Due Date for Answers, Conforming Applications, or Motion to Modify Scope: July 24, 2007.
Description: Application of Thomas Cook Airlines UK Limited, (“Thomas Cook UK”) requesting a foreign air carrier permit so that Thomas Cook UK will be able to exercise new rights made available to European air carriers pursuant to the Air Transport Agreement between the United States and the European Community and the Member States of the European Union (US–EC Agreement). Thomas Cook UK also requests an amendment to its existing exemption to the extent necessary to enable it to provide the services covered by this application while the Department evaluates Thomas Cook UK’s application for a foreign air carrier permit.
Date Filed: July 5, 2007.

Due Date for Answers, Conforming Applications, or Motion to Modify Scope: July 25, 2007.
Description: Application of Zoom Airlines Limited (“Zoom”), requesting amendment no. 2 to its application for a foreign air carrier permit and an exemption to conduct: (i) Foreign scheduled and charter air transportation of persons, property and mail from any point(s) in the United States and beyond; (ii) foreign scheduled and charter air transportation of persons, property and mail between any point(s) in the United States and any point(s) in any member of the European Community via any point(s) in any Member State(s) and intermediate points to any point(s) in the United States and beyond; (iii) foreign scheduled and charter air transportation of persons, property and mail between any point(s) in the United States and any point(s) in any member of the European Common Aviation Area; (iii) foreign scheduled and charter cargo air transportation between any point(s) in the United States and any other point(s); (iv) other charters pursuant Part 212; and (v) other points(s); (iv) other charters.

Description: Application of Virgin Blue International Airlines Pty Ltd (“VBIA”), requesting a foreign air carrier permit and an exemption in order to engage in charter trips in foreign air transportation and other charters.

Renee V. Wright, Program Manager, Docket Operations, Federal Register Liaison.
[FR Doc. E7–17848 Filed 9–10–07; 8:45 am]
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DEPARTMENT OF TRANSPORTATION
Office of the Secretary

Informational Notice Regarding Certain Substituted Specimens

AGENCY: Office of the Secretary, U.S. Department of Transportation.

SUMMARY: The Office of Drug and Alcohol Policy and Compliance (ODAPC) is taking action to rectify what may be a mischaracterization of some test results as being substituted specimens. In appropriate cases, ODAPC will reconsider the employee’s original refusal result, when reported from September 1998 through May 2003, and based upon a “substitution” finding in a given numerical range.

FOR FURTHER INFORMATION CONTACT: Mark Snider, U.S. Department of Transportation, Office of the Secretary, Office of Drug and Alcohol Policy and Compliance, 1200 New Jersey Avenue, SE., Washington, DC 20590; or Telephone (202) 366–3784; or E-mail mark.snider@dot.gov.

SUPPLEMENTARY INFORMATION: In September 1998, Department of Health and Human Services (HHS) issued guidance (Program Document 035; September 28, 1998), for laboratories to determine when to report a urine specimen to the Medical Review Officer (MRO) as substituted. Under this guidance, a substituted specimen must have had a creatinine level of 5 mg/dL and a specific gravity less than or equal to 1.020.

On the same date—September 28, 1998—ODAPC issued a memorandum to MROs as a companion piece to HHS’s PD 035. In its memorandum, ODAPC instructed MROs to consider laboratory reported substituted results as refusals to test. There were no provisions for MRO review of substituted laboratory results.

The Department of Transportation amended part 40 (65 FR 79462), effective January 18, 2001, to put into practice, among other things, procedures for MRO review of substituted specimens. The amendment held that employees could show MROs that they had medical reasons for producing the result and present evidence that they could naturally produce specimens meeting the HHS criteria for substituted specimens. MROs could cancel a “substituted” result in these circumstances.

In May 2003, in response to scientific information that suggested that some people could naturally produce urine with creatinine in the 2 to 5 mg/dL range, the Department of Transportation issued an interim final rule (68 FR 31624; May 28, 2003) directing MROs not to treat these results as substituted, but as negative-dilute. Unlike part 40 procedures with other negative-dilute results however, MROs were instructed to direct the employer to have the employee return to the collection site for a directly observed collection with no prior notice. The result of the observed collection would be the result of the record for the entire testing event.

