



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

JUN 19 2003

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

Mr. Eric A. Barton
Vice President
Tri-Tech, Inc.
4019 Executive Park Boulevard, SE
Southport, NC 28461

Reference No. 03-0051

Dear Mr. Barton:

This is in response to your letter concerning forensic blood and urine specimens that are packaged in your company's collection kits and offered to the U.S. Postal Service (USPS) or a commercial carrier for overnight carriage to a police department crime lab for analysis. You stated that the specimens are collected by medical personnel from the general public and, while there is a possibility of the presence of alcohol or drugs in the specimens, they are not suspected of containing a pathogen. You asked whether your classification of the material as a Division 6.2, Risk Group 1, is correct under the Hazardous Materials Regulations (HMR; 49 CFR Parts 171-180; see § 173.134(a)(6)).

The answer is yes. A diagnostic specimen that does not contain a pathogen, or that contains a Division 6.2, Risk Group 1 pathogen, and does not meet the definition of any other hazard class, is not subject to the HMR. See § 173.134(b)(2).

Also, for your information, under § 173.134(b)(12), we except forensic material known or suspected to contain a Risk Group 2 or 3 infectious substance from most requirements under the HMR when transported on behalf of the federal government, a state or local government, or tribal government agency, provided the material is shipped in a packaging conforming to the provisions of § 173.24.

I hope this satisfies your request.

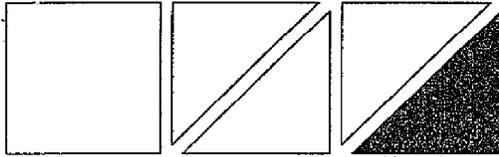
Sincerely,

Hattie L. Mitchell, Chief
Regulatory Review and Reinvention
Office of Hazardous Materials Standards



030051

173.134



Tri-Tech Inc.

4019 EXECUTIVE PARK BOULEVARD, SE • SOUTHPORT, NC 28461
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Edmonson
§ 173.134
Exceptions
03-0051

February 10, 2003

Mr. Edward T. Mazzullo, Director
Office of Hazardous Materials Standards
DHM-10
400 7th St., S.W.
Washington, DC 20590-0001

Dear Mr. Mazullo:

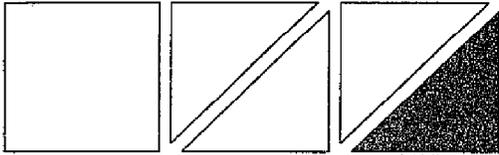
This letter is in response to the new shipping and packaging requirements prescribed in Federal Register 49 CFR Part 171 et al., dated August 14, 2002, and effective February 14, 2003.

Tri-Tech, Inc. is a manufacturer and distributor of forensic evidence collection kits and supplies. Tri-Tech, Inc. has been in business for twenty years. Tri-Tech, Inc. is regulated by the Food and Drug Administration, and we have FDA 510K approval to manufacture various types of specimen collection kits. Our FDA Registration Number is 1036781.

Tri-Tech, Inc. manufactures DWI specimen collection kits for the majority of state crime laboratories throughout the United States. The specimens (blood or urine) are collected by medical personnel, then sent by a police department to crime labs for analysis, via USPS or overnight courier. Tri-Tech, Inc. has always met or exceeded the current shipping and packaging requirements of the DOT and USPS. To the best of our knowledge, specimens from our kits have never posed any health or safety problems.

Under the Federal Register 49 CFR, Section 173.134 (a) (4), "Diagnostic specimen means any human or animal material, including excreta, secreta, blood and its components, tissue, and tissue fluids being transported for diagnostic or investigational purposes." It is our belief the kits we manufacture fall under the guidelines of this definition.

Under Section 173.134 (b) "Exceptions. The following are not subject to the requirements of this subchapter as Division 6.2 materials: (b) (2) 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 in which the pathogen has been neutralized or inactivated so it cannot cause disease when exposure to it occurs." While there is a suspected possibility of the presence of alcohol or drugs of abuse, the specimens are collected from the general population and are not suspected of containing a pathogen. It is our belief that the diagnostic specimens collected are a Risk Group 1, and therefore are not subject to HMR requirements.



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We have discussed our kits and these regulations at length with Mr. George Cushmac, Chemist, Office of Hazardous Materials Technology, (202) 366-4493. Mr Cushmac agrees with and supports our assessment.

Please advise if our assessment is indeed, correct. Since we supply the majority of state crime laboratories and police departments in the United States with DWI kits, and obviously do not want to disrupt their DWI programs, we would appreciate hearing from you as soon as possible concerning this matter.

If you should have any questions, please do not hesitate to contact me.

Sincerely,

Eric A. Barton
Vice-President

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