



SRI International – Clinical Analysis Laboratory (CAL) Guideline for Transporting Biological Materials

Introduction

The U.S. Department of Transportation (DOT) regulates the transportation of hazardous materials when transported by air, highway, rail, or water in the United States under the Hazardous Materials Regulations (HMR; 49 CFR, Parts 171-180) (http://www.access.gpo.gov/nara/cfr/waisidx_99/49cfrv2_99.html). These regulations include shipment of biological and/or infectious materials. Biological materials including specimens for research must be properly packaged and identified before transportation. This policy applies to all biological/infectious materials shipped to and from all SRI locations.

Each person who offers for transport or transports biological and/or infectious materials on public highways must be trained and documented. SRI –(CAL) will not transport any biological material package unless the following is adhered to.

The following categories of materials are subject to DOT Regulations (Division 6.2) and may **NOT be transported on a public highway or road **by SRI**. They include:**

- Infectious substances as defined by 49 CFR S173.134 as Category A are materials known to contain or suspected of containing a pathogen. A pathogen is a microorganism (including its viruses, plasmids, or other genetic elements, if any) or a prion that has the potential to cause serious disease in humans or animals (see page 6 for list),
- Category B substances as defined by 49 CFR S173.134 are infectious substances which do not typically cause permanent disability or life threatening or fatal disease to humans or animals when exposure to it occurs, and those diagnostic or research specimens, from human or animals, which are known to or suspected of having one of these infectious agents. Typically these will be Risk Group 2 Organisms (NIH or WHO classifications) and include specimens that are collected for diagnosis because of a suspected or known infectious disease which are not Category A materials.
- Any infectious substance that is in a form capable of causing permanent disability or life threatening or fatal disease to otherwise healthy humans or animals when exposure to it occurs. Typically these will be Risk Group 3 or 4 organisms (NIH, WHO classifications).
- Patient specimens **LIKELY** to cause disease in humans and animals: including, but not limited to, excreta, secreta, blood and its components, tissue, and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected humans or animals .
- Biological products: virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product used in the prevention, diagnosis, treatment, or cure of diseases in humans or animals. Biological products that do

NOT contain a pathogen or that contain a Risk Group 1 pathogen are NOT considered regulated under this section.

- Cultures and stocks: material prepared and maintained for growth and storage and containing a Risk Group 2, 3, or 4 (<http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4s3.htm>) infectious substance,
- Sharps: any object contaminated with a pathogen or that may become contaminated with a pathogen through handling or during transportation and also capable of cutting or penetrating skin or a packaging material. This includes needles, syringes, scalpels, broken glass, culture slides, culture dishes, broken capillary tubes, broken rigid plastic, and exposed ends of dental wires.
- Materials which require a permit from USDA (http://www.aphis.usda.gov/plant_health/permits/index.shtml) or CDC (<http://www.cdc.gov/od/sap/docs/salist.pdf>): contact EH&S (Rainbow.leung@sri.com) to verify transportation requirements,
- Any material that is being shipped across state borders.