HHS revised its Mandatory Guidelines with an effective date of November 1, 2004 (69 FR 19659; April 13, 2004). Among the revisions contained in the HHS Guidelines was the requirement that laboratories modify substituted specimen criteria. Under the revised HHS Guidelines, there were, and are, no specimens with creatinine levels greater than or equal to 2 mg/dL being reported by laboratories as substituted.

Substituted results with creatinine in the 2 to 5 mg/dL range occurring between September 1998 and May 2003 were, according to the valid regulations in effect at that time, properly interpreted as refusals to test. However, in the interest of fairness the Department of Transportation is providing to individuals with such results the opportunity to have their drug test result reconsidered. If an employee’s substituted drug test result is reconsidered, employers will be instructed not to report the substituted result to other DOT regulated employers requesting the employee’s drug and alcohol testing history as required in 49 CFR part 40.25.

The Department of Transportation is issuing this notice to set forth the procedures for such reconsideration. According to the notice, we intend to grant reconsideration only to those employees who present credible medical documentation that demonstrates their ability to naturally produce urine specimens with creatinine concentrations equal to or greater than 2, but less than or equal to 5 mg/dL and a specific gravity less than or equal to 1.001 or greater than or equal to 1.020.

The Department of Transportation is issuing this notice to set forth the procedures for such reconsideration. According to the notice, we intend to grant reconsideration only to those employees who present credible medical documentation that demonstrates their ability to naturally produce urine specimens with creatinine concentrations equal to or greater than 2, but less than or equal to 5 mg/dL and a specific gravity less than or equal to 1.001 or greater than or equal to 1.020.
Employers who discover that an employee was reported to have a refusal to test as the result of a laboratory finding of creatinine concentration equal to or greater than 2, but less than or equal to 5 mg/dL, prior to May 28, 2003, should inform the employee that he or she may submit documentation to ODAPC for reconsideration. To be viewed by ODAPC as credible medical documentation, the employee would have to submit information from a licensed physician or a MRO which documents that the employee can physiologically produce urine meeting the creatinine and specific gravity criteria. ODAPC will also accept an MRO verified drug result from the employee which resulted from a Department of Transportation required drug testing event that demonstrates the employee’s ability to produce a creatinine level equal to or greater than 2, but less than or equal to 5 mg/dL. This verified result must have been reported by the MRO to the employer after May 28, 2003.

The notice also provides the address that employees should send their documentation. ODAPC will carefully review every submission and will respond in writing to each employee who seeks to have his or her original refusal to test result reviewed.

Issued this 5th day of September 2007, at Washington, DC.

Jim L. Swart,
Acting Director, Office of Drug and Alcohol Policy and Compliance.
U.S. Department of Transportation  
Office of the Secretary  
Office of Drug and Alcohol Policy and Compliance (ODAPC)  

NOTICE TO EMPLOYERS AND EMPLOYEES COVERED  
BY DOT DRUG AND ALCOHOL TESTING REGULATIONS  

REGARDING EMPLOYMENT RECORDS OF  
EMPLOYEES REPORTED AS A “REFUSAL TO TEST” DUE TO THE  
VERIFICATION OF A SUBSTITUTED URINE SPECIMEN  

We recommend that employers review past drug testing employment records, where records indicate an employee refused to test before May 28, 2003.

For substituted specimens that were reported as refusals to test prior to May 28, 2003, employers should be aware of the following:

**Before May 28, 2003:** Specimens with creatinine concentrations equal to or greater than 2, but less than or equal to 5 mg/dL [hereafter, “2-5 mg/dL range”] and a specific gravity of less than or equal to 1.001 or greater than or equal to 1.020 were considered to be substituted urine samples and therefore reported by the MRO as refusals to test.

**May 28, 2003:** An interim final rule change required that any test results meeting these criteria must be considered dilute specimens warranting recollections under direct observation. They would no longer be considered refusals to test. The preamble for this interim final rule stated that if the employer was notified of a substituted test result prior to May 28, 2003, the employer should continue to consider the result a refusal to test.

