
Omaha Sentinel Laboratories

Packaging and Shipping to Nebraska Public Health Laboratory

Category A Infectious Substances, Affective Humans UN2814

Category B Biological Substances, UN3373

Principle:

The shipper is responsible to comply with the rules and guidelines for transport of Division 6.2 infectious substances, which is regulated as a hazardous material under the U.S. Department of Transportation's (DOT) Hazardous Materials Regulations (HMR; 49 CFR Parts 171-178). These regulations are based on and in substantial agreement with the International Civil Aviation Organization (ICAO) and the International Air Transportation Association (IATA) regulations.

The following steps are specifically described for sentinel laboratories in Nebraska to package and ship a Category A infectious substance to the Nebraska Public Health Laboratory (NPHL), which may pose any material capable of posing an unreasonable risk to health and safety when transported in commerce. Purpose of adherence to these regulations and requirements is to minimize the potential for damage to the contents of the package during transport and to reduce the exposure of the shipper to the risks of criminal and civil liability associated with the improper shipment of dangerous goods.

Definitions:

1. **DIVISION 6.2 (INFECTIOUS SUBSTANCE):** A material known or reasonably expected to contain a pathogen. A pathogen is a micro-organism (including bacteria, viruses, rickettsiae, parasites, fungi) or other agent, such as a proteinaceous infectious particle (prion) that can cause disease in humans or animals.
2. **Infectious substances, affecting humans, UN2814 (Category A):** 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. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals.
3. **Biological Substance UN3373 (Category B):** An infectious substance not in the form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans when exposure to it occurs. **Former proper shipping names "Diagnostic Specimen" or "Clinical Specimen" is no longer acceptable and will be rejected.**
4. **Select Agents:** Category A pathogens that have been designated as agents of bioterrorism. United States federal regulations require shippers to have special permits to possess, use, transfer, and receive these agents.
5. **Classification:** Criteria used to determine acceptable levels of safety during transportation. Developed by ICAO and published in the *52nd Edition (2010) of the IATA Dangerous Goods Regulations (DGR)*. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source. Infectious substances are now classified either as Category A or Category B.
6. **Patient Specimen:** Material collected directly from human for transport for research, diagnosis, investigational activities, or disease treatment or prevention including but not limited to excreta, secretions, blood and its components, tissue and swabs, body parts and specimens in transport media (e.g. transwabs, culture media and blood culture bottles prior to growth). Patient specimens (dried blood spots, blood or urine tests ordered as part of routine medical exams to monitor levels of cholesterol, blood glucose, hormones or organ functions; tests conducted for insurance or employment purposes such as drug screens) should be packed and shipped as Exempt Human Specimens (IATA and US Postal Service) or are not subject to the requirements as Division 6.2 material.
7. **Culture:** An infectious substance containing a pathogen that is intentionally propagated.
8. **Proper Shipping Name and UN/ID Number:** Terminology used with Category A that is required on label of box and paperwork, cannot be abbreviated. Correct format is "Infectious substance, affecting humans UN2814." The technical pathogen name is no longer allowed (as of Jan 1, 2012) on the outer box but the correct technical name (IATA List of Dangerous Goods) must be listed on the Shipper's Declaration or the NPHL Ground Courier Shipping Paper in parenthesis.

Procedure Notes:

1. In accordance with Dangerous Goods regulations, only personnel trained and certified for packaging and shipping are allowed to package Category A at the sentinel laboratory. Initial training is recommended through the Association of Public Health Laboratories (APHL). Laboratory/clinical managers are responsible for assuring their staff is capable of correctly packaging and shipping and upon doing so, is responsible for certifying the employee. Managers should keep records for each employee, include employee’s name, location and date of training, name of the trainer, course content, documentation of testing, and a copy of the certificate of training. IATA certification is valid for 2 years.
2. IATA rules apply to transportation with the FedEx Corporation. All Category A shipments transported by FedEx require additional measures, therefore strict compliance with NPHL Packaging Instructions (PI) is mandatory.
3. Packaging Instructions - DOT regulations, IATA requirements, and IATA Packing Instructions (PI) describe the minimum standards for the safe transport of various biological materials. **The shipper is legally responsible for complying with these regulations**, for following prescribed PI, and for packing substances correctly to ensure the safety of all personnel who handle the package before, during, and even after shipment to the point of acceptance of the package by the consignee. After determining the exact nature and category of the substance to be shipped, the shipper must select the most appropriate packing instructions to use.
4. Category A packaging is required by IATA and DOT to be tested and certified for internal pressure requirements of 95kPa and only those components that have been tested together can be used together for packaging. Therefore, no substitution is allowed between manufacturers nor can components be interchanged from the same company unless the user has tested those multiple components together. The manufacturer provides certification stating what components can be used together, using UN specification packaging. **Certification should be kept with all shipping documents and made available to CAP inspectors upon request.**
5. Category A and B pathogens required by state regulation Title 173 to be shipped to NPHL are as follows (not all inclusive and subject to change):