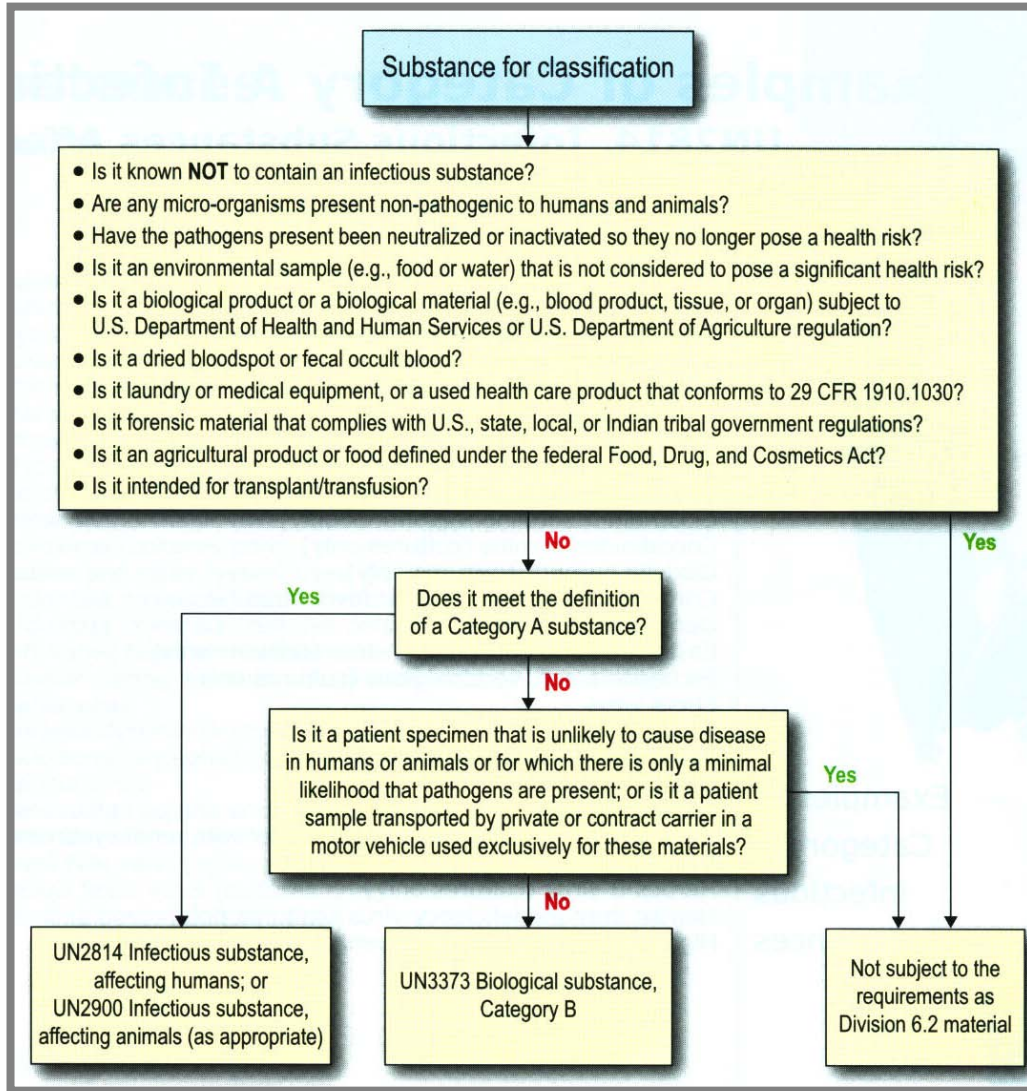
The following materials are NOT regulated by DOT shipping and handling regulations (Division 6.2) for the purpose of highway transportation and SRI may transport:

- Human or animal materials collected from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention and for which, in the professional judgment of the shipper, there is minimal likelihood of an infectious agent or pathogen being present,
- Patient specimens that contain no Category A infectious substance being transported for research, diagnosis, investigational activities or disease treatment or prevention (see Category A table of infectious substances, page 5),
- Biological products that do not contain a pathogen or that contain a Risk Group 1 pathogen,
- Blood or organs collected for transfusion or transplant,
- A material that previously contained an infectious substance that has been treated by steam sterilization, chemical disinfection, or other appropriate method, so it no longer meets the definition of an infectious substance,
- Environmental microbiological samples collected to evaluate occupational and residential exposure risks,
- DNA, RNA, or protein samples from biosafety level 1 organisms,
- Cell lines which are not known to be infected with Risk Group 2 or 3 agents.

If the material is NOT subject to shipping/handling requirements of DOT (Division 6.2) use the following procedures to transport samples:

