



U.S. Department
of Transportation
**Research and
Special Programs
Administration**

400 Seventh St., S.W.
Washington, D.C. 20590

JUL 7 2003

Ms. Patricia Mancos
Methodist Hospital Laboratory
Microbiology Department
600 Grant St.
Gary, IN 46402

Ref No. 03-0140

Dear Ms. Mancos:

This is in response to your June 4, 2003 letter, requesting clarification of the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180) applicable to diagnostic specimens and infectious substances. Specifically you ask about the packaging requirements for paternity testing specimens, newborn metabolic screens, drug screens, and occult blood; and record keeping for shipments of diagnostic specimens and infectious substances.

On August 14, 2002, RSPA published significant changes to the regulations for the transport of infectious materials (including diagnostic specimens). A copy of this final rule is available at the following URL: <http://hazmat.dot.gov/67fr-53118.pdf>

A diagnostic specimen known to contain or suspected of containing a micro-organism in risk group 1, or that does not contain a pathogen, or a diagnostic specimen which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure occurs is not subject to the HMR as a Division 6.2 material (§ 173.134(b)(2)). If, in the judgement of a medical professional, a diagnostic specimen is unlikely to contain an infectious substance, then it is not subject to the requirements of the HMR. This determination should be based on the known medical condition, history, or symptoms of the source patient. Paternity testing specimens, newborn metabolic screens, urine samples for drug screens, fecal samples being tested for non-infectious disease, and blood samples tested for cholesterol or other non-infectious conditions are not subject to the HMR if a medical professional determines that they are not likely to contain infectious substances. A diagnostic specimen known to contain or suspected of containing a micro-organism in Risk Group 2 or 3 must meet the packaging requirements, including capacity, found in § 173.199. A diagnostic specimen containing a Risk Group 4 pathogen must be shipped as an infectious substance.



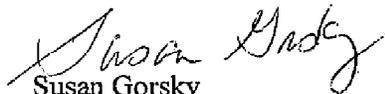
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173.134

The HMR do not require or address "initialing" of shipping papers; however, under §172.202(b) additional information may not be interspersed in a shipping description.

I hope this satisfies your inquiry.

Sincerely,

A handwritten signature in cursive script that reads "Susan Gorsky".

Susan Gorsky

Senior Transportation Regulations Specialist
Office of Hazardous Materials Standards



THE METHODIST HOSPITALS

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To: Shane C. Kelley
International Transportation Specialist
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400 7th Street, S.W. Room 8421
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Foster
§ 173.134
Infectious Substance
Diagnostic Specimens
03-0140

From: Patricia Mancos
Microbiology Department
Methodist Hospital Laboratory
600 Grant St.
Gary, IN 46402

Date: June 4, 2003

RE: ~~Shipment of Diagnostic and Infectious Substances~~

Dear Mr. Kelley:

Per our recent telephone conversation, I am submitting these questions for clarification. I appreciate your help in obtaining information. We will be awaiting your written reply. If you have any questions, please feel free to contact me via Email (pmancos@methodisthospitals.org) or at 219-886-4578. (These would be shipments within the continental U.S.)

1. Paternity testing specimens

These are "kits" supplied by private DNA testing companies for legal paternity issues. They contain buccal (inside of cheek) swabs. Do these have to be packed as diagnostic specimens?

2. Newborn metabolic screens

These are dried blood spots on cards from newborns. Do these have to be packed as diagnostic specimens? Since these can not be "crushed", would a Tyvek envelope be considered sufficient as a secondary container, would an outer cardboard container be necessary?

3. Drug screens for legal / forensic or pre-employment purposes

Are these considered diagnostic specimens? Specimens include urine drug screens and newborn meconium drug screens.

4. Occult blood screens

These are thin cardboard envelopes containing a card with a dried smear of stool. Usually these are given to outpatients by the hospital or their physicians. The patients are instructed to mail them back to us in the paper envelope or bring them back to the hospital laboratory. Are we required to instruct the patients about proper shipping? Are these considered diagnostic specimens requiring 650 packaging?

5. Blood drawing service

Out patients (apparently healthy) come to the hospital to have their blood drawn and sent to a specific laboratory, for which they already have the packaging and paperwork. Can we draw the specimen and hand it back to the patient to be packed and shipped? Patient would use the materials provided by the outside lab for packaging and ship from a site other than the hospital.

6. Record keeping

Do we need to keep records of both diagnostic 650 and infectious substance 602 shipments? What type of records are required? Will copies of the airbills and/ or Shipper's Declaration forms suffice?

Thank you for your consideration of these matters.

Sincerely,

Patrice Mancos

Patricia Mancos