<u>Category A Shipper</u>	<u>Category B Shipper</u>
<p>Infectious Substance UN2814 (White Shipper)</p> <p>Culture reasonably suspected to be:</p> <p><i>Bacillus anthracis</i>* <i>Brucella spp.</i>* <i>Burkholderia mallei</i> * <i>Burkholderia pseudomallei</i> * <i>Francisella tularensis</i>* <i>Yersinia pestis</i>* <i>Escherichia coli, verotoxigenic</i> (shigatoxin positive) <i>M. tuberculosis complex</i> <i>Shigella dysenteriae</i></p> <p>*Select Agent once confirmed, requires CDC permit to transport</p>	<p>Biological Substance UN3373 (Brown Shipper)</p> <p>Culture or Tube:</p> <p><i>Bordetella pertussis</i> <i>Haemophilus influenza</i> (sterile site) <i>Listeria monocytogenes</i> <i>Neisseria meningitides</i> (sterile site) <i>Salmonella spp</i> <i>Vibrio cholerae</i></p>

6. Certified shipper must hand-deliver non-select Category A shipments directly to the courier. Include the necessary shipment paperwork.
7. **Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.**

Shipping Instructions for Category A – Omaha Only (NPHL Ground Courier Only)

Supplies and Equipment:

1. White Shipper - Infectious substances, affecting humans, UN2814 (Category A):
 - a. Leak proof primary container – supplied by sentinel laboratory, must be leakproof and sealed by parafilm or tape.
 - b. Secondary & Outer Packaging - must use corresponding products certified to meet the internal pressure requirements of 95kPa(13.8 lbs/in²) because shipments are likely to be placed into unpressurized cargo sections of aircraft which fly at high altitudes. Therefore, the shipping systems are provided by NPHL which contain corresponding components including a leak proof, pressure-resistant secondary vessel, absorbent material, bubble wrap and rigid durable outer box which measures at least the required 4x4 inch on one surface and labeled with strict UN manufacturing markings:
 - i. Ambient temperature: Safety T Pak™ (STP-100 Category A Shipping System, Ambient. Maximum Capacity: four 10 mL vials. System includes secondary, absorbent, and rigid outer packaging.) See drop/pressure certification.
 - ii. Use only for: *Eschericia coli*, verotoxigenic culture (O157 and non-O157), *Mycobacterium tuberculosis* complex, *Shigella dysenteriae*, or organisms reasonably suspected or cannot be ruled out for *Bacillus anthracis*, *Brucella* spp, *Burkholderia mallei* or *pseudomallei*, *Francisella tularensis*, *Yersinia pestis*.
 - c. Leakproof Biohazard bag
 - d. Extra adsorbent (gauze or paper towel) may be necessary
 - e. Clear Tape
 - f. DOT Shipper’s Certification Statement
 - g. Emergency Response Information – Specific organism MSDS or Guide 158 (provided by NPHL)

Certification:

Certification must be kept at original site of shipment. If requested by inspectors, this can be found in the NPHL Shipping Notebook, labeled “Saf-T-Pak Proprietary Information – Development Report.”

Procedure:

Appropriate biological safety cabinet level must be used and appropriate PPE worn when performing this procedure. Standard Universal Precautions must be followed.

An organism classified as Category A to be transported outside of NPHL requires the following guidelines:

1. Locate white NPHL shipping system with UN2814 label (see above Supplies & Equipment).
2. The propagated organism to be shipped is transferred to a primary container using standard laboratory protocol and must be performed in a biological safety cabinet. The primary container must be leak proof and sealed with tape or parafilm. It is highly recommended tube media be used as the primary container. If time does not permit subculture to tube media, please page NPHL (402) 888-5588
3. Label primary container with at least 2 patient identifiers, date and the name of the contents.
4. Place primary container and adsorbent in biohazard bag. NPHL provides sufficient absorbent for one primary container. If multiple primary containers are used, add additional adsorbent.
5. Expel all air and seal.