- All materials must be transported and stored in a secondary container to prevent breakage. A secondary container must be capable of containing the materials if the primary container breaks or leaks. Absorbent materials must be included in the secondary container to absorb any liquids. Cushion the materials to prevent container breakage. Consult the attached Guide for Packaging Biological/Infectious Materials for Transportation as an example.
- Small amounts of biological materials in sealed containers can be transported in a cooler with a latching lid. The cooler will act as the approved secondary container. Inside this cooler must be enough absorbent or cushioning to prevent shifting during transport. The cooler must also be secured to prevent it from sliding or toppling during transport.
- Include on the cooler or container a Packing List (see page 6) including a list of the materials being transported and the emergency phone numbers (see attached packing list). Retain a copy with the driver.
- Mark the outer container (or cooler) with the words “EXEMPT HUMAN/ANIMAL SPECIMEN”.
- It is best if the materials can be transported within the trunk if the vehicle has one. It is also recommended, though not required, that an SRI vehicle be used for the transportation. For security and safety purposes minimize stops along the route.
- It is prudent to carry a cell phone in case of any problems or emergencies along the way. If there is a problem during transport, contact EH&S during normal business hours at 650-859-2211. After normal hours contact Security at 650-859-2900.
- Any release of the material must be reported to one or both of the emergency numbers.

Guide for Determining Classification of Biological/Infectious Materials for Transportation



Genetically modified organisms that are not infectious but can alter animals, plants or microorganisms in a way that is not normally the result of natural reproduction are considered a miscellaneous hazard (Class 9) and are shipped under UN3245. If infectious, they are assigned to UN2814, UN2900, or UN3373.

Category A Infectious Substances

Table 3.6.D
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.1)

UN Number and Proper Shipping Name	Micro-organism
UN 2814	<i>Bacillus anthracis</i> (cultures only)
Infectious substance affecting humans	<i>Bruceella abortus</i> (cultures only)
	<i>Bruceella melitensis</i> (cultures only)
	<i>Bruceella suis</i> (cultures only)
	<i>Burkholderia mallei</i> – <i>Pseudomonas mallei</i> – Glanders (cultures only)
	<i>Burkholderia pseudomallei</i> – <i>Pseudomonas pseudomallei</i> (cultures only)
	<i>Chlamydia psittaci</i> – avian strains (cultures only)
	<i>Clostridium botulinum</i> (cultures only)
	<i>Coccidioides immitis</i> (cultures only)
	<i>Coxiella burnetii</i> (cultures only)
	Crimean-Congo hemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	<i>Escherichia coli</i> , verotoxigenic (cultures only)
	Ebola virus
	Flexal virus
	<i>Francisella tularensis</i> (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)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus

UN Number and Proper Shipping Name	Micro-organism
	Kyasanur Forest disease virus
	Lassa virus
	Machupo virus
	Marburg virus
	Monkeypox virus
	<i>Mycobacterium tuberculosis</i> (cultures only)
	Nipah virus
	Omsk hemorrhagic fever virus
	Poliovirus (cultures only)
	Rabies virus (cultures only)
	<i>Rickettsia prowazekii</i> (cultures only)
	<i>Rickettsia rickettsii</i> (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)
	Sabia virus
	<i>Shigella dysenteriae</i> 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)
	<i>Yersinia pestis</i> (cultures only)
UN 2900	African swine fever virus (cultures only)
Infectious substances affecting animals	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Goatpox virus (cultures only)
	Lumpy skin disease virus (cultures only)
	<i>Mycoplasma mycoides</i> – 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)

PACKING LIST for EXEMPT HUMAN/ANIMAL BIOLOGICAL MATERIAL

From:

Sender's name

Sender's address

To:

**SRI International
Clinical Analysis Laboratory, PN124
333 Ravenswood Avenue
Menlo Park, CA 94040
(650) 859-2335**

Sender's phone number

**EMERGENCY CONTACT (24 HR)
(650) 859-2900 Security**

**OTHER INFORMATION:
(650) 859-2211 EH&S Department**

EXEMPT HUMAN/ANIMAL SPECIMENS

List of Shipment Contents:

This shipment contains the above described Exempt human/animal biological specimens that are exempted under 49 CFR Section 173.134 (b) as Division 6.2 materials. It does not contain an infectious substance or one that is likely to cause disease in humans or animals.

In case of spill, material can be cleaned by application of bleach and then wiped up with absorbent. Spill cleanup materials are stored in accompanying sealed plastic bag. Report all spills to EH&S (650-859-2211).

**ATTACHED THIS FORM TO THE OUTSIDE OF THE SHIPPING CONTAINER
Driver should retain a copy inside vehicle.
Persons presenting this form for shipment must be trained.**