Concept Note [Final Draft]

Regional Infectious Substance Shipping Program and Standard Operating Procedure Development Workshop

Date: 17-19 May 2023

Length: 3 days

Location: Bangkok, Thailand

Eligible Participants:

- 1. Senior managers representing national animal health laboratories and human health laboratories from Regional Public Health Laboratory (RPHL) network Member States who are responsible for shipping programs, bench scientists and others responsible for package receiving, preparation and shipping; laboratory biosafety/biosecurity officers; trainers and others responsible for shipping programs at their facilities.
- 2. A full support including a round trip economy airfare and accommodation will be provided for two nominated participants from RPHL Member States, from both human health laboratories and animal health laboratories. Details of support will be varied based on sources of funding.
- 3. For logistic arrangement, participant should submit their registration form to the secretariat at rphlnetwork@gmail.com by 31 March 2023.
- 4. Other arrangement will be informed upon receiving completed registration.

Background/Rational:

There are many risks when shipping infectious substances. The goal of this workshop is to help facilities develop a sustainable shipping program that includes at least the following elements: records retention; written safety and security plans; emergency response plans; written policies; Standard Operating Procedure [SOPs]; access control and personnel assurance.

The launching of the Global Health Security Agenda (GHSA) in Washington DC on February 13, 2014 and Helsinki Meeting in May 5-6, 2014 marks collectively global efforts in moving towards a safe and secure world from infectious threats, as well as promoting global health security as an international security priority. During the Helsinki Meeting, the Royal Thai Government, through the Ministry of Public Health, announced its leadership in taking up the two Actions Packages including "Detect 1: National Laboratory System".

Working closely with key development partners and lead countries of Detect1, a series of regional activities to strengthen collaboration of human health laboratory and animal health laboratory as well collaboration with Detect 5 have been conducted through the Department of Medical Sciences of Thailand since 2015.

Led by Thailand through the Department of Medical Sciences, the RPHL Network has been established using a regional approach. Among others, the RPHL Network aims to enhance capacity on laboratory preparedness and response for its members in order to fulfill the identified gaps resulting from the Joint External Evaluation [JEE]. The National Contact Points from RPHL Member States have been identified.

Cited the Inception Workshop for Public Health Laboratory Network in late October 2019, Bangkok, Thailand, one of priorities proposed by the participants is the issue related to specimen referral and shipment.

To continue its efforts in promoting **One Health lab networks** in enhancing national capacity on laboratory preparedness and response, the Department of Medical Sciences in collaboration with Defense Threat Reduction Agency (DTRA), WHO SEARO, WOAH, and FIND will organize a "Regional Infectious Substance Shipping Program and SOP Development Workshop, 24-24 May 2023 Bangkok, Thailand".

<u>TWO</u> nominated national representatives; one each from human health laboratory and animal health laboratory will be supported to attend this significant Workshop. Support will be varied by different sources of funding.

The goal of this workshop is not only training scientist in infectious substance shipping but also train them on writing SOPs and assist and mentor them as they develop SOPs, policies and program plans related to shipping.

Specific Objectives:

- Review relevant and applicable regulations for transporting infectious substances with a focus on applicable regional and international requirements including the International Air Transport Association (IATA) Dangerous Goods Regulations (list others?)
- Become certified as a shipper of infectious substances according to applicable international requirements
- Understand risk assessment as it applies to infectious substance shipping. Be able to classify any biological material according to risk and transport requirements.
- Properly package infectious substances for transport to avoid contamination and meet safety requirements
- Appropriately mark, label and document infectious substance packages according to risk and regulatory requirements
- Know the difference between a policy, program, plan and procedure
- Review external and internal requirements or conditions that influence shipping policy at a facility with a focus on the applicability of International regulations (ICAO TI); International Standards (IATA DGR); other guidance (CDC, WHO, CWA) on a shipping policy
- Contrast the different ways a shipping program can be set up (Centralized, decentralized, hybrid) and understand their advantages and disadvantages of each
- Write and revise a policy statement that covers shipping infectious substances for their institution
- Write the draft of a shipping program plan for their institution that includes all of the necessary and appropriate elements taking into account both safety and security

 Write and validate SOPs related to shipping activities to include: packaging, marking and labeling, package receiving, shipping authorization, material control and accountability, transport operations, spill and incident management

