Transport of Infectious Substances Introduction

Biosafety and Biosecurity Awareness Training Event for Afghan and Pakistani Bioscientists

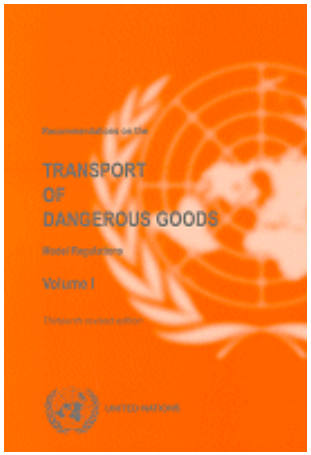
December 7 to 9, 2009

SAND No. 2008-0480P
Sandia is a multiprogram laboratory operated by Sandia Corporation, a Lockheed Martin Company, for the United States Department of Energy's National Nuclear Security Administration under contract DE-AC04-94AL85000.

International
BIOLOGICAL THREAT REDUCTION

Determine Requirements to Ship

- **Discussion: Authorizing shipments**
  - Who at your facility is authorized to approve the shipment of samples?
  - What needs to be considered in determining whether to approve a shipment from your facility?
  - Do all shipments require the same process?
  - What documentation is required?



Regulations That May Impact Shipping

- **Regulations that impact approvals and process**
  - Biosecurity regulations
  - Export and import control regulations
- **Regulations that impact shipping process**
  - UN Model Dangerous Goods regulations
  - Regional regulations
    - **European rail and road regulations, NAFTA**
  - National shipping regulations
  - Local shipping regulations
  - Regulations for each mode of transportation
    - **Air, Road, Rail, Sea**
  - Postal regulations
  - Carrier requirements
  - WHO recommendations

Import, Export, and Biosecurity Regulations

- **Many countries have import regulations requiring recipients to get a permit prior to importation**
  - Helps expedite clearance of infectious materials through customs
- **Export controls and export licensing help facilitate legitimate trade and ensure compliance with international treaties**
  - Some countries abide by Australia Group recommendations for export controls
  - Biological and Toxin Weapons Convention requires State Parties to:
    - **Prevent the transfer of materials which might assist the manufacture, or any means of acquiring biological weapons (Article III)**
  - United Nations Security Council Resolution 1540 requires all States to:
    - **Establish and maintain appropriate effective national export and trans-shipment controls**
- **National biosecurity regulations**
  - Typically require approval of recipient prior to shipment

UN : Transport of Dangerous Goods Sub-Committee

- **Meets 4 times in every 2 year period**
- **Develops Model Regulations on the Transport of Dangerous Goods**
- **27 countries with voting status**
  - Argentina, Australia, Austria, Belgium, Brazil, Canada, China, Czech Republic, Finland, France, Germany, India, Iran, Italy, Japan, Mexico, Morocco, Netherlands, Norway, Poland, Portugal, Russian Federation, South Africa, Spain, Sweden, UK, and US
- **Non-voting observers (numerous countries and non-governmental organizations), including**
  - ICAO (International Civil Aviation Organization)
  - IATA (International Air Transport Association)
  - EBSA (European Biological Safety Association)
  - ABSA (American Biological Safety Association)
  - WHO (World Health Organization)

- **UN Transport Secretariat's Website**
  - http://www.unece.org/trans/main/dgdb/dgsubc/c3age.html

Development of Regulations for Transport of Infectious Substances

UN Transport of Dangerous Goods Sub-Committee

Model Regulations on the Transport of Dangerous Goods

ADR (road) | **RID (rail)** | **IMO (sea)** | **ICAO (air)** → **IATA (air)**

National Regulations

International BIOLOGICAL THREAT REDUCTION

Definitions

- **Dangerous Goods**
  - Articles or substances which are capable of posing a risk to health, safety, property or the environment
  - Those goods which met the criteria of one or more of the nine UN hazard classes
- **Infectious substances**
  - Substances which are known or are reasonably expected to contain pathogens
  - Pathogens are microorganisms (including bacteria, viruses, rickettsiae, parasite, fungi, and other agents such as prions), which can cause disease in humans or animals
  - Divided into 2 categories: Category A and Category B