6. Wrap primary container/biohazard bag snugly in piece of bubble wrap included in system. Multiple primary containers must be wrapped to prevent contact between them.
7. Place biohazard bag/bubble wrap in the round secondary vessel. Use sufficient bubble wrap to keep the inner contents from shifting. **DO NOT PLACE DRY ICE INSIDE SECONDARY VESSEL.**
8. Thread lid onto the vessel and close tightly.
9. Place vessel into the outer box with Fibreboard Coil.
10. Place the following between the vessel and outer container:
 - a. Completed NPHL Special Microbiology Requisition. This serves as the list of contents.
 - b. Emergency Response Guide:
 - i. ERI Guide 158 or
 - ii. Specific MSDS for *Bacillus anthracis* or *Mycobacterium tuberculosis*.
11. At this point, it is strongly suggested the Responsible Person (supervisor) or other certified shipper evaluate package to confirm it is correctly packaged.
12. Seal box using clear tape.
13. **OUTER BOX LABEL** - Manually complete the following lines on pre-printed label on outer box:
 - a. "Shipper" name and "24 hr Emergency Phone Number" lines. **Responsible person from sentinel lab MUST have immediate access to phone number given during entire duration of shipment (approximately 24 hours) and must have knowledge of the contents of the shipper. Pager numbers not acceptable.**
 - b. Do NOT enter quantity on outside of box (as it will be reused).
14. **DOT Shipper's Certification Statement** – Complete the following:
 - a. "Person Responsible" and "24 hr Emergency Phone Number" line on pre-printed label. **Responsible person from sentinel lab MUST have immediate access to phone number given during entire duration of shipment (approximately 24 hours) and must have knowledge of the contents of the shipper. Pager numbers not acceptable.**
 - b. Shipping Description:
 - i. In space below "UN2814 Biological Substance, Category A", write in exact proper shipping name (technical name):
 1. Suspected Category A infectious substance
 - ii. Total Quantity - please list number of plates or tubes AND their total volume (mL or gm)
 - c. Complete Shipper Name Box:
 - i. Print Shipper Name – who actually physically packaged the Category A material
 - ii. Signature
 - iii. Date
 - d. Make 3 copies of Certification Statement
 - i. One copy for your lab records
 - ii. One for NPHL – place inside pouch
 - iii. One for Capital Express Courier – tape on outside of pouch
15. Make copy of all other paperwork (NPHL requisition, shipping paper, etc). Save **all shipping documents for 2 years** in NPHL Packaging and Shipping Division 6.2 Materials Notebook or other designated area.
16. Place **Emergency Response** Guide (ERI) Guide 158 or specific MSDS for *Bacillus anthracis* or *Mycobacterium tuberculosis* on outside of pouch (with Shipping Statement) or give to courier.
17. Have Responsible person (supervisor) or other certified shipper evaluate paperwork to confirm it is correctly completed. If not correctly completed, courier will NOT accept.
18. **Notify NPHL at 24/7 pager (402) 888-5588 to arrange for courier, if routine pickup is not available.**

Shipping Instructions for Category B (NPHL Ground Courier Only)

Supplies and Equipment:

2. Biological Substances UN3373 (Category B):
 - a. Leak proof primary container – supplied by sentinel laboratory, must be leakproof and sealed by parafilm or tape.
 - b. Secondary & Outer Packaging - must use corresponding products certified to meet the internal pressure requirements of 95kPa(13.8 lbs/in²) because shipments are likely to be placed into unpressurized cargo sections of aircraft which fly at high altitudes. Therefore, the shipping systems are provided by NPHL which contain corresponding components including a leak proof, pressure-resistant secondary vessel, absorbent material, and rigid durable outer package which measures at least the required 4x4 inch on one surface and labeled with strict UN manufacturing markings:
 - i. Ambient temperature: Safety T Pak™ (STP-200 Category B Shipping System, Ambient. Maximum Capacity: four 10 mL vials. System includes secondary, absorbent, and rigid outer packaging.) See drop/pressure certification.
Example: *Bordetella pertussis*, *Haemophilus influenzae* (sterile site), *Listeria monocytogenes*, *Neisseria meningitidis*, *Salmonella* spp, *Vibrio cholerae*.
 - c. Leakproof Biohazard bag
 - d. Extra adsorbent (gauze or paper towel) may be necessary
 - e. Clear Tape
 - f. NPHL Ground Courier Category B Shipping Paper (provided by NPHL)

Certification:

Certification must be kept at original site of shipment. If requested by inspectors, this can be found in the NPHL Shipping Notebook, labeled “Saf-T-Pak Proprietary Information – Development Report.”

