



# Training on Proficiency Testing Scheme (Microscopy PT)

**Module 7: SHIPPING INFECTIOUS SUBSTANCES AND BIOLOGICAL SPECIMENS**

**24<sup>th</sup>- 29<sup>th</sup> April 2018**

**Uganda Supranational Reference Laboratory**

# Content outline

- Legal requirements for shipping
- Import, export and biosecurity regulations
- Material transfer agreement (MTA)
- Terms used for shipping infectious substances
- Categorization and identification of infectious substances
- Packaging of infectious substances
- Marking and labeling packages of infectious substances
- SOP of packaging infectious substances
- Shipping limitations



# Introduction

- Uganda has approx. 1,200 health centers supposed to provide basic laboratory services.
- Samples are always moved from one point to another to be tested or referred in country or outside.
- Samples may contain infectious agents or the medium in which they are carried may be hazardous to human health.
- Adequate safety precautions should be taken during packaging, transportation and storage.

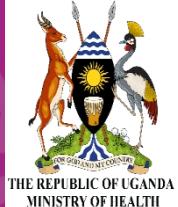


# AMP model

Assessment

AMP Mode      Mitigation

Performance



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# Legal requirements 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
  - National shipping regulations
  - Local shipping regulations
  - Regulations for each mode of transportation
  - Postal regulations
  - Carrier requirements
  - WHO recommendations



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# Import, Export and Biosecurity Regulations

- Import regulations requiring recipients to get a permit prior to importation: clearance of infectious materials through customs
- Export controls and export licensing: help facilitate legitimate trade and ensure compliance with international treaties
- National biosecurity regulations: typically require approval of recipient prior to shipment.



# Material Transfer Agreement (MTA)

- A material transfer agreement is a contract between the sender and recipient organizations
  - Defines the rights and responsibilities of each
  - Provides a record of the transfer
- Issues with sharing materials that may be addressed in a MTA include:
  - Ability to publish / academic freedom
  - Ownership of materials to be shared
  - Ownership of intellectual property
  - Further distribution of materials
  - Liability



# Terms used for Shipping Infectious Substances

- Dangerous Goods
- Infectious Substances
- Cultures and Patient Specimens
- Packaging
- Labels
- Markings



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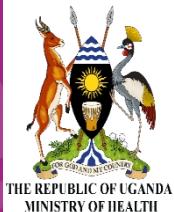
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# Terms used for Shipping Infectious Substances

## Dangerous Goods

- Dangerous goods pose a risk during transport
- There are **nine classes** of dangerous goods
- Three are important to shippers of infectious substances
  - Class 3: Flammable liquids
  - **Class 6: Toxic and infectious substances**
  - Class 9: Miscellaneous dangerous goods



## **Categorization and Identification of Infectious Substances**

### **Infectious Substances (Class 6.2)**

- Under the dangerous goods classification - class 6.2
- Class 6.2 addresses:
  - 1. Infectious substances (Category A)
  - 2. Biological substances (Category B)
  - 3. Biological products
  - 4. Genetically modified microorganisms and organisms
  - 5. Medical and clinical waste
  - 6. Infected live animals
  - 7. Exempt human/animal patient specimens
  - 8. Other exemptions



# Categorization and Identification of Infectious Substances

- Substance Categories (Division 6.2)
- Category A (Infectious Substances)
  - Ebola virus  
*Bacillus anthracis* (culture only)  
(see list provided in exercise)
- Category B (Biological Substances)
  - *Bacillus anthracis* (patient specimen)  
Highly pathogenic avian influenza virus (patient specimen)



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# Categorization and Identification of Infectious Substances

- Substance Categories (Division 6.2)
- Exempt human/animal specimens
  - Medical assessment has determined a minimal likelihood that pathogens are present
- Pregnancy test
- Drug screening



# Categorization and Identification of Infectious Substances

## Category A – Infectious Substances

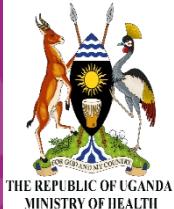
- An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals.



# Categorization and Identification of Infectious Substances

## Category B – Biological Substances

- An infectious substance which does not meet the criteria for inclusion in Category A and has not been determined by a medical professional to have a minimal likelihood that pathogens are present.



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# Categorization and Identification of Infectious Substances

## Biological products

- 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 to.



