infectious Substance." Always refer to public health authorities (e.g., US Centers for Disease Control and Prevention (CDC), World Health Organization, or other state or local public health agencies) for guidance when transporting a new or emerging pathogen.

CATEGORY A—INFECTIOUS SUBSTANCE EVALUATION FORM

Use this form and Diagrams 1 and 2 to evaluate Category A shipments received, including those that may include dry ice or use overpack. Category A packing requirements are listed within the DOT HMR, 49 CFR § 173.196, and the IATA DGR, PI 620.

Shipping Laboratory:	
Shipped Date:	Received Date:
Shipment Method (carrier or courier):	

Organism(s) Shipped: Was specimen classified appropriately? No Yes Did shipment arrive satisfactorily? No Yes

Evaluation

	Item		Present / Included?		Accep Appro	table / priate?	Item(s) in Need of Follow Up / Notes
		Yes	No	N/A	Yes	No	Follow up / Notes
		0ι	ıter Con	tainer			
1	UN-certified specification package marking.						
2	Total quantity of hazardous material listed in volume (mL) or weight (g). Ground Transport: No quantity limit. Air Transport: In passenger craft: cannot exceed 50mL or 50g In cargo craft: cannot exceed 4L or 4kg						
3	Orientation marks (Up Arrows) on two opposite sides if shipping liquids greater than 50mL by air.						
4	Shipper name and complete address.						
5	Recipient (consignee) name and complete address.						
6	Name and phone number of Responsible Person for providing emergency response information.						
7	Marked with the appropriate UN hazard identification number and proper shipping name: UN 2814 Infectious Substances, Affecting Humans UN 2900 Infectious Substance, Affecting Animals Note: No technical name of organism needed on outer container.						
8	Class 6 infectious hazard label.						

	Item	Present / Acceptable / Included? Appropriate?		Item(s) in Need of			
		Yes	No	N/A	Yes	No	Follow Up / Notes
		0	uter Con	tainer			
9	 24 hour emergency contact number listed: Required on outer container and shipper's declaration for air transport Must be listed on shipping papers for ground transport Note: The emergency response telephone number must be monitored at all times while the shipment is in transit. The use of beepers, answering machines and switchboards is not authorized. The phone number must be to someone capable of providing information on the material. 						
10	Emergency response information included that can be used in the mitigation of an incident involving the hazardous material shipped, as required by 49 CFR, Part 172, Subpart G. It must be printed legibly in English, and include the following: 1. Basic description and technical name of the hazardous material 2. Immediate hazards to health 3. Risks of fire or explosion 4. Immediate precautions to be taken in the event of an accident or incident 5. Immediate methods for handling fires 6. Initial methods for handling spills or leaks in the absence of fire 7. Preliminary first aid measures The above information may be presented on a shipping paper (if shipped by ground) or included on other documents, such as: • Copy of Guide 158 from the Emergency Response Guidebook • Canadian Pathogen Safety Data Sheet for organism specific hazard information • Information provided by the shipper The information must be accessible away from the package (on outer package) such as within a pouch affixed to top of package.						
11	Dimension of outer package meets the minimum size requirements of 100mm (4 in) x 100mm (4 in).						
12	Irrelevant markings or labels covered or removed (if box is reused).						
13	Hazard labels and markings meet the minimum requirements of 6mm font and 2mm border lines.						
14	Outer box and inner packaging system is clean and undamaged.						

	Item		Present / Included?			table / priate?	Item(s) in Need of		
		Yes	No	N/A	Yes	No	Follow Up / Notes		
15	Hazard labels and markings do not overlap and are on same side of box.								
		Seco	ndary P	ackagin	g				
17	Sealed and leakproof (for liquids) or siftproof (for solids).								
18	Itemized list of contents located outside the secondary container.								
19	Sufficient absorbent material included for entire quantity of hazardous liquid (included within secondary container).								
20	Optional: Additional cushioning material placed between primary and secondary, or between secondary and outer as needed to provide structural support.								
	Primary Container OR Secondary Packing								
21	Pressure resistant (95kPa compatible) if transported by air.								
22	Biohazard symbol present.								
		Priı	mary Co	ntainer					
23	Liquids: Sealed and leakproof Solids: Siftproof Note: A Petri dish is not an acceptable primary container for shipping purposes because it is not leakproof by design. If a Petri dish is shipped, it must be placed inside an appropriate leakproof container (e.g., a sealed specimen transport bag).								
24	Primary container is made of material that is either glass, metal or plastic.								
25	Contents cannot exceed 50mL or 50g if shipped in passenger aircraft.								
26	When shipped at ambient temperature or higher, must have positive means of ensuring a leakproof seal is provided, such as heat seal, skirted stopper or metal crimp seal. If screw caps are used, they must be secured by positive means, such as with adhesive tape, paraffin sealing tape or manufactured locking closure.								