**Why the rule changed:** The U.S. Department of Transportation (DOT) became aware that a small number of people could naturally produce specimens with creatinine within this 2-5 mg/dL range.

**What this means:** That in a rare number of cases, individuals determined to have substituted urine specimens, and which were ultimately reported as a refusal to test, might not have substituted their urine samples. The purpose of this notice is to provide employers with accurate information for interpreting employment records regarding substituted/refusal test results prior to May 28, 2003. DOT would like to see employers make informed decisions.

**Warning:** This information applies only to a small number of tests, and most refusals to test determinations prior to May 28, 2003 will remain applicable.

Many responsible employers look back farther than the DOT rules require in evaluating whether to hire someone. While regulations require employers to review two or three or even five years of past drug and alcohol testing records (the length of time depends on type of your transportation industry) when an employee applies for or transfers into a safety sensitive position, DOT believes it is important for employers to take this notice into consideration when reviewing those records.
What's the remedy: The DOT will reconsider an employee's drug test result if each of the following conditions are met:

1. The substitution / refusal to test determination was reported before May 28, 2003;

2. The test had a creatinine concentration in the 2-5 mg/dL range and a specific gravity of less than or equal to 1.001 or greater than or equal to 1.020; and

3. There exists credible medical documentation that the individual naturally produces urine specimens with creatinine concentrations and specific gravity in these ranges.

NOTE: One example of what the DOT could consider credible medical documentation could be a controlled medical examination during which the individual produces the same result during a collection under direct observation. Another could include any subsequent required DOT drug test in which the individual demonstrated the ability to produce another urine specimen with creatinine concentration in the 2-5 mg/dL range and a specific gravity of less than or equal to 1.001 or greater than or equal to 1.020.

What can employees do: If you meet the above criteria, you should send documentation to DOT thoroughly addressing the above three points. Send your request to:

U.S. Department of Transportation
Office of the Secretary
Office of Drug and Alcohol Policy and Compliance
ATTN: Mark Snider [ODAPC]
1200 New Jersey Avenue, SE
Washington, DC 20590

What can employers do: If you discover through a background check or other means that a current employee or an applicant or employee who is being hired or is transferring into a safety-sensitive function was reported as refusing due to having a substituted drug test result before May 28, 2003, you may choose one or more of the following:

If you are a current or previous employer:

1. You may inform employees that the DOT can reconsider their substitution / refusal results if they meet the three conditions outlined above.

2. When you receive a 40.25 inquiry on a previous employee and have written documentation that the DOT reconsidered the employee's original refusal result, you should not report the refusal result on this test to the requesting employer.
**If you are a gaining employer:**

1. You may permit the employee to perform safety-sensitive functions if he or she has successfully completed the DOT return-to-duty process.

2. You may inform the employee that he or she may submit documentation (see above) regarding his or her substituted test result to the DOT for reconsideration. You may permit the employee to perform safety-sensitive functions upon receipt of DOT documentation that the employee has been shown to naturally produce creatinine concentrations in the 2-5 mg/dL range and a specific gravity of less than or equal to 1.001 or greater than or equal to 1.020.

3. If after reconsideration ODAPC provides written documentation stating that the original results should not be considered substituted, you should attach that written documentation to the original substituted drug test result, as proof that the test should not be considered as substituted.

**NOTE:** Under DOT regulations, all decisions to hire or fire an employee are left to the employer, but these options are provided because DOT would like employers to make the most informed decisions possible. DOT does NOT require that employers hire or fire any specific individual.

Our review will be on a case-by-case basis. Following our review, the DOT and the DOT Agencies will take appropriate action to notify employees of our determinations.

**NOTE:** This Informational Notice is time limited, and submissions must be sent to the DOT no later than six months from the date of publication of this notice in the Federal Register.

For more information, contact Mark Snider by phone at 202.366.3784 or by Email at mark.snider@dot.gov; or visit our website at: www.dot.gov/ost/dapc.