# DG Form

**NOTE:** this is a  
fill and print  
form.

Can't be saved



SHIPPER'S DECLARATION FOR DANGEROUS GOODS																				
<b>Shipper</b> National TB Reference Laboratory P.O.Box 16041 Loudel Road Kampala - Uganda			Air Waybill No. 706-24399476 Page 1 of 1 Pages Shipper's Reference Number <small>(optional)</small>																	
<b>Consignee</b> Chest Diseases Laboratory International Airport Road P.O.Box 34568 <b>ZAMBIA LUSAKA</b> <b>TEL: +26097779819</b>			<small>For optional use for Company logo name and address</small>																	
<small>Two completed and signed copies of this Declaration must be handed to the operator.</small>																				
<b>TRANSPORT DETAILS</b> <small>This shipment is within the limitations prescribed for: (delete non-applicable)</small> <table border="1" style="margin-left: auto; margin-right: auto;"> <tr> <td>PASSENGER AND CARGO AIRCRAFT</td> <td>CARGO AIRCRAFT ONLY</td> </tr> </table> <small>Airport of Departure:</small> Entebbe <small>Airport of Destination:</small> Lusaka							PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY												
PASSENGER AND CARGO AIRCRAFT	CARGO AIRCRAFT ONLY																			
<small>Failure to comply in all respects with the applicable Dangerous Goods Regulations may be in breach of the applicable law, subject to legal penalties.</small>																				
<small>Shipment type: (delete non-applicable) <b>(NON-RADIOACTIVE)</b></small>																				
<b>NATURE AND QUANTITY OF DANGEROUS GOODS</b> <small>Dangerous Goods Identification</small> <table border="1" style="width: 100%;"> <tr> <td style="width: 15%;">UN or ID No.</td> <td style="width: 40%;">Proper Shipping Name</td> <td style="width: 15%;">Class of Division (Subsidiary Risk)</td> <td style="width: 15%;">Pack- ing Group</td> <td style="width: 15%;">Quantity and type of packing</td> <td style="width: 15%;">Packing Inst.</td> <td style="width: 15%;">Authorization</td> </tr> <tr> <td>UN2814</td> <td>Infectious substance affecting humans, (Tuberculosis cultures)(Liquid)</td> <td>6.2</td> <td>1</td> <td>Fibre board box x 20ml</td> <td>620</td> <td></td> </tr> </table>							UN or ID No.	Proper Shipping Name	Class of Division (Subsidiary Risk)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization	UN2814	Infectious substance affecting humans, (Tuberculosis cultures)(Liquid)	6.2	1	Fibre board box x 20ml	620	
UN or ID No.	Proper Shipping Name	Class of Division (Subsidiary Risk)	Pack- ing Group	Quantity and type of packing	Packing Inst.	Authorization														
UN2814	Infectious substance affecting humans, (Tuberculosis cultures)(Liquid)	6.2	1	Fibre board box x 20ml	620															
<small>Additional Handling Information</small>																				
<small>Emergency contact for responsible person: William Kasule +256774715028</small>																				
<small>I hereby declare that the contents of this consignment are fully and accurately described above by the proper shipping name, and are classified, packaged, marked and labeled/placarded, and are in all respects in proper condition for transport according to applicable international and national governmental regulations. I declare that all of the applicable air transport requirements have been met.</small>					<small>Name/Title of Signatory K.William Lab supervisor Place and Date Kampala 21 October 2014 Signature  (see warning above)</small>															

Telephone: General Lines: 340874/231563/9  
Permanent Secretary's Office: 256 - 41 - 340872  
Fax: 256 - 41 - 231584



Ministry of Health,  
P. O. Box 7272,  
Kampala,  
Uganda.

IN ANY CORRESPONDENCE ON  
THIS SUBJECT PLEASE QUOTE No:

## CUSTOMS INVOICE

Date: 23<sup>RD</sup> November 2015

**Shipper:**  
National TB Reference Laboratory  
P.O.Box 16041  
Loudel Road  
Wandegeya  
Kampala – Uganda  
Tel: +256774199811

**Consignee:**  
Mr. Salih Mohammed,  
Director  
National Health Laboratory  
STATE OF ERITREA  
Ministry of Health  
National Health Laboratory  
Denden Street 83  
P.O. Box 1686-Tel 12 35 96/12 44 13  
Asmara-Eritrea  
[musalih58@gmail.com](mailto:musalih58@gmail.com)

**Contents:** Biological Substance cat A, UN2814 PI620 Infectious TB  
*Isolate culture samples*

Quantity: 20 mL  
Packed ambient

For laboratory testing only.

Customs invoice

No Commercial Value - For Customs Purposes Only \$ 10 USD

Signature and Job Title



P059 F9  
Version 1.0  
Effective date: 22-Nov-2013

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706

24016182

Shipper's Name and Address

NATIONAL TB REFERENCE LAB  
WANDEGEYA INDUSTRIAL ROAD.  
KAMPALA-UGANDA.