	Item		Present / Included?			table / oriate?	Item(s) in Need of
		Yes	No	N/A	Yes No		Follow Up / Notes
27	If multiple primary containers are included, they are individually wrapped to prevent contact.						
28	Wrapped in cushioning material as needed to provide structural integrity support. If multiple primary containers are included, each one is individually wrapped to help prevent breakage or leakage.						

Dry ice (if included)

Dry ice is considered a hazardous material when shipped by air or water transportation in quantities greater than 2.5kg (5.5lbs). (Note: Water transportation requirements not covered in this evaluation tool). Dry ice must never be placed in a tightly sealed container as this may result in explosion from excessive pressure being released as the dry ice sublimates (turns from solid carbon dioxide directly to gas).

Requirements derived from: 49 CFR § 173.217 (ground) and IATA DGR, PI 954 (air).

neq	urrements derived from: 49 CFR § 173.217 (ground) a	IIU IAIA D	GR, FI 95	4 (all).		
29	Outer box marked with UN 1845.					
30	UN 1845 font size is: 12mm or larger (>30kg of dry ice) 6mm or larger (5kg-30kg of dry ice) Of adequate size if <5kg					
31	Outer box marked with miscellaneous hazard Class 9 label.					
32	Outer box marked with either proper shipping name: • Dry ice • Carbon dioxide solid					
33	Proper shipping name, UN 1845 and Class 9 labels are all on same side of outer box.					
34	Net quantity of dry ice included within shipment listed on outer package in kg. Notes: Air Transport: 200kg max quantity Ground Transport: No quantity limit					
35	Insulated box used (e.g., layer of Polystyrene foam within a box).					
36	Properly ventilated outer package to allow for the release of carbon dioxide gas.					
37	Dry ice is placed outside of secondary container or within an overpack (if used).					
38	Additional absorbent material included to help absorb any excess moisture and maintain the structural integrity of packaging.					

		`	gory A E		1		
	Item		Present Included			table / priate?	Item(s) in Need of
	iteili	Yes	No	N/A	Yes	No.	Follow Up / Notes
39	Dry ice information listed correctly on Dangerous Goods Shipper's Declaration, if used.						
40	Sufficient amount included to keep shipment material frozen.						
eit pa the to	hough not very frequently used, overpack may be utilize ther to reduce shipping costs, or to ship items at difference ckaging requirement. Items (packages) inside an over their own (all items inside overpack need to be properly a the marked on the outside. When packages are overpa tearrier-provided shipping envelope), all required marking	zed to incent tempe pack, mu and fully p acked (e.g	eratures to st be com backaged, g., shrink v	ce within a cone loca pleted (m , labeled a vrapped, (ition). Use arked and and marke consolida	e of overpa d labeled) ed). Hazar ted or pla	ack does not substitute for a rigid outer as if they would be shipped separately on dous material inside an overpack needs ced in additional outer packaging, such as
41	Outer packaging marked with "Overpack" and font size is at least 12 mm.						
42	Inner packages are each properly packed and labeled.						
43	Outermost packaging labeled with the highest hazard level of the inner contents.						
44	Quantity of total included hazardous contents listed on outer packaging.						
45	"Overpack" must be listed on a Dangerous Goods Shipper's Declaration form if used.						
inf The ite	itemized list of contents is required to be included wit ormation that must be listed, how the information nee e key information to be listed is indicated below. The it mized list information may be listed on the secondary ted on other paperwork such as the specimen test rec	hin all Ca ds to app emized li packagin	ear (what st may be g itself (e.	shipments order), and a standa .g., on the	s. Neither nd they do lone docu seconda	not prov ment tha ry contain	ide a template form for shippers to use. t is included within the shipment, or the er), or the required information may be
46	An itemized list of contents is properly contained within the shipment (outside the secondary container and within the outer container).						
47	Lists the total number of specimens included (e.g., 1 vacutainer of blood).						
48	Lists the total quantity of hazardous material (e.g., 5 mL).						
49	Lists the form of the hazardous material (e.g., liquid or solid).						
50	The itemized list of contents properly lists the total quantity and type of material that was included with the shipment.						

ltem		Present / Included?				table / priate?	Item(s) in Need of
		Yes	No	N/A	Yes	No	Follow Up / Notes
	est request form will be required to accompany specin st request forms and their required information will var	nens sent		ostic testi			
51	A completed test request form specific to the testing laboratory is included within the shipment outside the secondary container, and within the outer box.						
52	If multiple specimens are shipped, there is a test request form for each patient / specimen where a diagnostic test is being requested.						
53	The test request form is completed accurately for the diagnostic test being requested.						
			Othe	r			
54	A copy of any permit(s) that may be required are included with shipment records.						
55	Chain of custody form is included if required.						
56	A copy of a completed APHIS/CDC Form 2 is included for any confirmed select agent shipment.						
57	Insulated box used if refrigerants (e.g., dry ice or frozen gel packs) included.						
58	Packaging is used according to the manufacturer's packaging instructions (if known).						
59	Contains appropriate specimen/material identifying information, such as a patient identification number or other unique identifiers required by testing laboratory.						
60	Specimen(s) correctly correlate with included laboratory test request form(s).						
61	Specimens arrived at desired temperature.						
62	Specimens arrived in good condition (not damaged or leaking).						
63	Shipment and specimen(s) received conform to the laboratory-specific acceptance / rejection policy.						
64	Other requirements of the receiving laboratory:						

Follow Up & Notes

Signature:	
Evaluated by:	Date:

Diagram 1: Example of Category A, Ambient Temperature Shipment.

