The United States Court of Appeals for the District of Columbia Circuit decided on May 15, 2009 (Case Number 08-1264) that the 2008 Department of Transportation (DOT) regulation requiring transportation industry employers to use direct observation for all return-to-duty and follow-up testing will stand as written. On July 1, 2009, the court made its final decision and lifted the stay on this issue. The Department of Transportation will issue a Final Rule in the Federal Register at a later date to place a starting date on this rule.

On June 25, 2008 the DOT published an amendment that modified the drug and alcohol testing procedures (49 CFR Part 40) for collectors, laboratories, medical review officers, and employers regarding adulterated, substituted, diluted, and invalid urine specimen results (See FTA Drug and Alcohol Regulation Updates, Issue 37). §40.67(b) was modified to state that observed collections for return-to-duty and follow-up testing would no longer be optional, but would be a required component. Originally, the rule was to become effective on August 25, 2008.

In response to petitions from certain transportation industry and labor groups, the Department of Transportation changed the effective date of §40.67(b) from August 25, 2008, to November 1, 2008 and solicited comments. After carefully considering the comments, the DOT published the “Direct Observation Rule” in the Federal Register (Volume 73, pages 62910 – 62918) on October 22, 2008. The rule requires that specimens be collected under direct observation any time there is specific reason to believe that any employee may be attempting to thwart the rule or has sufficient reason to evade the testing process, including return-to-duty and follow-up testing.

The U.S. Court of Appeals for the D.C. Circuit temporarily delayed the Direct Observation (DO) requirement for DOT return-to-duty and follow-up tests pending the court decision on the merits of the petitioners’ challenge to the provisions of §40.67(b). The U.S. Court of Appeals heard oral arguments on March 26, 2009. The DOT argued that even though it had no statistics on the rates of actual use of cheating devices, the DOT inferred their use from the growing number of products on the market (e.g., products would not be on the market if there was no demand and these products have no other use than to beat a drug test). The DOT also argued that employees returning to duty following a positive test result have a heightened incentive to cheat due to the heavy sanctions (usually termination) reserved for repeat offenders. Its position was further substantiated by testimony from several Substance Abuse Professionals who testified that employees who have tested positive in the past and continue to use are more likely to try to beat the drug test. In summary, the DOT concluded that returning employees have a heightened incentive to cheat, and that this incentive, coupled with the increased availability of cheating devices, creates a high risk justifying the need to perform direct observations.

Against claims that §40.67(b) violates the Fourth Amendment, DOT argued that the government’s interest in conducting the search outweighs the individual’s privacy interest. Furthermore, employees returning to work following a positive test result “have less of a legitimate interest in resisting a search intended to prevent future violations of that regulation than do employees who never violated the rule.”

The Court agreed and on May 15, 2009, the U.S. Court of Appeals ruled that the mandatory Direct Observation (DO) requirement for DOT return-to-duty and follow-up testing is constitutional. The court found that “the Department’s considered justification for its policy neither arbitrary nor capricious, and although we recognize the highly intrusive nature of direct observation testing, we conclude that the regulation complies with the Fourth Amendment.”

We Need Your Help!

The FTA’s Prescription and Over-the-Counter Accident surveys are still live and accepting results. If you have not already done so, please stop by the FTA’s website and fill out both surveys, which can be found at http://transit-safety.volpe.dot.gov/survey1 and http://transit-safety.volpe.dot.gov/survey2.
MRO Procedures Clarified

Medical Review Officers (MRO) serve as the independent, impartial gatekeeper responsible for the accuracy and integrity of the drug testing process. The majority of the changes that were made to the June 25, 2008 amendments to 49 CFR Part 40 have direct impact on MROs and the procedures they use to verify test results. FTA auditors have found that several MROs are confused by the latest changes and are unaware of the procedures they must follow. The following paragraphs clarify these issues.

No Contact Positives: Prior to verifying a confirmed positive test result or test refusal, the MRO must interview the employee to determine if there is a legitimate medical explanation for the test result. However, there are three circumstances when an MRO may verify a result without an interview— if the employee expressly declines the opportunity to discuss the result with the MRO; the employee fails to contact the MRO after the employer has instructed the employee to do so and 72 hours have passed; and, after ten days when neither the MRO or employer have been able to contact the employee. Similarly, the same “no contact” procedures must be followed before an MRO can verify an invalid test result as cancelled without an interview.