Definitions (continued)

- **Infectious substance, Category A**
  - Infectious substance which is transported 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
- **Infectious substance, Category B**
  - An infectious substance that does not meet the criteria for inclusion in Category A
- **Cultures (laboratory stocks)**
  - Cultures are the result of a process by which pathogens are intentionally propagated
  - This definition does not include human or animal patient specimens as defined below.
- **Patient specimens**
  - These are human or animal material collected directly from humans or animals and transported for research, diagnosis, investigational activities, or disease treatment or prevention
  - Includes, but is not limited to, excreta, secreta, blood and its components, tissue and tissue swabs

Definitions (continued)

- **Biological products**
  - Those products derived from living organisms which are manufactured and distributed in accordance with the requirements of appropriate national authorities, which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto
- **Genetically modified microorganisms and organisms**
  - Microorganisms and organisms in which genetic material has been purposely altered through genetic engineering in a way that does not occur naturally
- **Medical or clinical wastes**
  - Wastes derived from the medical treatment of animals or humans or from bioresearch

Nine Classes of Dangerous Goods for Shipping

- **Class 1 Explosives**
- **Class 2 Gases**
- **Class 3 Flammable Liquids**
- **Class 4 Flammable Solids**
- **Class 5 Oxidizing Substances and Organic Peroxides**
- **Class 6 Toxic and Infectious Substances**
  - 6.1 Toxic Substances
  - 6.2 Infectious Substances
- **Class 7 Radioactive Material**
- **Class 8 Corrosives**
- **Class 9 Miscellaneous Dangerous Goods**

Classifying and Identifying Samples for Shipping

- **The United Nations assigns a number to every type of dangerous goods**
- **The Proper Shipping name must be used**
  - If not exactly as in regulations, airlines will reject the package
- **Classification determines requirements and which Packing Instructions must be followed**

- **Examples:**
  - UN 2814 INFECTIOUS SUBSTANCES, AFFECTING HUMANS
  - UN 2900 INFECTIOUS SUBSTANCES, AFFECTING ANIMALS ONLY
  - UN 3373 BIOLOGICAL SUSBSTANCES, CATEGORY B
  - UN 1845 CARBON DIOXIDE, SOLID or DRY ICE

- **If samples of GMOs, patient specimens, regulated medical waste, or biological products also meet the definition of infectious substances, classify as UN 2814, 2900, or 3373.**
  - Otherwise, refer to the regulations for UN numbers and shipping requirements.

Determining if a Sample is Category A or Category B

- **Risk-based classification**
  - Risk from a shipping perspective, not a laboratory biosafety perspective
    - **Damage to Package**
    - **Pathogens Released**
    - **Exposure Incident**
    - **Entry to Host**
    - **Infectious Dose**
    - **Host Susceptibility**
    - **Infection**

- **Tables of Indicative Samples of Category A; Tables not exhaustive**
  - New or emerging pathogens meeting same criteria shall be classified as Category A
  - Cultures may be Category A or B depending on microorganisms