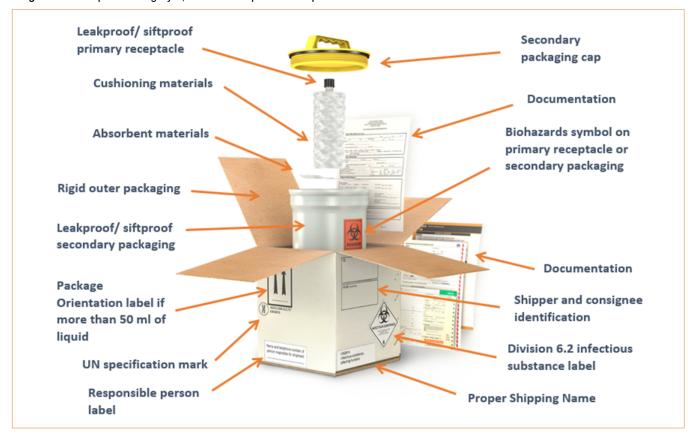


Diagram 2: Example of Category A Shipment with Dry Ice.



CATEGORY B—BIOLOGICAL SUBSTANCE EVALUATION FORM

Use this form and Diagrams 3 and 4 to evaluate Category B shipments received, including those that may include dry ice or use overpack Category B packing requirements are listed within the DOT HMR, 49 CFR § 173.199, and the IATA DGR, PI 650.

	ipment Information ping Laboratory:									
Ship	ped Date:		_ Re	eceived [Oate:					
Ship	ment Method (carrier or courier):									
Orga	nism(s) Shipped:									
Was	specimen classified appropriately? No	Yes	Di	d shipme	ent arrive	satisfacto	rily?	No	Yes	
Ev	aluation									
	Item		Present ncluded			table / priate?	Item(s	s) in Need No	of Follow Up /	
		Yes	No	N/A	Yes	No		140	100	
		0ι	ıter Con	ntainer						
1	Package is rigid and of good quality. Note: UN certified container is not required.									
2	Air Transport: Total quantity contains less than 4L or 4kg. Ground Transport: No quantity limit.									
3	Orientation marks (Up Arrows) on two opposite sides if shipping liquids greater than 50mL by air.									
4	Shipper name and complete address.									
5	Recipient (consignee) name and complete address.									
6	Name and phone number of Responsible Person for providing emergency response information included on a written document (e.g., an air waybill) or on the outer package. Notes: Responsible Person is one who is either knowledgeable about the material being shipped and has comprehensive emergency response and incident mitigation information for the material, or has immediate access to a person who possesses such knowledge and information. The number must be monitored during a com-									

pany's administrative hours (normal operational

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business hours).

contrasting color.

7

Marked with UN 3373 in a square

on-point and on a background of

	Item		Present / Included?			table / oriate?	Item(s) in Need of Follow Up /
		Yes	No	N/A	Yes	No	Notes
		0ι	ıter Con	tainer			
8	Dimension of outer package meets the minimum size requirements of > 100mm (4 inches) x 100mm (4 inches).						
9	Marked with proper shipping name: Biological Substance, Category B (No technical name of organism)						
10	Irrelevant markings or labels covered or removed (if box is reused).						
11	Dimensions of UN 3373 markings meets the minimum size requirements: • <6mm font • <2mm border lines around square • >50mm length of square border lines						
12	Outer box and inner packaging system is clean and undamaged.						
13	Hazard labels and markings do not overlap and are on same side of box.						
		Seco	ndary P	ackagin	g		
14	Sealed and leakproof (for liquids) or siftproof (for solids).						
15	Itemized list of contents located outside the secondary container.						
16	Sufficient absorbent material included for entire quantity of hazardous liquid (included within secondary container).						
17	Optional: Additional cushioning material placed between primary and secondary, or between secondary and outer as needed to provide structural support.						
	Primary	Contai	ner OR S	Seconda	ary Pack	king	
18	Pressure resistant (95kPa compatible) if transported by air.						
19	Biohazard symbol present.						