Procedure:

Appropriate biological safety level must be used and appropriate PPE worn when performing this procedure. Standard Universal Precautions must be followed.

An organism classified as Category B to be transported outside of NPHL requires the following guidelines:

1. Locate NPHL brown shipping system with UN3373 label (see above Supplies & Equipment).
2. The organism to be shipped is transferred to a primary container using laboratory protocol. The primary container must be leak proof and sealed with tape or parafilm. It is highly recommended tube media be used as the primary container.
3. Label primary container with at least 2 patient identifiers, date and the name of the contents.
4. Place primary container and absorbent material in biohazard bag. Expel all air and seal.
5. Wrap primary container/biohazard bag snugly in piece of bubble wrap to prevent shifting in secondary vessel. Multiple primary containers must be wrapped to prevent contact between them.
6. Place biohazard bag/bubble wrap in the round secondary vessel above the absorbent material provided. Use sufficient bubble wrap to keep the inner contents from shifting. **DO NOT PLACE DRY ICE INSIDE SECONDARY VESSEL.**
7. Thread lid onto the vessel and close tightly.
8. Place vessel into the outer box with Fibreboard Coil.

9. Place completed NPHL Special Microbiology Requisition between the vessel and outer container.
10. Seal box using clear tape.
11. Manually complete the following lines on label on outer box if not already pre-printed:
 - a. Responsible Person – print name
 - b. Facility Name
 - c. Address, City, State and Zip Code
 - d. Phone number. **Responsible Person MUST have immediate access to phone number given during business day and must have knowledge of the contents of the shipper.**
12. **NPHL Ground Courier Category B Shipping Paper** – complete the following:
 - a. Responsible Person and Phone Number, same as listed on outside of box.
 - b. List of Contents – list all organism shipped in secondary vessel
 - c. Total Quantity – list number of plates or tubes
 - d. Complete Shipper Name Box:
 - i. Print Name – who actually physically packaged the Category B material
 - ii. Signature
 - iii. Date
13. Make copy of all paperwork (requisition, shipping paper, etc) for laboratory documentation. **Save all shipping documents for 2 years** in NPHL Packaging and Shipping Division 6.2 Materials Notebook or other designated area.
14. Place Category B Shipping Paper into clear resealable pouch attached to top flap.
15. Give to NPHL courier if your facility has a daily route or call NPHL at 24/7 pager (402) 888-5588 to arrange courier.

References:

1. Transporting Infectious Substances Safely, US Department of Transportation Pipeline and Hazardous Materials Safety Administration. October 1, 2006
2. Sentinel Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases, Packing and Shipping Infectious Substances, American Society for Microbiology. 15 November 2010.
3. FedEx Ship Manager® User Guide:
[http://fedex.com/us/software/pdf/FedEx_Ship_Manager_Software_User_Guide_v2440_\(English\)_0312_2010.pdf](http://fedex.com/us/software/pdf/FedEx_Ship_Manager_Software_User_Guide_v2440_(English)_0312_2010.pdf)
4. IATA Volume 2 Air Operator and Agency Certification and Application Process, Chapter 2 General Information for Air Carrier Certification and Fractional Ownership Application, Section 6 Hazardous Materials or Dangerous Goods 7/24/2009:
[http://fedex.com/us/software/pdf/FedEx_Ship_Manager_Software_User_Guide_v2440_\(English\)_0312_2010.pdf](http://fedex.com/us/software/pdf/FedEx_Ship_Manager_Software_User_Guide_v2440_(English)_0312_2010.pdf)
5. Packaging & Shipping Division 6.2 Materials Workshop, National Laboratory Training Network, Presented by Patricia L Payne, PhD, MT(ASCP), consultant to APHL, 2012