POSTAL SERVICE

39 CFR Part 113

New Mailing Standards for COVID-19 related Category B Infectious Substances

AGENCY: Postal Service™.

ACTION: Temporary final rule.

SUMMARY: The Postal Service is revising its Hazardous, Restricted and Perishable Mail regulations by replacing Publication 52, *Hazardous, Restricted, and Perishable Mail,* Appendix C, Packaging Instructions 6C, currently incorporated by reference, to support the rapid deployment of coronavirus (COVID-19) diagnostic tests using the mail during this public health emergency. In addition to the updated packaging instructions, all shippers of COVID-19 related Infectious Substances Category B UN3373 must obtain authorization from the Postal Service prior to mailing. These measures are necessary to ensure that diagnostic kits potentially containing Category B Infectious Substances are packaged, marked and labelled properly to ensure safety and containment throughout transport.

DATES: *Effective:* April 27, 2020 until the Federal public health emergency first declared on March 13, 2020 is terminated (following procedures prescribed in 50 U.S. Code § 1622). The Postal Service will publish a document announcing the termination date in the *Federal Register*.

FOR FURTHER INFORMATION CONTACT: Mary J. Collins at (202) 268-5551 or Dale Kennedy at (202) 268-6592 or by email at pcfederalregister@usps.gov.

SUPPLEMENTARY INFORMATION:

OVERVIEW

The United States Postal Service is currently experiencing a greater demand for the transportation of Infectious Substances, Category B UN3373 as a result of the ongoing COVID-19 pandemic. Due to the infectious nature of these materials, there exists a need for higher levels of awareness, safety and compliance in order to protect our employees, customers, and transportation partners.

When a package containing infectious substances is moved between the point of origin and its destination, it may be subjected to physical challenges, including movement, vibration, and changes of temperature, humidity and pressure. It is therefore, essential that the packaging used to contain infectious substances meets all required standards, and is able to withstand the normal conditions of transportation. It is the responsibility of the shipper to ensure they comply with all applicable regulations. The revisions will provide conformity and harmonization with other regulatory entities, prevent the shipment of fraudulent test kits in the mail, and reduce risk to employees and the general public by preventing exposure to this infectious substance.

The current packaging requirements incorporated by reference in Publication 52 Appendix C, Packaging Instruction 6C are replaced with new required shipper authorization and updated packaging requirements added as § 113.3. Section 113.3 will be in place until the end of this public health emergency.

The Postal Service will publish a document announcing the termination date in the *Federal Register*. If you want to know whether this rule has been terminated, email or call either person identified in **FOR FURTHER INFORMATION CONTACT**.

The specific requirements to be used in place of Appendix C, Packaging Instruction 6C to Publication 52, *Hazardous, Restricted, and Perishable Mail* adopted in this document will be published in *Postal Bulletin 22544* on April 23, 2020, and can be viewed at http://about.usps.com/postal-bulletin.**List of Subjects in part 113**

Administrative practice and procedure, Postal Service.

For the reasons set forth above, the Postal Service amends 39 CFR part 113 as follows:

PART 113 - HAZARDOUS, RESTRICTED, AND PERISHABLE MAIL

1. The authority citation for part 113 continues to read as follows:

Authority: 5 U.S.C. 552(a); 13 U.S.C. 301-307; 18 U.S.C. 1692-1737; 39 U.S.C. 101, 401, 403, 404, 414, 416, 3001-3011, 3201-3219, 3403-3406, 3621, 3622, 3626, 3632, 3633, and 5001.

2. Amend § 113.1 by adding a final sentence to read as follows:

§ 113.1 Scope and purpose.

* * * Follow the requirements of § 113.3 in place of Publication 52, Appendix C, Packaging Instruction 6C.

3. Add § 113.3 to read as follows:

§ 113.3 Mailing Standards for COVID-19 related Category B Infectious Substances

(a) *Required Shipper Authorization.* (1) All shippers of COVID-19 related Infectious Substances Category B must obtain an authorization from the Postal Service prior to mailing. It is the responsibility of the shipper to ensure that they are aware of, and comply with, all other applicable requirements and regulations for the mailing of these materials; and they must be able to provide evidence of compliance before a written request is submitted to the manager of Product Classification, Postal Service Headquarters.

(2) Under this section, only tests developed and being performed by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) or equivalent clinical oversight regulations, and commercial tests and home collection kits authorized by either the FDA or an Institutional Review Board will be considered for mailing.

(b) *Required Packaging.* The materials must be triple-packaged, meeting the packaging requirements in 49 CFR 173.199. Such materials must be properly packaged to withstand shocks, pressure changes, and other conditions related to ordinary handling in transit, and surrounded by absorbent material sufficient to protect the primary receptacle and to absorb the total amount of liquid should the primary receptacle leak or break. The outer packaging must be of adequate size to accommodate all required shipping information and marks and will include the size of the mark on each side must not be less than 50 mm (1.97 inches) in

length, the width of the border lines at least 2 mm, and letter and numbers must be at least 6 mm (0.24 inches) high.

(c) *Package Drop Test.* The completed triple packaging must be capable of successfully passing the drop test in 49 CFR 178.609(d) at a drop height of at least 1.2 meters (3.9 feet). Following the drop test, there must be no leakage from the primary receptacle, which must remain protected by absorbent material, when required, in the secondary packaging.

(d) *Instructions*. Shippers must provide clear instructions to users regarding the procedures to be followed for preparing the samples and packaging used to transport an Infectious Substance Category B. Shippers must instruct users to adhere to all applicable mail related preparation requirements before mailing, to ensure the package is properly prepared for safe transportation.

(e) *Optional Outer Packaging*. A polybag covering may be acceptable as the outer packaging, providing that the interior triple packaging is complete, the selvage edge of the wrapping is less than 2 inches, all required markings and address information are applied both on the interior rigid box and the additional outer polybag wrapping.

(f) *Use of a Refrigerant (If Applicable)*. (1) Only cold packs or dry ice may be used as a refrigerant and must be placed outside of the secondary packaging. Interior supports must be provided to secure the secondary packaging in the original position. If a cold pack is used, the packaging must be leak-proof. If dry ice is used, the outside packaging must permit the release of carbon dioxide gas

and otherwise meet the provisions in 49 CFR 173.217. The primary receptacle and secondary packaging must maintain their integrity at the temperature of the refrigerant used, as well as the temperatures and pressures of transport by aircraft they could be subjected to if refrigeration were lost, and sufficient absorbent material must be provided to absorb all liquid, including melted ice.

(2) When dry ice is used, the package must include the markings “Carbon dioxide, solid” or “Dry ice” and an indication that the material being refrigerated is used for diagnostic or treatment purposes (e.g., frozen medical specimens). Marking requirements in USPS Packaging Instruction 9A are not applicable.

(g) *Other Allowance*. Only small quantities of Class 3, Class 8, Class 9, or other materials in Packing Groups II and III may be used to stabilize or prevent degradation of the sample, provided the quantity of such materials does not exceed 30 mL (1 ounce) or 30 g (1 ounce) in each inner packaging.

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[END DOCUMENT]

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