U.S. Department
of Transportation

**Pipeline and Hazardous
Materials Safety
Administration**

1200 New Jersey Avenue, SE
Washington, D.C. 20590

DEC 0 8 2015

Mr. Brian Gootee
Safety Officer
South Carolina Department of Health and Environmental Control
Bureau of Laboratories
8231 Parklane Road
Columbia, SC 29223

Reference No. 15-0020

Dear Mr. Gootee:

This is in response to your January 27, 2015 e-mail requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to the transportation of cultures classified as Division 6.2, Category A infectious substances. In your letter, you propose to transport the cultures as simulated patient specimens to hospitals within your state to assess their ability to identify biological agents. You ask if these simulated patient specimens must be transported as Category A materials or if they can be transported as Category B.

In accordance with § 173.134(a)(1) of the HMR, if a material is known or reasonably expected to contain a pathogen, or other 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, it must be classified as a Category A infectious substance. There is no exemption to this requirement based on the intended purpose of transportation (e.g., a simulation exercise etc.).

However, shipping a simulated patient specimen for proficiency testing does not require identification of the organism on the shipping paper. When a material is described on a shipping paper by one of the proper shipping names identified by the letter "G" in column (1) of the § 172.101 Table, the technical name of the hazardous material must be entered in parentheses in association with the basic description (see § 172.203(k). Both of the identification numbers associated with Category A infectious substances, "UN 2814" and "UN 2900," require the use of technical names. The definition of a "technical name" as specified in § 171.8 states that "[g]eneric descriptions are authorized for use as technical names provided they readily identify the general chemical group, or microbiological group" and that "[f]or proficiency testing only, generic microbiological descriptions such as bacteria, microbacteria, fungus, and viral samples may be used."

Therefore, a simulated patient specimen classified as a Category A infectious substance may be shipped for the purpose of proficiency testing using a generic technical name that readily identifies the microbiological group, without identifying the specific organism.

I hope this satisfies your request.

Sincerely,

T. Glenn Foster
Chief, Regulatory Review and Reinvention Branch
Standards and Rulemaking Division

Babcock
§173.134(a)3, 173.134(a)4
Definitions
15-0020

Dodd, Alice (PHMSA)

From: Ciccarone, Michael CTR (PHMSA)
Sent: Wednesday, January 28, 2015 10:08 AM
To: Hazmat Interps
Subject: FW: Interpretation Letter Request

Shante/Alice,

Please submit this for a formal letter of interpretation.

Thanks,

Mike

From: Gootee, Brian [mailto:Gooteebe@dhec.sc.gov]
Sent: Tuesday, January 27, 2015 5:02 PM
To: PHMSA HM InfoCenter
Subject: Interpretation Letter Request

We are a Laboratory Response Network (LRN) lab required to access the hospitals within our state for their readiness and ability to identify biological agents. We would like to provide a Proficiency Test exercise to access their abilities. This would require sending the sentinel labs within our state simulated patient specimens and asking them to identify the organism. The organisms provided would be select agent exempt strains on culture media. Some of these organisms would normally be considered Category A as cultures only. 173.134(a)3 and 173.134 (a)4 do not address simulated patient specimens. Sending these Category A would require identifying the organism on the shipper's declaration and defeat the purpose of the simulated patient specimen being unknown to the sentinel lab. Can these simulated patient specimens be sent Category B. Thank you.

Non-Select Agent Strains Lower Risk

Brian Gootee, MPH
Safety Officer
Responsible Official for Select Agents
South Carolina Department of Health and Environmental Control (DHEC)
Bureau of Laboratories
8231 Parklane Road
Columbia, SC 29223
803-896-0956 office
803-767-8110 cell
803-896-0983 fax
gooteebe@dhec.sc.gov