	ltem		Present Included		Accep Appro	table / oriate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
		Pri	mary Co	ntainer			
	Sealed and leakproof (for liquids) or siftproof (for solids). Note: A Petri dish is not an acceptable primary						
20	container for shipping purposes because it is not leakproof by design. If a Petri dish is shipped, it must be placed inside an appropriate leakproof container.						
21	Primary container is made of material that is either glass, metal or plastic.						
22	Contents cannot exceed 1L if shipped by air. Note: Cargo aircraft only label not required.						
23	Not required, but recommended as a best practice: Seal with adhesive tape, parrafin sealing tape or manufactured locking closure.						
24	If multiple primary containers are included, they are individually wrapped to prevent contact.						
	Wrapped in cushioning material as needed to provide structural integrity support.						
25	If multiple primary containers are included, each one is individually wrapped to help prevent breakage or leakage. (Absorbent material may also be used as cushioning material).						
		Drv	Ice (if ir	ncluded)			
tran	ice is considered a hazardous material when shipped sportation requirements not covered in this evaluatior osion from excessive pressure being released as the	by air or tool). D i	water tran y ice mus	sportation t never be	n in quant e placed i	n a tightly	sealed container as this may result in
Req	uirements derived from: 49 CFR § 173.217 (ground) a	nd IATA E	GR, PI 95	4 (air)			
26	Outer box marked with UN 1845.						
27	UN 1845 font size is: 12mm or larger (>30kg of dry ice) 6mm or larger (5kg-30kg of dry ice) Of adequate size if <5kg						
28	Outer box marked with miscellaneous hazard Class 9 label.						
29	Outer box marked with either proper shipping name: • Dry ice • Carbon dioxide solid						

	Item		Present . Included			table / priate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
30	Proper shipping name, UN 1845 and Class 9 labels are all on same side of outer box.						
31	Net quantity of dry ice included within shipment listed on outer package in kg. Notes: Air Transport: 200kg max quantity Ground Transport: No quantity limit						
32	Insulated box used (e.g., layer of Polystyrene foam within a box).						
33	Properly ventilated outer package to allow for the release of carbon dioxide gas.						
34	Dry ice is placed outside of secondary container or within an overpack (if used).						
35	Additional absorbent material included to help absorb any excess moisture and maintain the structural integrity of packaging.						
36	Dry ice information listed correctly on Dangerous Goods Shipper's Declaration, if used. Note: A Dangerous Goods Shipper's Declaration is not required when shipping Category B specimens alone, but would be required if a Category B material was shipped together with a Category A material by air.						
37	Sufficient amount included to keep shipment material frozen.						
Overpack (if used) Although not very frequently used, overpack may be utilized to include dry ice within a shipment, or to combine packages into one shipment (usually either to reduce shipping costs, or to ship items at different temperatures to one location). Use of overpack does not substitute for a rigid outer packaging requirement. Items (packages) inside an overpack must be completed (marked and labeled) as if they would be if shipped separately on their own (all items inside overpack need to be properly and fully packaged, labeled and marked). Hazardous material inside an overpack needs to be marked on the outside. When packages are overpacked (e.g., shrink wrapped, consolidated or placed in additional outer packaging, such as a carrier-provided shipping envelope), all required markings must be clearly visible or reproduced on the outside of the overpack.							
38	Outer packaging marked with "Overpack" and font size is at least 12 mm.						
39	Inner packages are each properly packed and labeled.						
40	Outermost packaging labeled with the highest hazard level of the inner contents.						
41	Quantity of total included hazardous contents listed on outer packaging.						

	Item		Present .		Accep Appro		Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
42	"Overpack" must be listed on a Dangerous Goods Shipper's Declaration form, if used.						
inf The ite	itemized list of contents is required to be included wit ormation that must be listed, how the information nee e key information to be listed is indicated below. The it mized list information may be listed on the secondary ted on other paperwork such as the specimen test rec	hin all Ca ds to app emized li packagin	ear (what st may be g itself (e.	shipments order), an a standa g., on the	s. Neither nd they do lone docu secondar	not provi ment that ry containe	de a template form for shippers to use. is included within the shipment, or the er), or the required information may be
43	An itemized list of contents is properly contained within the shipment (outside the secondary container and within the outer container).						
44	Lists the total number of specimens included (e.g., 1 vacutainer of blood).						
45	Lists the total quantity of hazardous material (e.g., 5 mL).						
46	Lists the form of the hazardous material (e.g., liquid or solid).						
47	The itemized list of contents properly lists the total quantity and type of material that was included with the shipment.						
	est request form will be required to accompany specin st request forms and their required information will var	nens sen		ostic test			
48	A completed test request form specific to the testing laboratory is included within the shipment outside the secondary container, and within the outer box.						
49	If multiple specimens are shipped, there is a test request form for each patient / specimen where a diagnostic test is being requested.						
50	The test request form is completed accurately for the diagnostic test being requested.						
			Othe	r			
51	A copy of any permit(s) that may be required are included with shipment records.						
52	Chain of custody form is included if required.						
53	Insulated box used if refrigerants (e.g., dry ice or frozen gel packs) included.						