MROs must follow the required timelines for no contact positives and invalids as specified in §40.133. The test results must also be communicated to the Designated Employer Representative (DER) using the methods outlined in §40.163, §40.165, and §40.167. The MRO or Third Party Administrator (TPA) must report all positive test results and any other results that require immediate action by the employer to the DER on the same or next business day the MRO verifies the result. The report must be made in a confidential manner. The preferred method of immediate reporting is by direct telephone contact followed up with the appropriate documentation specified in §40.163. The electronic transmission of test results must be done in a manner that ensures the security of the transmission and limits access to any transmission, storage, or retrieval systems.

Unavailability of Split Specimen: The DOT drug testing process requires that the urine specimen be split and poured into two specimen bottles. The split specimen process provides the employee with the option of having an analysis of the split specimen performed at a separate DHHS-certified laboratory should the employee question the result of the primary specimen test result. Even though it is extremely unlikely, the MRO must know what to do in the rare event where the split specimen is unavailable for testing.

In the first circumstance where the split specimen is not available for testing (e.g., specimen leaked or was lost in transport) or there is no laboratory qualified to perform the split analysis, the MRO must cancel the test; report the result to the DER and the employee; and direct the DER to immediately send the employee to the collection site for another specimen collected under direct observation without any advanced notification. The MRO must also notify the Office of Drug and Alcohol Policy and Compliance (ODAPC) of the failure to reconfirm.

Split Specimen Fails To Confirm Primary Result: In instances where the second laboratory fails to confirm all of the primary specimen test results because the drug or its metabolite were not detected and there is no evidence of adulteration or substitution, the MRO must cancel the test and report the result to the DER and the employee. In this case, the employee should only be sent for a retest under direct observation if the specimen was invalid or the specimen was severely diluted with a specimen creatinine concentration equal to or greater than 2 mg/dL, but less than or equal to 5mg/dL. The MRO must also notify ODAPC of the failure to reconfirm.

In instances where the second laboratory fails to confirm all of the primary specimen results, but the split specimen had an adulterated, or substituted result, and the MRO determines that there is no legitimate medical explanation for the result, the MRO must report the result as a test refusal to the DER, and the employee and notify the employee that he/she has 72 hours to request a retest of the primary specimen. If the primary confirms the split result, the MRO should verify the test refusal. If the primary does not confirm the split result, the MRO should cancel the test. If the split was reported as invalid, the MRO should cancel the test and tell the DER to send the employee for a retest under direct observation. If the test of the split confirms one or more, but not all of the primary specimen results, the MRO should instruct the DER to take action only on the confirmed results.
On January 21, 2009, Cindy Ingrao was named the new Senior Policy Advisor for the Office of Drug and Alcohol Policy and Compliance (ODAPC). Ms. Ingrao has held several positions within the U.S. Department of Transportation including being the Drug and Alcohol Program Manager for the Pipeline and Hazardous Materials Safety Administration and as a Drug and Alcohol Compliance Enforcement Inspector for the Federal Aviation Administration. Ms. Ingrao joins Jim L. Swart, ODAPC Director, Patrice M. Kelly, Deputy Director, Mark Snider, Senior Policy Advisor, and Bohdan Baczara, Senior Policy Advisor.

Presentations were made by representatives from the Federal Transit Administration (FTA), the Office of Drug and Alcohol Policy and Compliance (ODAPC), FTA auditors, FTA Drug and Alcohol MIS Program and Newsletter staff, the Transportation Safety Institute, and professionals from the drug testing industry. Presentations from the Conference listed below can be viewed at the FTA website: http://transit-safety.volpe.dot.gov/DrugAndAlcohol/Training/NatConf/2009.