Shipper's Account Number

706- 24016182

Not Negotiable

Air Waybill

Issued by

Kenya Airways Ltd.

P.O. Box 19002-00501

Embakasi Airport

Nairobi, Kenya



Tel +254 20 642 2000  
Fax +254 20 627 031/2

Copies 1, 2, and 3 of this Air Waybill are originals and have the same validity.

Consignee's Name and Address

ETHIOPIAN HEALTH & NUTRITION  
RESEARCH INSTITUTE  
P.O. BOX 1242 ADDIS ABABA STREET.  
+251911167787  
ADIS ABABA-ETHIOPIA.

Consignee's Account Number

It is agreed that the goods described herein are accepted in apparent good order and condition  
(except as noted) for carriage SUBJECT TO THE CONDITIONS OF CONTRACT ON THE REVERSE  
HEREOF. ALL GOODS MAY BE CARRIED BY ANY OTHER MEANS INCLUDING ROAD OR ANY  
OTHER CARRIER UNLESS SPECIFIC CONTRARY INSTRUCTIONS ARE GIVEN HEREON BY THE  
SHIPPER. THE CARRIER IS NOT RESPONSIBLE FOR DELAY OR DAMAGE WHICH OCCURS  
STOPPING PLACES WHICH THE CARRIER DEEMS APPROPRIATE. THE SHIPPER'S ATTENTION  
IS DRAWN TO THE NOTICE CONCERNING CARRIER'S LIMITATION OF LIABILITY. Shipper may  
increase such limitation of liability by declaring a higher value for carriage and paying a  
supplemental charge if required.

Issuing Carrier's Agent Name and City

DAS HANDLING LTD.

Accounting Information



Agent's IATA Code

Account No.

Reference Number

Optional Shipping Information

Signature

SECURITY CHECKED

Airport of Departure (Addr. Of First Carrier) and Requested Routing

ENTEBBE INT'L APT EBB/NBO/ADD

To By First Carrier Routing and Destination

NBO

KE

to by to by

ADD. KQ

Requested Flight/Date

Currency

CHG

WT/VAL

PPD

COLL

Other

COLL

USD P F

PPD

COLL

PPD

COLL

Other

COLL

Declared Value for Carriage

NVD

NCV

Declared Value for Customs

Amount of Insurance

XXXXXX

Insurance - If carrier offers insurance, and such insurance is requested in accordance with the conditions thereof, indicate amount to be insured in figures with box marked "Amount of Insurance".

Handling Information

**DANGEROUS GOODS AS PER ATTACHED SHIPPER'S DECLARATION.****NOTIFY CONSIGNEE UPON ARRIVAL.**

SCI

These commodities, technology or software were exported from the United States in accordance with the Export Administration Regulations. Division contrary to USA law prohibited.

No. of Pieces RCP	Gross Weight lb	Kg Commodity Item No.	Rate Class	Chargeable Weight	Rate Charge	Total	Nature and Quantity of Goods (Incl. Dimensions or Volume)
1	1.0	K		1.0 K	AS..... AGREED.		INFECTIONOUS SUBSTANCE AFFECTING HUMAN CAT AT UN 2814 PI 626 DIMS: PT 13X13X24 X1
1	1.0	K			AS... AGREED.		Uganda
Prepaid AS... AGREED.				Weight Charge	Collect	Other Charges	
				Valuation Charge			
				Tax			
Total Other Charges Due Agent AS... AGREED.							
Total Other Charges Due Carrier AS... AGREED.							
Total Prepaid AS... AGREED.		Total Collect					
Currency Conversion Rates		CC Charges in Dest. Currency					
For Carrier's Use only at Destination		Charges at Destination					
				Total Collect Charges			

AS..... AGREED.

ENTEBBE

EBB 06

EXPORTS

Signature of Shipper or his Agent

Deborah

Signature of Issuing Carrier or its Agent

706- 24016182

Original 3 (For Shipper - blue)

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Jun-2019

AWB form

# References

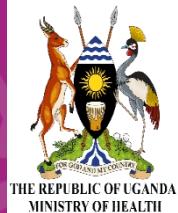
- ISO 13528:2005, *Statistical methods for use in proficiency testing by interlaboratory comparisons*
- ISO Guide 34, *General requirements for the competence of reference material producers*
- ISO Guide 35, *Reference materials – General and statistical principles for certification IATA shipping guidelines*
- Ministry of Health (2015); Biosafety and Biosecurity Manual
- Public Health Agency of Canada (2012); Bio-risk Management Notes
- Sandia (2015); Global Bio-risk Management Curriculum



# Acknowledgments



**KOFIH**  
Korea Foundation for International Healthcare  
한국국제보건의료재단



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