Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

20 November 2018

DEPARTMENT MEMORANDUM
No. 2018 - 0413

FOR: **ALL UNDERSECRETARIES, DIRECTORS OF CONCERNED BUREAUS AND SERVICES, PRESIDENT OF THE PHILIPPINE HEALTH INSURANCE CORPORATION, EXECUTIVE DIRECTORS OF POPULATION COMMISSION AND NATIONAL NUTRITION COUNCIL**

SUBJECT: **Interim Guidelines on Transportation of Biological Specimens**

I. BACKGROUND AND RATIONALE:

The Bureau of Quarantine is the sole regulatory health authority at all points of entry, mandated to ensure maximum security against the introduction or spread of diseases subject to the International Health Regulations (IHR), particularly infectious diseases, emerging and re-emerging diseases and Public Health Emergencies of International Concern (PHEIC), from foreign countries into the Philippines and from one port or airport to another within the country.

Part of the scope of the bureau's mandate is to regulate the importation and exportation of Biological Materials as stated in Section 58 of Implementing Rules and Regulations (IRR) of RA 9271 "Quarantine Act of 2004".

This year, the bureau had revisited the process of its regulations. As a result, the following has been observed:

1. Existing specific guidelines focused on exportation of Biological Specimens/Materials for the purpose of clinical research as stated in Bureau Memorandum Circular 2011-2 dated March 24, 2011.

2. Administrative Order 2012-0015 dated August 22, 2012, to which the fee for Biological Specimen clearance was stated is irrelevant to the continuous growth of Biological Specimens being transported locally and internationally.

Keeping in mind the principles of FOURmula One Plus, the following interim guidelines is provided to facilitate a more efficient implementation of regulating the biological specimens being transported that may pose risk to the public health.

II. INTERIM GUIDELINES:

1. All biological specimens regardless of purpose (diagnostic, research, etc.) must secure a Quarantine Clearance before transportation. This includes domestic transportation, exportation and importation.

2. The Quarantine Clearance shall be acquired from the Bureau of Quarantine (BoQ) office where the biological specimen will be originating. In cases where there is no BoQ office at the point of origin, Quarantine Clearance shall be acquired at the nearest BoQ station from the originating location of the biological specimen.

Building 1, San Lazaro Compound, Rizal Avenue, Sta. Cruz, 1003 Manila • Trunk Line 651-7800 local 1108, 1111, 1112, 1113
Direct Line: 711-9502; 711-9503 Fax: 743-1829 • URL: http://www.doh.gov.ph; e-mail: ftduque@doh.gov.ph

3. For biological specimens originating from Manila, Quarantine Clearance shall be acquired at BoQ Main office during Monday-Friday 8:00am to 5:00pm. On Saturday, Sunday and Holiday, it should be acquired at NAIA BoQ offices.

4. The Quarantine Clearance for transportation of biological specimens shall be issued for **each package** to be transported.

Table of Reference for each package to be transported:

Description/ Category	Proper Shipping Name	UN number	Hazard class	Packing instruction	Max. Net Qty per Package for passenger aircraft	Max. Net Qty per Package for cargo aircraft
Category A Infectious substance, affecting humans	Infectious substance, affecting humans (Technical name)	UN 2814	6.2	620	50 ml or 50g	4L or 4 kg
Category B Infectious substance	Biological substance	UN3373	6.2	650	4L or 4 kg (including outer packaging)	4L or 4 kg (including outer packaging)
Patient Specimens	"Exempt human specimens"			Triple packaging	4L or 4 kg	4L or 4 kg

Source: a.) WHO Guidelines for Safe Transport of Infectious Substances and Diagnostic Specimens
b.) IATA Infectious Substances Shipping Guidelines

5. One package shall contain one type of specimen only (e.g., one package contains blood samples only; one package contains tissue samples only).

6. All Quarantine Clearance issued (no exemptions) shall be charged with a fee of Five Hundred Pesos (Php 500.00).

7. Quarantine Clearance is valid only for the specified specimens indicated in the issued Quarantine Clearance.

8. Quarantine Clearance is valid only up to the point of destination indicated in the issued Quarantine Clearance.

9. Quarantine Clearance is valid only within 5 days from the date of issuance.

10. The following documents are required for the processing of the Quarantine Clearance for transportation of biological specimens:

a) Request Letter addressed to the Bureau Director (if acquiring from BOQ provincial stations, attention to the BOQ Station Chief) and with the following contents:
   1) Type of specimen and net quantity per package
   2) Name and address of facility where specimen is collected
   3) Name and address of facility where specimen is to be transported. If multiple facilities/locations, declare up to its final destination.
   4) Purpose to which the specimen will be used
   5) Declaration that the specimen is infectious or non-infectious
   6) Date of shipment
b) FDA approval of the study (for clinical research)
c) Accomplished application forms

d) License/document stating that the shipper, courier, or individual who handled and packed the biological specimens are trained and abided to the rules and regulations of IATA and IHR of WHO
e) Airway bill (for Import)

11. The Bureau of Quarantine reserves the right to ask for additional documents when deemed necessary.

12. The Bureau of Quarantine reserves the right to cancel any issued Quarantine Clearance anytime without prior notice as deemed necessary in the interest of public health.

13. All orders, memoranda and/or other Bureau of Quarantine issuances in conflict herewith are hereby rescinded, revised or modified accordingly.

14. The above mentioned policies are effective immediately *until officially rescinded.*

For strict compliance.

By Authority of the Secretary of Health

ROLANDO ENRIQUE D. DOMINGO, MD, MPH, DPBO
Undersecretary of Health
Office of the Chief of Staff and Health Regulation Team

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MARIA CRISTINA P. RIVERA
KMITS - RECORDS SECTION
Department of Health