- The FTA Drug & Alcohol Audit Process by George Gilpatrick Jr. & John Morrison
- Best Practices by Rod Sams
- How to Review your Collection Site for Compliance by Joseph Lofgren
- Mock Collection and EBT Demonstration by Manny Chavez
- Evaluation of FTA Drug Abuse Testing Program: Cost/Benefit Analysis by Jerry Powers
- FTA vs. FMCSA: A Regulatory Comparison by John Morrison
- How to Develop your FTA Drug and Alcohol Policy by Leila Procopio-Makuh
- How to Save Money on your Drug and Alcohol Program by Michael Redington
- Beginner Drug and Alcohol Program Manager (DAPM) Training by George Gilpatrick & Joe Lofgren
- Post-Accident Thresholds by Rod Sams
- Reasonable Suspicion Training by Robbie Sarles
- The Role of the Medical Review Officer by Michelle Alexander, M.D.
- The Role of a Substance Abuse Professional (SAP) by William Mock
- Developing Tools for the Random Selection Process by Mike Redington & Brian Baker
- U.S. DOT/ODAPC Interpretations and Regulations by Mark Snider
- What Happens at the Lab by Barry Sample
- Prescription and Over-the-Counter Medications by Robbie Sarles
Random Selection Methods

Transit agencies must use a scientifically valid random number selection method to select safety-sensitive employees for a random test. Valid methods include the use of a random-number table or a computer-based random number generator that is matched with safety-sensitive employees’ identification numbers. Each covered employee must have an equal chance of being tested each time selections are made.

Most employers covered by the FTA drug and alcohol regulations contract out the random selection process to their Consortium, Third Party Administrator (TPA), or other vendor. This method has the advantage of having the random selections performed by an outside, objective vendor that is an arm’s length away from system management. For many employees and bargaining units, this approach provides additional security from perceived company biases or potential impropriety.

Many transit systems also have the perception that outside vendors use very sophisticated, scientifically valid means of selection that are designed and operated by statisticians. The reality is that most vendors use fairly basic random number generator software that is inexpensive, easy to use and readily available to transit systems to use themselves. The software does not require any special expertise or training and is usually administered by agency office personnel.

In some cases, contracting out this service has lead to problems with maintaining up-to-date employee lists, potential confidentiality leaks, untimely selection notices, billing issues, and compromised compliance. Consortium pools with multiple employers have also been known to compromise member agency compliance when not managed correctly. Contracting out the random selection process can be expensive and, for many, is unnecessary.

Transit systems may choose to administer their random number selection process in-house by using a random number table or a computer-based random number generator. Most entry level statistics books that can be purchased on-line or from commercial or college bookstores have random number generator tables and directions for their use. The process includes assigning employee numbers, selecting a starting point on the table, and then using a previously chosen systematic rule for choosing successive numbers (e.g., selecting every eighth number moving vertically across the table). There are also several free or low cost online random number generators. Examples include, but are not limited to: http://stattrek.com/Tables/Random.aspx; http://www.randomizer.org; http://www.random.org; http://graphpad.com/quickcalcs/randomN1.cfm.

Whether the random selections are made manually, via an online computer generator or contracted out, the transit system Drug and Alcohol Program Manager (DAPM) must ensure that the random pool is updated prior to every draw. The transit system may choose to select numbers for drug and alcohol random tests separately or may choose to “piggyback” alcohol tests on select drug tests. Piggy backing is acceptable as long as the decision about which tests are going to be piggy-backed is made prior to the number selection. For example, if ten drug tests and two alcohol tests are going to be performed in a testing period, the system need only pick ten numbers, as long as the system predetermines which of the ten will be drug and alcohol tests (e.g., the second and eighth number chosen) prior to the number selection.

The random selection process must be scientifically valid with employees having an equal chance of selection each time numbers are picked. Most random number selection methodologies select all of the numbers for the testing period at once and replace the selected numbers back in the pool for the next testing period selection. Using this procedure, individuals may only be selected once during a testing period. Other pool managers, replace the number back in the pool after every number draw within the testing period. This practice results in the potential for one person to be selected more than once during a testing period. Either of these options is acceptable.

Makers of “Whizzinator” Plead Guilty in Federal Court

George Wills and Robert Catalano recently pleaded guilty in a U.S. District Court in Pittsburgh. Their company, Puck Technologies, manufactured a range of prosthetic devices (such as the Whizzinator and Number 1) designed to defeat drug and alcohol tests. These devices typically took the form of a false penis connected to a hidden bladder, allowing the user to provide a known clean urine sample from the device. Their company website included numerous anonymous testimonials proclaiming these devices’ use in cheating drug and alcohol tests. The company’s descriptions of these devices also hailed their use as the “undisputed leader in synthetic urine.”