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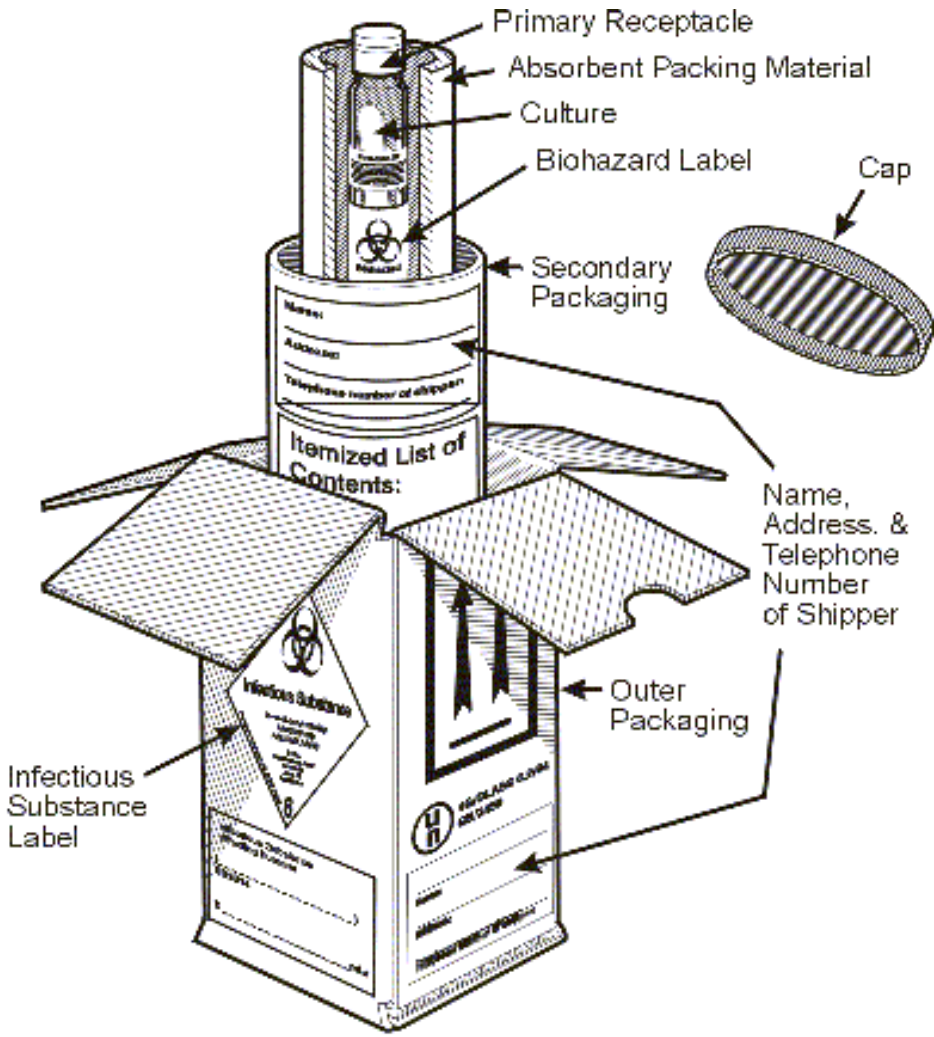
Examples of Category A Infectious Substances

Table 3.6.D
Indicative Examples of Infectious Substances Included in Category A in Any Form Unless Otherwise Indicated (3.6.2.2.2.1)

UN Number and Proper Shipping Name	Micro-organism
UN 2814	*Bacillus anthracis* (cultures only)
Infectious substance	*Brucella abortus* (cultures only)
affecting humans	*Brucella melitensis* (cultures only)
	Brucella suis (cultures only)
	Burkholderia mallei – Pseudomonas mallei – Glanders (cultures only)
	Burkholderia pseudomallei – Pseudomonas pseudomallei (cultures only)
	Chlamydia psittaci – avian strains (cultures only)
	Clostridium botulinum (cultures only)
	Coccidioides immitis (cultures only)
	Coxiella burnetii (cultures only)
	Crimean-Congo hemorrhagic fever virus
	Dengue virus (cultures only)
	Eastern equine encephalitis virus (cultures only)
	Escherichia coli, verotoxigenic (cultures only)
	Ebola virus
	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)
	Human immunodeficiency virus (cultures only)
	Highly pathogenic avian influenza virus (cultures only)
	Japanese Encephalitis virus (cultures only)
	Junin virus
	Kyasanur Forest disease virus
	Lassa 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 (cultures only)
	Rickettsia rickettsii (cultures only)
	Rift Valley fever virus (cultures only)
	Russian spring-summer encephalitis virus (cultures only)
	Sabia virus
	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)
UN 2900	African swine fever virus (cultures only)
Infectious substances	Avian paramyxovirus Type 1 – Velogenic Newcastle disease virus (cultures only)
affecting animals	Classical swine fever virus (cultures only)
	Foot and mouth disease virus (cultures only)
	Goatpox 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)