	Item		Present Included			table / priate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
54	Packaging is used according to the manufacturer's packaging instructions (if known).	Yes					
55	Contains appropriate specimen/material identifying information, such as a patient identification number or other unique identifiers required by testing laboratory.						
56	Specimen(s) correctly correlate with included laboratory test request form(s).						
57	Specimens arrived at desired temperature.						
58	Specimens arrived in good condition (not damaged or leaking).						
59	Shipment and specimen(s) received conform to the laboratory-specific acceptance / rejection policy.						
60	Other requirements of the receiving laboratory:						

Follow Up & Notes

Item(s) in need of follow up or other notes. Include any photo (Please note that images can only be added when the file is	os of actual shipment received that open in Adobe Acrobat):	t may assist with follow up
Evaluated by:		Date:
Signature:		

Diagram 3: Category B, Ambient Temperature Shipment Example.

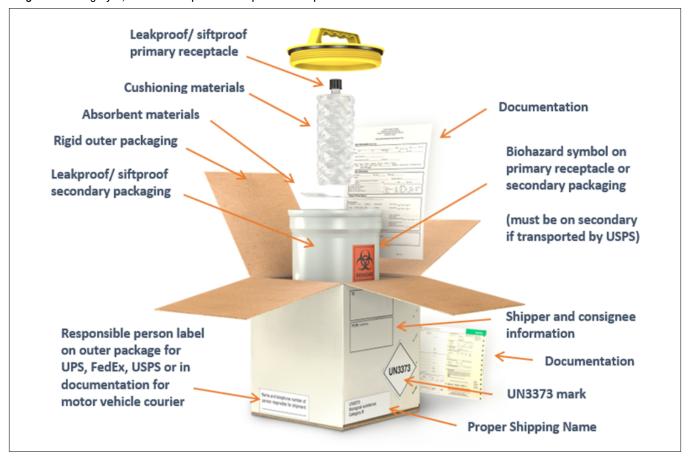


Diagram 4: Category B, Shipment with Dry Ice Example.



DOCUMENT EVALUATION

Carriers (e.g., FedEx, UPS, etc.) and couriers can and will conduct their own inspections of requirements (e.g., packaging, labeling, marking, inclusion of required documents, etc.) of dangerous goods they transport. Use the relevant evaluation form(s) within this section to further assess the accurate completion of required shipping related documents such as those listed below in order to conduct any follow up that may be needed with a shipping laboratory.

Air Waybill Evaluation Form

An air waybill will be required by air carriers (e.g., FedEx) to acknowledge possession, receipt, tracking, and payment information about shipments they transport. Air waybills are also referred to as a 'shipping label'.

Dangerous Goods Shipper's Declaration Evaluation Form

A dangerous goods shipper's declaration form is required by IATA for transporting Category A shipments by air by an IATA member carrier (e.g., FedEx). Use Diagram 6, a labeled Dangerous Goods Shipper's Declaration to assist with evaluation.

Shipping Papers Evaluation Form

Shipping papers are required by DOT to accompany Category A shipments transported by ground. DOT outlines the information that must be present on a shipping paper, but does not provide a template for shippers to use. Therefore, a shipper may either develop and use their own paperwork with the required information to satisfy the shipping paper requirement, or use a dangerous goods shipper's declaration form to meet the DOT shipping paper requirement since the dangerous goods declaration will have all the required fields present on the form.

The itemized list of contents and test request forms will be included within the outer container. Dangerous Goods Shipper's Declarations, Shipping Papers, air waybills, and emergency response information all need to be accessible from outside of the box and typically are contained in a clear plastic pouch, such as with the example below.



Example of a shipping documents pouch that can be affixed to the outside of the outer container.

AIR WAYBILL EVALUATION FORM

An air waybill will be required by air carriers (e.g., FedEx) to acknowledge possession, receipt, tracking, and payment information about shipments they transport. Air waybills are also referred to as a "shipping label." Not all air waybills will be the same and will vary between carriers (e.g., FedEx vs. UPS, etc.); they may be in the form of paper or adhesive label. Use this form to evaluate the accurate completion of common air waybill fields. Use <u>Diagram 5</u> for reference.

	Item		Present . Included			table / priate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
1	Air Waybill is affixed to outer package or accessible on outer package (e.g., contained within an affixed pouch).						
2	"To" and "From" information is completed correctly.						
3	Type of packaging used is correctly noted.						
4	Category B shipments: "UN 3373" and "Biological Substance, Category B" is noted. Note: There may not be a place on the form to include this information.						
5	Category B shipments with or without dry ice: The answer to "Does this Shipment contain dangerous goods?" is marked as, "Yes, Shipper's Declaration not required."						
6	Category A shipments are noted as either: UN 2814 Category A Infectious Substance Affecting Humans UN 2900 Category A Infectious Substance Affecting Animals Note: There may not be a place on the form to include this information.						
7	Category A shipments with or without dry ice: The answer to "Does this Shipment contain dangerous goods?" is marked as "Yes, as per attached Shipper's Declaration."						
8	If dry ice is included, the "Dry Ice" box is marked.						
9	If dry ice is included, the total number of packages and weight is listed in the space for " xkg"						
	Example: One box shipped with 3.5 kg of dry ice will be noted as: "1 x 3.5 kg"						
10	"Cargo Aircraft Only" box is marked if the shipment contains >50mL of a Category A substance within a primary container.						
11	Total number of packages is listed.						
12	Total weight is listed.						