Sentencing could result in prison time of up to eight years and fines of as much as $500,000. In addition, prosecutors are seeking to seize the company’s bank accounts and web domains.
Blanket Travel Allowances Not Permitted

Once employees are notified that they have been selected for a random test, they must proceed immediately to the collection site for testing. Failure to appear for any test within a reasonable time, as determined by the employer, is considered to be a test refusal (§40.191). The employer must define what constitutes a “reasonable time” for each employee on a case-by-case basis taking into consideration the location of the employee, proximity of the collections facility, weather conditions, traffic congestion, parking proximity and other circumstances unique to the time, day, and location of the testing event. Transit systems that use a blanket travel time allowance for all employees are in violation of the intent of this provision and may be compromising the integrity of the testing process. By providing all employees the same amount of time to get to a collection site regardless of the actual time needed, some employees will have excess time that could be used to attempt to beat a test or excess time for alcohol to metabolize.

An industry best practice is to provide employees with a form that tells the employee they must go to the collection site for a test immediately. The form clearly states when the employee is required to arrive at the site and notifies the employee of the consequence for being late. The required arrival time is estimated by the agency’s Drug and Alcohol Program Manager (DAPM) or other employee supervisor based on the circumstances of the testing event. The supervisor should emphasize that the employee should go immediately to the site with no delay or detour. If the collection site is ten minutes away, a reasonable arrival time might be 15 to 20 minutes. If the collection facility is 30 minutes away, a reasonable arrival time might be 40 to 45 minutes. Upon arriving at the collection site, the receptionist can record the arrival time on the form providing documentation of the travel time. By controlling the amount of time given the employee to arrive at the collection site, the transit system minimizes the opportunity to obtain a substitute specimen, adulterant, or masking agent.

If an employee uses hand sanitizer after they provide a urine specimen as part of a drug test, will the alcohol in the hand sanitizer result in a positive test on a subsequent alcohol test?

No, unless the employee drinks the hand sanitizer. Any alcohol that is present on the hands will quickly evaporate into the air. In the extremely unlikely event that alcohol in the air would be concentrated enough to register a reading, the air blank test would register the amount and the test could not go forward until the airblank registered 0.00. The alcohol test should also be performed prior to the drug test further reducing the possibility of hand sanitizer impacting the alcohol test.

What should a Breath Alcohol Technician (BAT) do if the employee is unable to provide a sufficient breath specimen?

The BAT must instruct the employee to try again. At least two additional attempts should be provided. Additional attempts can be made if the BAT believes there is a good chance that a subsequent attempt will be successful. If the Evidential Breath Testing device (EBT) has the capability of operating manually, the BAT should attempt to conduct the test in manual mode. In most cases, use of an EBT in manual mode will result in a successful breath specimen collection. If the BAT is a qualified Screen Test Technician (STT) or an STT is available, the initial screen can be conducted using a saliva alcohol screening device. This option is not available for the confirmation test should the screen test indicate a test result of 0.02 or higher. BATs may also choose to conduct the test at a different site using a different EBT that might be easier to obtain a breath specimen. In this case, the BAT must follow the steps defined in §40.27(b)(3).
It is allergy season again and you probably have a number of employees whose congestion, coughing, sneezing, and itchy eyes, ears, and throat just won’t go away. The most common medications used to treat allergies are antihistamines and decongestants. Often, because the symptoms typically appear only during a few months, most individuals tend to “self medicate” instead of seeing a physician.

Because the body reacts to allergens by releasing histamine, most people choose an antihistamine, to counteract or calm the symptoms. The problem with this is that antihistamines can also cause drowsiness, impaired coordination, inability to concentrate, and dizziness. Therefore, FTA has strongly encouraged transit systems to directly notify safety-sensitive employees regarding the associated dangers of sedating antihistamine use (FTA Drug and Alcohol Regulation Updates, Issue 29). But, the fact is, the number of individuals with allergies seems to be increasing. Therefore, during the allergy season, (usually early April to the first frost in mid to late October), the use of Prescription and Over-the-Counter medications to address allergy symptoms will continue to be a concern, thus the reason for this reminder about common allergy medications and their potential impact on employee performance.