DRAFT PROGRAM

Pre- Session virtual Workshop	Topics/Activities	Instructors
2 Hours	 Introduction to elements of a shipping program Discussion of various types of shipping programs (centralized, decentralized, hybrid) Review of GBRMC core documents related to shipping program planning Assign Take Away Activity: Working in teams or as individual, prepare and analyze existing institutional systems utilizing the "Institution Shipping Program Self-Assessment Tool". Participants will need to be prepared to discuss at in-person workshop. 	Eric Cook
Day 1	Topics/Activities	Instructors
8:30 – 9:00 9:00 – 10:00	 Welcome and Introductions Workshop overview Objectives and expectations Infectious Substance Shipping Certification course Session I Introduction to shipping infectious substances, why is it important, what are we going to learn Facilitated, group discussions of the risks associated with shipping Group discussion of shipping challenges in Georgia. What do you ship, how is it transported, where is it going to, how often, etc.? 	TBD – 4 Identified RPHL Instructors
10:00-10:15	Break	
10:15 – 12:30	Session II Review of applicable regulations with a focus on IATA	

	 Introduction to the nine classes of dangerous goods, and general definitions Detailed analysis and discussion of Infectious substance definitions and classification: Category A, Category B and exempt materials Group classification exercises: participants are given a list of various biohazardous materials and using definitions from the regulations, work as a group to proper classify them
12:30 – 1:30	Lunch
1:30 – 3:00	 Session III How to use the list of dangerous goods Proper shipping names for infectious substances; individual naming exercise: participants assign proper shipping names to the materials classified previously as a group Small group discussion "How to mitigate risks of shipping?"
3:00 – 3:15	Break
3:15 – 5:00	 Group discussion and facilitated exercise to determine the principles of packaging Key components of Packing Instruction 620, 650 and 954 Marking and labeling infectious substance packages and dry ice Overpacks: what are they, when to use, how to mark and label
5:00 – 5:30	End of Day Review

Day 2	Topics/Activities	Instructors
8:30 – 10:00 10:10:15 10:15 – 12:30	Session V Review of yesterday's lecture Group exercise: marking and labeling an infectious substance package Required Documentation: packing lists, pro forma invoice, waybills, item lists of contents, shipper's declaration for dangerous goods How to complete the shipper's declaration for a Category A shipment Required information on air waybill (for Category B) Class activity: Completing a Shipper's Declaration Break Session VI Final Group Activity: Putting it all together. Each group will be given a scenario and a "mock" infectious agent. Teams will have access to PPE, packaging and other materials. Each team must properly classify, package, mark/label and prepare appropriate documentation for their given scenario. Teams will be evaluated on their performance and given feedback on how to improve Additional scenarios and practice	
	will take place until each team is able to complete the exercise with no mistakes.	
12:30 – 1:30	Lunch	
1:30 – 2:00	Review session	
2:00 – 5:00	Final Certification Exam	

Day 3	Topics/Activities	Instructors
8:30 – 9:00	SOP Course overview	
	 Objectives and expectations 	
	• Review of principles of AMP	
9:00 – 10:00	• What is an SOP?	
	Paper folding SOP exercise	
10:00 – 10:15	Break	
10:15 – 11:00	Differences between SOP, Policy, and Program Plan	
11:00-12:30	How to write an SOP	
	 Four major sections of an SOP 	
	 Practice writing an M&M candy sorting 	
	SOP	
12:30 – 1:30	Lunch	
1:30 - 3:00	• Evaluating an SOP	
	 Validating an SOP 	
	 Behavioral Observation Data 	
	• Good vs. Bad SOPs	
3:00-3:15	Break	
3:15 – 5:30	 Group activity: Review Pre-Event "Institution Shipping Program Self- Assessment Tool" results and identify a list of all the SOPs, Polices, and Program Plans that might be necessary for a shipping program. Divide into groups and determine which groups will draft identified SOPs, Policies and Program Plans related to shipping. Determine Post-Event Remote Schedule 	
	assignments (office hours sign-up)	
Post-Event Remote Workshops	Topics/Activities	Instructors
Remote Workshop #1: 2 Weeks Post Event Office Hours: 30m	 Each team will sign-up for a 30-minute review session to discuss progress on completion of assignments. Teams improve and validate their SOPs, Teams draft Policies and Program Plans developed. 	Eric Cook
Remote Workshop #2: 4 Weeks Post Event Office Hours: 30m	 Each team will sign-up for a 30-minute review session to discuss progress on completion of assignments. Teams improve their SOPs, Policies, and Program Plans developed Final suggestions and edits are incorporated 	Eric Cook

Remote Workshop #3:	 Final/overall workshop review 	Eric Cook	
6-8 Weeks Post Event	• Teams will share final policy statements		
	and program plans, and SOPs		
2 Hours	 Future plans and next steps 		
	 Distribution of certificates 		