



U.S. Department
of Transportation
**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, DC 20590

NOTICE OF ENFORCEMENT DISCRETION REGARDING MONKEYPOX MEDICAL WASTE

The U.S. Department of Transportation Pipeline and Hazardous Materials Safety Administration (PHMSA) plays a leading role in ensuring the safe transportation of hazardous materials throughout the United States. The current multi-national outbreak of West African monkeypox has caused a noticeable increase in medical waste generated during the diagnosis and treatment of suspected or confirmed cases. Monkeypox virus is an orthopoxvirus that has two distinct lineage clades¹, the West African clade and the Congo Basin clade. According [to guidance issued by PHMSA](#) in consultation with the U.S. Centers for Disease Control and Prevention (CDC), the West African clade of the virus is classified as a Category B infectious substance² and thus waste derived from medical treatment that is contaminated with this virus can be safely transported as UN3291, Regulated medical waste, provided it is packaged in accordance with the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180).

PHMSA understands that members of the medical and waste disposal communities generating and transporting this medical waste have concerns about storage of waste materials while awaiting test results from a laboratory conducting sample analysis. Testing is needed to ensure that the suspected case is not the Congo Basin clade of the monkeypox virus, which is classified as a Category A infectious substance³ and thus subject to more stringent transportation requirements under the HMR. Waste from the Congo Basin clade is not eligible to be transported as UN3291, Regulated medical waste. After consultation with the CDC, PHMSA understands that in the United States no Congo Basin cases have been identified, and laboratory testing has continued to indicate that the current outbreak is associated with the West African clade of monkeypox virus. Therefore, a patient who tests orthopoxvirus positive can be assumed to be infected with the West African monkeypox virus, and waste generated during diagnosis, treatment, and immunization of suspected or confirmed cases, can be safely transported as UN3291, Regulated medical waste in accordance with the HMR, provided that screening outlined below indicates no risk factors for the Congo Basin Clade.

¹ Clade is a biological term for a group of organisms that are descendants of a common ancestor, and therefore having similar genetic and physical traits.

² As defined in 49 CFR 173.134(a)(1)(ii): An infectious substance that is not in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs

³As defined in 49 CFR 173.134(a)(1)(i): An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs.



Therefore, PHMSA will exercise regulatory enforcement discretion for persons who offer for transportation waste generated from medical treatment of known or suspected monkeypox patients, and who are unable to obtain results via molecular assays or genetic sequencing of patient samples to confirm the clade of monkeypox virus for classification determination. If a clinician or public health authority determines that a patient does not have known epidemiological risk for the Congo Basin clade of monkeypox virus (e.g., history of travel to the Democratic Republic of the Congo, the Republic of Congo, the Central African Republic, Cameroon, or Gabon in the prior 21 days) it is appropriate to manage the patient's waste as UN3291, Regulated medical waste. However, if epidemiological risk factors indicate a risk for Congo Basin clade monkeypox virus, waste must be managed as a Category A infectious substance pending clade confirmation, and while local and state public health authorities are consulted. The relief offered in this notice facilitates safe movement of medical waste to approved disposal facilities via motor vehicle for the purposes of protecting public health.

This document is a temporary notice of enforcement discretion. Regulated entities may rely on this notice as a temporary safeguard from Departmental enforcement as described herein. To the extent this notice includes guidance on how regulated entities may comply with existing regulations, it does not have the force and effect of law and is not meant to bind the regulated entities in any way.

This notice of enforcement discretion is effective through December 31, 2022.

Issued July 26, 2022, in Washington D.C.

William S. Schoonover
Associate Administrator for Hazardous Materials Safety