



Safety Advisory Notice¹—Classification of MPXV Diagnostic Samples and Waste

Today’s Action: The U.S. Department of Transportation’s Pipeline and Hazardous Materials Safety Administration (PHMSA) is sharing new advice from the Centers for Disease Control and Prevention (CDC) regarding diagnostic samples and clinical waste containing Monkeypox virus (MPXV) in Clade I or II. The advice clarifies that samples and clinical waste should be designated as Category B infectious substances except when they contain or are contaminated with cultures of Clade I MPXV.

Background: PHMSA sets and enforces the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) to ensure the safe transportation of hazardous materials in commerce. The HMR contains risk-based provisions for classifying, identifying, packaging, and transporting hazardous materials by all modes of transportation—including highway, vessel, air, and rail transport. Materials regulated by the HMR include infectious substances that are classified as Division 6.2, and are further categorized as either Category A² or Category B³ based on the degree of likelihood that a particular form of a material is capable of causing severe health effects as defined in 49 CFR 173.134. As the U.S. public health authority, the CDC is the nation’s leading science-based, data-driven expert on infectious disease. PHMSA worked closely with the CDC to develop the current HMR provisions for Division 6.2 infectious substances, and continues to rely on the CDC to aid the regulated community in determining the appropriate classification for specific infectious substances in accordance with the relevant HMR criteria.

Recent Events: Recently, the CDC has alerted PHMSA to an outbreak of Mpox in the Democratic Republic of Congo (DRC)⁴ attributable to Clade I MPXV. Previous studies have defined two distinct MPXV clades—Clade I (formerly known as Congo Basin) and Clade II (formerly known as West African)—with unique disease manifestations (i.e., how disease presents in people, the severity of its effects, and how readily it spreads). Both clades cause

¹ This document contains guidance provided to help the regulated community understand how to comply with regulations, but its contents are not substantive rules themselves, and do not create legally enforceable rights, assign duties, or impose new obligations not otherwise contained in the existing regulations and standards.

² The HMR defines a “Category A” infectious substance as 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. 49 CFR 173.134(a)(1)(i). See: [https://www.ecfr.gov/current/title-49/part-173/section-173.134#p-173.134\(a\)\(1\)\(i\)](https://www.ecfr.gov/current/title-49/part-173/section-173.134#p-173.134(a)(1)(i))

³ The HMR defines a “Category B” infectious substance as 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. 49 CFR 173.134(a)(1)(ii). See: [https://www.ecfr.gov/current/title-49/part-173/section-173.134#p-173.134\(a\)\(1\)\(ii\)](https://www.ecfr.gov/current/title-49/part-173/section-173.134#p-173.134(a)(1)(ii))

⁴ Mpox is formerly known as monkeypox. For updates, please see <https://www.cdc.gov/poxvirus/mpox/outbreak/2023-drc.html>

Mpox disease in humans. Human disease associated with Clade II MPXV infection is typically less severe and associated with less human-to-human transmission compared to infections with Clade I MPXV.⁵ Consequently, previous recommendations for classifying and managing materials containing or contaminated with MPXV have differed primarily based on the clade of the virus.

However, CDC has advised PHMSA that domestically available pre- and post-exposure prophylaxis and treatment options, and effective infection prevention and control measures, support re-evaluation of the risks presented by Clade I. CDC has analyzed the U.S. healthcare and public health systems' experience in managing domestic cases of Clade II MPXV since 2022—including some patients with severe illness. Based on their analysis, the CDC MPXV subject matter experts believe the countermeasures that are being used against Clade II are expected to be effective against Clade I as well, and that most forms of Clade I MPXV—other than cultures—are appropriately classified as Category B infectious substances based on the risk posed in transportation. Thus, consistent with the HMR, classification assessments should consider the form of the materials being transported in addition to the clade.

Synopsis: According to the CDC, most MPXV materials—including patient diagnostic samples and clinical waste—are appropriately classified for transportation as Category B infectious substances. As such, clinical waste containing MPXV materials of either clade may be transported as “UN3291, Regulated medical waste, n.o.s., 6.2,” and patient diagnostic samples may be transported as “UN3373, Biological substance, Category B, 6.2.” However, MPXV Clade I viral cultures—i.e., materials containing or contaminated with intentionally propagated virus—are still most appropriately classified as Category A infectious substances. Viral cultures contain higher concentrations of virus than other sample types and present a greater risk of infection upon exposure.

Future Actions: PHMSA will continue to monitor the current Mpox outbreak—as well as any future outbreaks—in partnership with the CDC and will update its guidance regarding the transportation of these infectious substances as necessary.

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⁵ Christina L. Hutson, Victoria A. Olson, Darin S. Carroll, Jason A. Abel, Christine M. Hughes, Zachary H. Braden, Sonja Weiss et al., “A prairie dog animal model of systemic orthopoxvirus disease using West African and Congo Basin strains of monkeypox virus,” *Journal of General Virology* 90, no. 2 (2009): 323–333.