Pollack

25-0048

From: INFOCNTR (PHMSA)
To: Dodd, Alice (PHMSA)
Cc: Hazmat Interps; Baker, Yul (PHMSA)
Subject: FW: DOT Letter of Interpretation for HHS Portable Biocontainment Unit
Date: Tuesday, April 22, 2025 12:57:21 PM
Attachments: DOT Letter of Interpretation for PBCU_s.pdf

Hi Alice,

Please see the attached Interpretation request.

Let me know if you need anything,

-Breanna

From: Lamana, Joseph (ASPR/RSPNS) <Joseph.Lamana@hhs.gov>
Sent: Tuesday, April 22, 2025 11:53 AM
To: PHMSA HM InfoCenter <PHMSAHMInfoCenter@dot.gov>
Cc: Muir-Paulik, Sarah (OST) <sarah.muirpaulik@dot.gov>; Vierling, Ryan (PHMSA) <ryan.vierling@dot.gov>
Subject: DOT Letter of Interpretation for HHS Portable Biocontainment Unit

PHMSA,

Please see the attached LOI for our new PBCU. I have been working with Ryan and Sarah to shape this letter.

If I need to physically mail this, let me know. If that is the case, please confirm the POC I was provided for this action.

Mr. Shane Kelley
Director, Standards and Rulemaking Division
U.S. DOT/PHMSA (PHH-10)
1200 New Jersey Avenue, SE East Building, 2nd Floor
Washington, DC 20590

And of course, please let me know if there are any questions.

Best,

Joseph P. Lamana

Director, Office of International Operations
Vice-Chair, NATO Joint Health Group
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Administration for Strategic Preparedness and Response
Washington, D.C. 20201

DATE: April 14, 2025

TO: Department of Transportation
Pipeline and Hazardous Material Safety Administration

FROM: Joseph Lamana
Director, Office of International Operations
Center for Response

SUBJECT: Letter of Interpretation for the Portable Biocontainment Unit (PBCU)

ISSUE

The Administration for Strategic Preparedness and Response (ASPR) has developed a Portable Biocontainment Unit (PBCU) to address transporting patients with high consequence infectious disease (HCID) like Ebola or Marburg[1]. ASPR is requesting a Letter of Interpretation for the PBCU. Specifically, ASPR is requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the PBCU.

BACKGROUND

The PBCU, built to support the transport of multiple HCID patients by air and ground, addresses an identified gap in infectious disease response and patient movement. When transported by air, the PBCU is self-sufficient with internal batteries, oxygen and HEPA-filtered heating, ventilation, and air conditioning (HVAC). When transported by ground, the PBCU is mounted on a support trailer that can provide continuous power via generators, and separate HEPA-filtered HVAC system.

As noted, the PBCU will transport one or more (up to six) HCID patients and a medical support team. The intended use case for the PBCU is for long-haul transport missions where it is impractical and logistically unsupportable to use Emergency Medical Service providers.

The concept of operations is to transport the PBCU to the patient(s) at their origin, load the patient(s) and the medical team into the PBCU, and transport them, via the PBCU, to one of the federally funded Regional Emerging Special Pathogen Treatment Centers (RESPTC). Prior to picking up the patient(s) at their site of origin, the PBCU will be transported empty (i.e., with out passengers) and following the delivery of the patient at the RESPTC will be transported similarly to its storage facility.

[1] https://ndc.services.cdc.gov/case-definitions/viral-hemorrhagic-fever-2022/

As mentioned above, the PBCU will be transported via ground and air transportation. Depending on the location, the unit may be transported entirely via ground transportation or a combination of ground and air transportation.

The PBCU will carry various medical supplies and equipment needed for patient care. Other hazardous commodities will be included on trailer and the PBCU:

- Deisel fuel (55 gallons),
- Engine Coolant 50/50 water glycol (21.2 liters),
- SAE 10W40 (16.8 quarts),
- 12VDC/80Ah Lead Acid battery, 585 CCA (QTY 1),
- 12VDC/170Ah AGM Super Cycle Battery (QTY 6),
- Hydraulic Lubricant ISO 15 HVI - Mobile DTE 10 Excel 15 (8 Gallons),
- Gill LT 7638-53 lead acid battery 25VDC/53Ah (QTY 12),
- Medical Oxygen – K-type oxygen tanks (QTY 4),
- Emergency Oxygen – Aerox PrO2-6 (QTY 4), and
- Fire extinguisher cylinders.

Additionally, if the patient(s) are "wet" or symptomatic, the PBCU will function as a transport vehicle/ambulance of person contaminated with a Category A pathogen. Once the patient has been removed from the PBCU, decontamination will be performed per the manufacturer's specifications. The patient will also generate Category A waste. Any waste generated will be contained within the PBCU until the waste can be safely disposed of at the receiving RESPTC.

REQUEST

Can the general exception for combustible liquids in non-bulk containers by applied in this instance? If yes, what materials would it be applicable to?

For other materials, would this scenario qualify as a "air ambulance, firefighting, or search and rescue operation" and the hazardous materials carried on the unit (such as those listed above) would then be exempted from the HMR under § 175.1 (d)?

While in transit, can the exception in § 171.823(a)(3) for emergency movement of a "transport vehicle containing hazardous materials" when "necessary to protect life or property" be used in this situation to transport a patient? Would the provision also permit the movement of a transport vehicle that contains a Category A infectious substance, such as patient generated waste, to a location where the material can be removed and disposed of safely?

Would the above exception apply to transporting the PBCU without a patient(s) as it is being transported to pick up a patient, staged to load on an aircraft, or be returned to its steady state, storage location?

Are Hazmat placards needed on the PBCU and/or the trailer? Would the exception for emergency movement of hazmat under 49 CFR 177.823(a)(3) without marking or placarding when it is necessary to protect life or property apply?

Lastly, what certification/exception, if any, must ASPR comply with for the driver and/or the trailer for the ground transport (i.e., Commercial Driver's License (CDL) with hazardous materials endorsement)?

If additional information is required for this decision, please let me know.

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Joseph Lamana
Director, Office of International Operations
Center for Response