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Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals

Sub-Committee of Experts on the Transport of Dangerous Goods

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Item 3 of the provisional agenda
Listing, classification and packing

Facilitation of the shipment of external quality assessment, proficiency and re-testing samples

Transmitted by the World Health Organization (WHO)*

I. Introduction

1. The objective of this proposal is to streamline the process of shipping External Quality Assessment (EQA), Proficiency Testing (PT) and re-testing samples across international borders. EQA/PT samples are critical for ensuring the accuracy and reliability of laboratory tests conducted worldwide, serving as a benchmark for laboratory performance and competency. Similarly, re-testing samples play an essential role in verifying test results, thereby guaranteeing the integrity and trustworthiness of laboratory data.

2. Global health initiatives and diagnostic services are increasingly dependent on the timely and efficient exchange of these samples. However, complexities in customs clearance, transportation logistics, and biosecurity measures pose significant challenges to their swift and efficient transfer. These obstacles not only impede the global health response efforts but also effect the overall quality and reliability of healthcare services.

3. By implementing the proposed changes, WHO aims to enhance the efficiency and reliability of the shipment processes for EQA/PT samples, thereby supporting global health security and ensuring the integrity of international health standards.

4. This is evidenced by the number of requests received by the WHO during emerging health situations for guidance on the transport of this samples including its classification.

5. This initiative aligns with Sustainable Development Goal 6, “peace, justice, and strong institutions,” in particular targeting the advancement of effective, accountable, and transparent institutions at all levels.

* A/78/6 (Sect. 20), table 20.5.

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II. Explanation

6. Delays in customs are often caused because of misunderstandings with the name on the packaging and the accompanying shipping declaration for EQA/PT and re-testing samples (e.g. SARS-CoV-2 EQA kits, Influenza Virus Proficiency Testing Panels, Influenza PT kits, EQA kits for Monkeypox, EQA Mpox, Ebola re-test sample) and the perceived risk associated with this shipment. Although these materials may be non-infectious or inactivated and pose no health risk, due to their naming, they are mistakenly perceived as infectious substances, leading to significant transportation delays.

III. Proposal

7. The following changes to paragraph 2.6.3.2.3.3 in the *Model Regulations* are proposed (new text is in **bold underline)**:

"2.6.3.2.3.3 Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to these Regulations unless they meet the criteria for inclusion in another class.

NOTE 1: *Medical equipment which has been drained of free liquid is deemed to meet the requirements of this paragraph and is not subject to these Regulations.*

NOTE 2: External quality assessment, proficiency- and re-testing samples are frequently subject to neutralization or inactivation processes or are inherently non-infectious. Therefore, notwithstanding containing names of infectious substances on the package or shipper's declaration, non-infectious, inactivated or neutralized external quality assessment, proficiency and re-testing samples, are not subject to these Regulations."

IV. Background information

8. The recommendations and actions outlined in this document are the result of comprehensive analysis and consultations conducted by WHO experts in collaboration with international stakeholders, including governmental bodies and regulatory agencies. Through collective effort and international cooperation, we aim to establish a more accessible, efficient, and secure system for the shipment of these vital samples, thereby ensuring that laboratories around the world can maintain high standards of quality and accuracy in their diagnostic services.

V. Definitions

9. **External quality assessment (EQA):** This is often used specifically in the context of laboratory medicine and refers to the process by which a set of samples are sent to different laboratories for testing. The results are then compared to assess the accuracy, reliability, and comparability of the laboratories' test results.

10. **Proficiency testing:** Proficiency testing is a quality evaluation process where laboratories are given samples to test. Their results are then compared against established standards or the results from other labs to ensure accuracy and reliability in their testing procedures.

11. **Re-testing:** Re-testing in laboratories refers to the process of conducting a second test or series of tests on a sample to verify the accuracy and reliability of the initial results. This is often done when the original results are unexpected, fall outside normal ranges, are critical for clinical decisions, or when there is a suspicion of error. Re-testing helps ensure the validity of the lab findings and is an important part of quality control and assurance practices in laboratory settings.