D	Document Evaluation
Follow Up & Notes Item(s) in need of follow up or other notes. Include a (Please note that images can only be added when the	any photos of actual shipment received that may assist with follow up the file is open in Adobe Acrobat):

Evaluated by:	Date:	

Signature:

Diagram 5: Air Waybill Form Example.

FedEx. US Airbill 1234 5678 901C 200	onder Copy
1 From new percent/pressured Data 10/5/07 Service 19999-9999-9 TRUMBER SELV FedEx Priority Overnight Sections recorded Covernment of Service Service Self-Section Covernment Service Service Self-Section Covernment Service Service Service Self-Section Covernment Service S	
Sandar's Tyler Hanlon Phone (602) 555-1812 FodEx Day FodEx Spress Sover	Salardin/Callers III available
Company 46 Express Freight Service	Prochagos over Mil Ba. Facility 20 by Freight Service Street on the
Address 1234 Main Street Street AZ 77 8503	Threat testion
Chy Phoenix State AZ ZP 8503% Packar Pack Pack Pack Pack Pack Pack Pack Pack	
Address 1234 Main Street Address 1234 Main Street State AZ ZIP 8503E Phoenix Yes Internal Billing Reference First Advances of Separate Indicated State Inc. First Advances of Separate Inc. The Phoenix Yes Internal Billing Reference First Advances of Separate Inc. First Inc	HOLD Saturday at Fed Ex Location Assistant Child for Helds Fronty-Dennyste and Fed Sizes to mixet bestern.
Company Ridgeway Design Company Ridgeway Design Yes Y	Dry los Bylos, List 1965 2 by G. S. Dry los Bylos, Bylo
Recipierts 2028 Vision Street Payment Bill ac Inter-Politic Act No. or Credit Cont N	
Address To dissue a peckage to find a begouilt findia beddies, prior findia sed was been One Atlanta Sente GA zip 30305 Total Peckages Total Weight Total O	Sectional Values O
T I s The shallows in the last of \$100 control of \$100 contro	450 as
Recursor - Sentence of Records - Sentence of Records - Sentence of Records	yes require a olgonium, check lifered or holmest. est Signantume to replication at footbook, apparatume 520
Simplify your shipping. Manage your account. Access all the tools you good.	Ch submin gottenen may harden gotten
socidor	atial deliverine calv. For continu
Does this shipment contain dangerous goods?	ntial deliveries only. Fee applies
One box must be checked.	
No As per attached Shipper's Declaration Dry ICe Dry Ice, 9, UN 1845 —	
Dangerous goods (including dry ice) cannot be shipped in FedEx packaging or placed in a FedEx Express Drop Box.	Aircraft Only

DANGEROUS GOODS SHIPPER'S DECLARATION EVALUATION FORM

A Dangerous Goods Shipper's Declaration Form is required by IATA/ICAO for all Category A specimens transported by air by IATA member air carriers. A Dangerous Goods Shipper's Declaration form may be used to satisfy the DOT HMR Shipping Paper requirements for Category A specimens sent by ground transport. Use Diagram 6 to assist with completion of this form as needed; the item numbers in this form correspond to the diagram's orange labels. Use this form to evaluate the accurate completion of a Dangerous Goods Shipper's Declaration form.

	Item		Present .		Accep Appro	table / priate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
1	Completed Shipper info (full name and complete address).						
2	Completed Consignee/Recipient info (full name and complete address).						
3	lf used, air waybill number listed on Shipper's Declaration.						
4	Page 1 of 1 completed. Note: Even though multiple copies are required with shipment, this will be noted as "1" since copies of a single page are being used.						
5	Optional: Sample/Specimen number listed as "Specimen Reference Number."						
6	Passenger vs Cargo Only marked. Note: For passenger cargo, contents of primary container must be <50mL.						
7	Airport of departure and airport of destination listed (OK to leave blank).						
8	Radioactive vs. Non-radioactive marked.						
9	UN hazard identification(s) listed: • Category A: UN 2814 or UN 2900 • Category B: UN 3373 • Dry Ice: UN 1845						
10	Proper shipping name listed (either): • UN2814 Category A Infectious Substance, Affecting Humans • UN2900 Category A, Infectious Substance, Affecting Animals						
10	Technical name of organism(s) listed after proper shipping name. Can be either the actual organ- ism name, or "Suspected Category A, Infectious Substance."						
11	Class or Division listed: • Category A & B: 6.2 • Dry Ice: 9						