In addition to the side effects from antihistamine use, decongestants have their own set of side effects, which can also pose major health risks. Individuals with diabetes, cardiovascular disease, and high blood pressure should use decongestants sparingly or only under the supervision of a physician as they can reduce the effectiveness of blood pressure medications and in some cases, cause convulsions. For individuals aged 60 and over, side effects can include convulsions as well as hallucinations. However, side effects are not just limited to older adults or those of us with health issues. Young, healthy adults can become jittery while taking decongestants. Because of this, caffeine consumption should be limited while taking decongestants (see FTA Drug and Alcohol Regulation Updates, Issue 38 for more information on the use of caffeine).

An added concern is that many individuals will employ more than one medication to relieve their symptoms, which can cause multiple side effects, or worse, develop other symptoms that may lead to taking additional medications (see the chart below for commonly used allergy medications, the symptoms they treat, and resulting side effects). This cycle can be dangerous and can, in some cases, impair an individual’s judgment and work ability. The bottom line is that employers must consistently reinforce the need for employees to report any and all Prescription and Over-the-Counter Medication use. And, employees should seek the advice and supervision of a physician or pharmacist for any prolonged use of Over-the-Counter medications. Chronic allergy problems, however, may be best treated by a physician.

### Commonly Used Over-the-Counter Allergy Medications

<table>
<thead>
<tr>
<th>Active Ingredient</th>
<th>Common Brand Names</th>
<th>Symptoms Treated</th>
<th>Common Side Effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diphenhydramine</td>
<td>Benadryl, Tylenol Flu Nighttime Products</td>
<td>Sneezing, Itchy throat, Itchy ears</td>
<td>Drowsiness, Dry mouth, Urinary retention</td>
</tr>
<tr>
<td>Chlorpheniramine</td>
<td>Chlor-Trimetron, Contrex, Actifed, Contac, TheruFlu, Triaminic</td>
<td>Sneezing, Itchy throat, Itchy ears</td>
<td>Drowsiness, Dry mouth, Urinary retention</td>
</tr>
<tr>
<td>Clemastine</td>
<td>Tavist</td>
<td>Sneezing, Itchy nose, Itchy throat, Itchy ears</td>
<td>Drowsiness, Dry mouth, Urinary retention</td>
</tr>
<tr>
<td>Doxylamine</td>
<td>TYLENOL Cold NightTime Alka-Seltzer Plus NightTime</td>
<td>Sneezing, Itchy nose, Itchy throat, Itchy ears</td>
<td>Drowsiness, Dry mouth, Urinary retention</td>
</tr>
<tr>
<td>Pseudoephedrine</td>
<td>Sudafed Non-Drowsy, Dimetapp Non-Drowsy</td>
<td>Congestion, Sinus pain, Post-nasal drip, Cough</td>
<td>Palpitations, Insomnia, Nervousness</td>
</tr>
<tr>
<td>Phenylephrine</td>
<td>Neo-Synephrine, Vicks Sinex</td>
<td>Congestion, Sinus pain</td>
<td>Headaches if used too long, Overuse may cause nasal congestion to recur or worsen</td>
</tr>
<tr>
<td>Oxymetazoline</td>
<td>Afrin, Original Nasal Spray, Neo-Synephrine 12 Hour</td>
<td>Congestion, Sinus pain</td>
<td>Headaches if used too long, Overuse may cause nasal congestion to recur or worsen</td>
</tr>
</tbody>
</table>
The Office of Drug and Alcohol Policy and Compliance (ODAPC) produced a new video that is intended to help collectors and collection site managers understand their important roles in the drug testing program. The video focuses on the responsibility of the collector to ensure that transportation employees do not have an opportunity to beat their drug test. The video shows how to follow DOT collection procedures to improve collection site security and integrity. The video will also help everyone understand the essential elements that will make collections suitable for DOT testing. The video can be downloaded by going to the ODAPC website at www.dot.gov/ost/dapc and clicking on the link to “DOT’s 10 Steps Video.” Follow the instructions on the page to download the video as a ZIP file. You will need Adobe Flash Player to view the video.