Overview of Packaging

- **Triple packaging required for Category A and B**
- **Primary receptacle**
  - A primary watertight, leak-proof receptacle containing the specimen
- **Secondary packaging**
  - A durable, watertight, leak-proof package to enclose and protect the primary receptacle(s)
  - Absorbent material shall be used to absorb all fluid in case of breakage
- **Outer packaging**
  - Secondary packagings are placed in outer packagings with cushioning material
  - Outer packagings protect their contents from physical damage while in transit
  - At least one external surface with a minimum dimension of 10x10 cm



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Required Documentation

- **For all shipments, consider**
  - Is an import and/or an export permit needed?
  - Material transfer agreement or other agreement to share materials prior to shipping?
  - Documentation indicating recipient is authorized to have material?
  - Packing list / proforma invoice, which includes
    - **Receiver's address**
    - **Number of packages**
    - **Detail of contents**
    - **Weight**
    - **Value (for customs purposes, indicate a minimal value if items supplied free of charge)**
  - Shipping waybill
- **Category A packages also require**
  - Shipper's Declaration for Dangerous Goods
  - An itemized list of contents (e.g. packing list) which is enclosed between the secondary and outer packaging

General Notes on Completing a Shipper's Declaration For Dangerous Goods

- **Must be an original document with red and white markings on sides**
- **Must be legible and perfect**
  - Carriers will wonder if sloppy paperwork indicates sloppy packaging
- **Must be in English**
- **Person signing form is responsible and must be trained**
- **Must be completed by shipper, except 3 fields**
  - Air Waybill number, Airport of Departure, Airport of Destination – these can be completed by carrier
- **No abbreviations except those listed in the Dangerous Goods Regulations**


SHIPPER'S DECLARATION FOR DANGEROUS GOODS

WARNING

TRANSPORT DETAILS

NATURE AND QUANTITY OF DANGEROUS GOODS

International BIOLOGICAL THREAT REDUCTION

Review: Shipping Category A and B Infectious Substances

Category A

- Most durable triple packaging
- Full dangerous goods documentation
- PI 602

Category B

- Less stringent triple packaging
- No dangerous goods documentation required
- PI 650

Program Management

- **Institution has a range of responsibilities related to the shipment of infectious substances**
  - From approvals prior to shipment through verification that sender receives the shipment
- **To support those responsibilities, institutions need to have**
  - Appropriate training
  - Maintenance of records
  - Written security and safety plans for transport
    - **Based on assessment of transportation safety and security risks**
    - **Address personnel, unauthorized access, en route security, training requirements, institutional requirements**

Facility Responsibilities in Shipping

- **As discussed at beginning, institution's need system to:**
  - Ensure appropriate approvals and paperwork in place prior to shipping
- **Ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during transport**
  - Classification, Packaging, Labeling, Marking, Documentation
- **Control of samples prior to shipping**
  - Which personnel are authorized to have access to the materials and information
  - Limited access to packages prior to hand over to carrier
    - **E.g secure storage for packages waiting to be picked up by carrier**
  - Using a chain of custody (CoC) may be appropriate for transport of higher security risk materials
    - **Record all individuals who have contact with the dangerous pathogens and toxins up until moment package turned over to carrier**

Facility Responsibilities in Shipping, continued

- **Selection of an appropriate carrier that can provide appropriate security by**
  - Ensuring reliable and trustworthy people handle the package
  - Controlling access to transport facilities, docks, and vehicles
  - Tracking shipping progress
  - Providing ongoing security training for employees

- **Verification that recipient receives package as expected**
  - Email or fax preferred since receipt is documented

Training

- **The dangerous goods regulations require *all personnel involved in transport* to undergo appropriate training**
  - Training for Shipping of Category A infectious substances
    - **Successful completion of a training course that includes a**
      - Written exam
  - Training for shipping of Category B infectious substances:
    - **Clear instructions should be supplied to the user**
- **Security training**
  - Security awareness training
  - Specific training as appropriate based on job duties
- **Institutions must keep training records that include**
  - Employee's name
  - Date of most recent training (every 24 months)
  - Description, copy, or location of training materials
  - Name and address of trainer
  - Certificate of successful completion