Document Evaluation

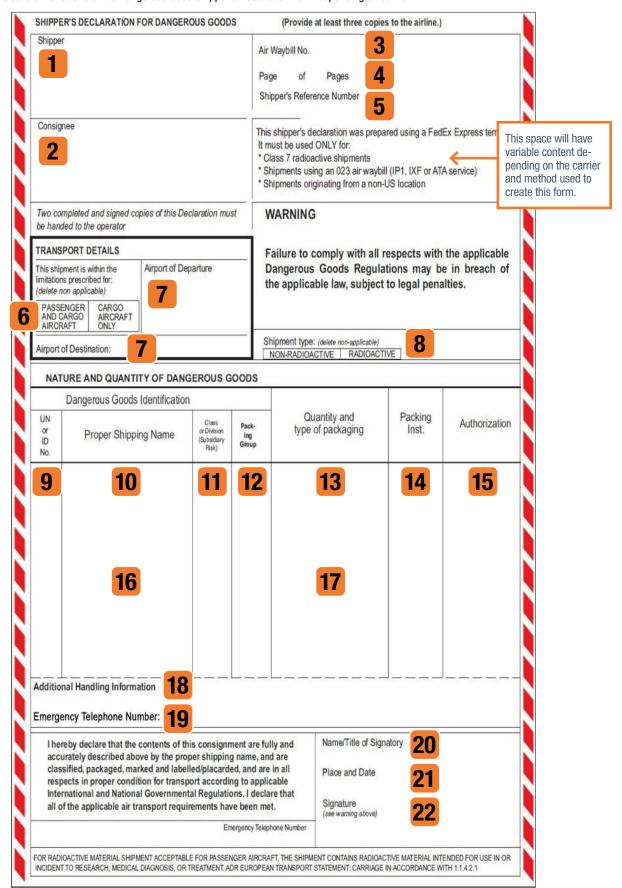
	Item		Present / Included?			table / oriate?	Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
12	Packing group Note: Leave blank for 6.2 material and for dry ice.						
13	Quantity and type of packaging listed (e.g., 5mL solid).						
14	Packing Instruction (PI) listed: • Category A: PI 620 • Category B: PI 650 • Dry Ice: PI 954						
15	Authorization code listed. Note: OK to leave blank for routine Category A and dry ice shipments.						
16	If more than one organism or dry ice is included, they are each listed here.						
17	Type of packaging listed (e.g., "All packed in one fiberboard box" or "Overpack used").						
18	 Additional handling information provided: Must list "Responsible Person" info for air transport. May also list "Attention To" info. 						
19	24-hour emergency contact listed (name and number).						
20	Name/Title of signatory listed.						
21	Place and date listed.						
22	Signed by currently-trained personnel.						

Do	Occument Evaluation
Follow Up & Notes Item(s) in need of follow up or other notes. Include a (Please note that images can only be added when the	any photos of actual shipment received that may assist with follow up he file is open in Adobe Acrobat):

Evaluated by:	Date:
Signature:	

Diagram 6: Numbered Dangerous Goods Shipper's Declaration Form.

Note: There are several variations of the Dangerous Good Shipper's Declaration Form depending on carrier.



SHIPPING PAPERS EVALUATION FORM

Shipping Papers are required by DOT for all Category A samples transported by ground. Information on the DOT Shipping Papers do not need to be in the same format as a Dangerous Goods Shipper's Declaration, but the required content is extremely similar. A Dangerous Goods Shipper's Declaration may be used to satisfy the DOT Shipping Papers requirement, otherwise, a shipper will need to develop and use their own document(s) to satisfy the DOT Shipping Paper requirements. For the purpose of the hazardous materials regulations, a shipping paper is any shipping document whose purpose is to communicate a hazard that conforms to the requirements contained in 49 CFR Part 172 Subpart C. Use this form and **Diagram 7** to evaluate the required shipping paper information.

Item		Present / Included?			Acceptable / Appropriate?		Item(s) in Need of Follow Up /
			No	N/A	Yes	No	Notes
1	Shipment contains shipping papers on out-side of package.	Yes					
2	Proper shipping name is listed.						
3	Hazard class is listed (6.2).						
4	 Identification number listed, such as: Category A Infectious Substance Affecting Humans: UN 2814 Category A Infectious Substance Affecting Animals: UN 2900 Category B Biological Substance: UN 3373 Dry Ice: UN 1845 						
5	Packaging Group: Not applicable to Category A, B, or dry ice (no information to list).						
6	Number of packages listed.						
7	Type of packaging listed.						
8	Total weight listed.						
9	 Emergency response phone number listed. Notes: The number must be monitored at all times when the material is in transport to include storage incidental to transportation. The number must be for a person who is knowledgeable of the hazardous materials being shipped and the appropriate emergency response procedures, or a person who has immediate access to a person who has such knowledge. Number must be readily identifiable on the shipping paper. If a service provider (e.g., CHEMTREC) is used to meet this requirement, the shipper has a valid con-tract with that entity. 						