This video complements the DOT’s 10 Steps to Collection Site Security and Integrity poster. By displaying these 10 steps, collection site personnel will communicate to employees and employers that their collection site is following DOT procedures for ensuring collection site security. Collection sites will also be ensuring that they are maintaining the integrity of the collection process by limiting the employee’s opportunity to alter or adulterate their specimens. The ten-step poster is available in English and Spanish and comes in two sizes (16 x 20 or 8 ½ x 11). Single or multiple copies can be ordered from the ODAPC website cited earlier by following the menu options.

Transit system Drug and Alcohol Program Managers should consult with their collection sites to ensure that the site managers are aware of these resources and encourage their use.

The FTA’s Drug and Alcohol Program is available to come to your transit agency or state DOT to provide one-day substance abuse seminars free of charge. These one-day sessions are designed to provide essential facts and information to facilitate employers’ compliance with DOT’s 49 CFR Part 40 and FTA’s 49 CFR Part 655. If focus on a particular area of the regulations is needed, the training can be tailored to accommodate your needs.

The audience for the seminars is generally transit agency drug and alcohol program managers, human resource managers, safety managers, and third party contractors for the transit substance abuse programs. Please call Felicity Shanahan at (617) 494-6336 or e-mail her at fta.damis@dot.gov.

FTA home page: http://www.fta.dot.gov
DHHS-Certified Laboratories: http://www.drugfreeworkplace.gov/DrugTesting/Level_1_Pages/CertifiedLabs.aspx
Center for Substance Abuse Prevention: http://prevention.samhsa.gov
FTA, Office of Safety and Security Clearinghouse: (617) 494-2116
Drug and Alcohol Consortia Manual
Drug and Alcohol Testing Results: 1995 through 2006 Annual Reports
Implementation Guidelines for Drug and Alcohol Regulations in Mass Transit, Revised 2003
Reasonable Suspicion Referral for Drug and Alcohol Testing (Leader’s Guide & Video)
FTA Drug and Alcohol Program Assessment
Prescription and Over-The-Counter Medications Toolkit
Urine Specimen Collection Procedures Guidelines, revised 2008
Substance Abuse Professional Guidelines
DOT’s 10 Steps to Collection Site Security and Integrity
What Employers Need to Know About DOT Drug and Alcohol Testing
USDOT Drug and Alcohol Documents FAX on Demand: (800) 225-3784
USDOT, Office of Drug and Alcohol Policy and Compliance: (202) 366-3784 or http://www.dot.gov/ost/dapc
Collection Site Security and Integrity Poster
DOT Direct Observation Instructions Sheet
MIS Data Collection Form and Instructions
DOT’s Ten Steps Video
FTA Drug and Alcohol MIS Project Office: (617) 494-6336
Where to find…?
49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations
August 9, 2001 Federal Register Vol. 66, Pages 41996–42036
December 31, 2003 Federal Register Vol. 68, Pages 75455-75466
Primary Topic: Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations

49 CFR Part 655, Prevention of Alcohol Misuse and Prohibited Drug Use in Transit Operations
August 30, 2005 Federal Register Vol. 70, Pages 45130-45142
Primary Topic: Clarifications and Corrections to Part 655

49 CFR Part 40, Procedures for Transportation Workplace Drug Testing Programs
Revised: December 19, 2000 Federal Register Vol. 65, Pages 79462-79579
Primary Topic: Revised Final Rule (49 CFR Part 40)
July 25, 2003 Federal Register Vol. 68, Pages 43946-43964
Primary Topic: Revised Final Rule (49 CFR Part 40)

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Primary Topic: Revised Final Rule (49 CFR Part 40)
July 25, 2003 Federal Register Vol. 68, Pages 43946-43964
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Who Should Be Receiving This Update?
In an attempt to keep each transit system well-informed, we need to reach the correct person within each organization. If you are not responsible for your system’s Drug and Alcohol program, please forward this update to the person(s) who is and notify us of the correct listing. If you know of others who would benefit from this publication, please contact us at the address on the right to include them on the mailing list. This publication is free.