Document Evaluation

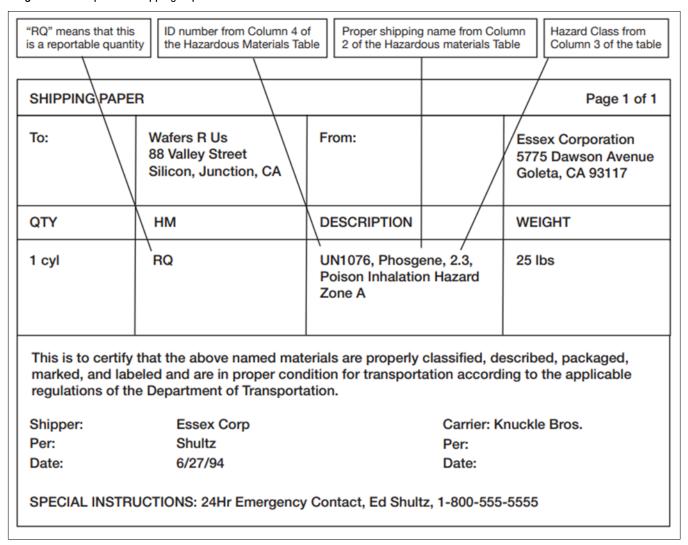
	Item		Present / Included?		Acceptable / Appropriate?		Item(s) in Need of Follow Up /	
		Yes	No	N/A	Yes	No	Notes	
10	The shipping paper is signed / certified. Note: DOT does not dictate who signs the certification on the shipping papers, but the individual who signs the certification should be the individual most knowledgeable of the shipment and currently trained.							

Follow	U	& q	N	otes
---------------	---	----------------	---	------

Item(s) in need of follow up or other notes.	Include any photos of actual ship	pment received that may	assist with follow up
(Please note that images can only be added	d when the file is open in Adobe	Acrobat):	

Evaluated by:		Date:
Signature:		

Diagram 7: Example of a Shipping Paper.



REFERENCES

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https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/Enhanced%20Security%20Brochure.pdf

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https://ai.fmcsa.dot.gov/NewEntrant/MC/Examples/Shipping_Paper_Guide.pdf

US DOT. (2020) Emergency Response Guidebook.

https://www.phmsa.dot.gov/hazmat/erg/emergency-response-guidebook-erg

World Health Organization. (2017, January). Guidance on Regulations for the Transport of Infectious Substances 2007-2008. https://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2cc.pdf

RESOURCES

Shipping Supplies

DOT Free Publication Resources
 https://hazmatonline.phmsa.dot.gov/services/
 Pub_Free.aspx

Emergency Response Guidebook
 https://www.phmsa.dot.gov/hazmat/erg/emergency-response-guidebook-erg

 Fillable IATA Dangerous Goods Shipper's Declaration Form

https://www.iata.org/contentassets/a9f496cd-8c87466b98142fa6d4cdb209/shippers-declaration-column-format-fillable.pdf

Air Sea Containers
 https://www.airseacontainers.com/

Berlin Packaging, LLC
 http://www.berlindangerousgoods.com/pages/shop-now

 CARGOpak Corporation https://cargopak.com/

• Labeline https://www.labeline.com/

• Inmark, Inc. http://www.inmarkpackaging.com/

 O'Berk International, Inc. (Elemental Container, Inc.)
 https://www.aluminumbottles.com/

 SCA ThermoSafe (formerly Polyfoam Packers Corp.)

http://www.thermosafe.com/

 Saf-T-Pak, Inc., An Inmark Company http://www.saftpak.com/

Trainings

WHO Shipping Training
 http://www.who.int/ihr/i_s_shipping_training/en/

OSHA

 $\underline{\text{https://www.osha.gov/dte/edcenters/course_description.html}}$

 Iowa Biosecurity Training for the Clinical Laboratory

https://www.training-source.org/training/courses/ Biosecurity%20for%20Clinical%20Labs/detail

CDC Lab Training
 https://www.cdc.gov/labtraining/

• Courier credentials http://safer.fmcsa.dot.gov/CompanySnapshot.aspx

Other Resources

APHL Packaging & Shipping Toolkit
 https://www.aphl.org/programs/infectious_disease/
 Pages/ID-Packaging-and-Shipping-Toolkit.aspx

• DOT Office of Hazardous Materials Safety Hotline

Technical support and questions:

o Email: infocntr@dot.gov

Toll-free phone number: 1-800-HMR-4922 (1-800-467-4922)

• IATA Dangerous Goods Hotline

Technical support and questions:

Email: dangood@iata.org

o Toll-free phone number: 1-800-716-6326

Canada Pathogens Safety Data Sheets
 https://www.canada.ca/en/public-health/services/
laboratory-biosafety-biosecurity/pathogen-safety-data-sheets-risk-assessment.html

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Association of Public Health Laboratories

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